DELIVERABLE 6

Methods To Capture User Perspectives in the Medical Device Technology Life Cycle: A Review of the Literature In Health Care, Social Science, and Engineering & Ergonomics.

Part A: Methods to Capture User Perspectives in Medical Device Development A Review of the Literature in Health Care

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DELIVERABLE 6 FORWARD

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The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) is an Engineering and Physical Sciences Research Council (EPSRC) funded Innovative Manufacturing Research Centre (IMRC). MATCH aims to support the healthcare sector by creating methods to assess the value of medical devices from concept through to mature product. Project 3 (engagement with users – methods and metrics) is concerned with devising approaches that can capture the requirements of the end-user throughout the product lifecycle and presenting these in a form that is appropriate to the medical device industry.

In this report [Deliverable 6] a substantial review of literature is undertaken in three distinct areas: healthcare (Part A), social science (Part B), and engineering and ergonomics (Part C). This is the first stage in a programme of research aimed at encouraging medical device design, development, production and deployment which takes fully into account user requirements at all stages of this process. In particular this component of MATCH is aimed at producing guidance to industry on how to embed such methods effectively in each and all of those stages.

As will be clear from the three reviews which make up this Report, building on current practice there are substantial methodological possibilities in the more systematic development of valid and reliable methods to assist in the incorporation of user perspectives in medical device development. However, unsurprisingly, given a very diverse industrial base, complex regulatory requirements, and the tendency to use – if possible – 'off the shelf' methods from other contexts both academic and industrial, there are a number of significant methodological problems which are very evident in the reviews undertaken in this Report. In addition the role attached to user perspectives in device development has itself been very varied, and in some cases has been very modest. Thus the three reviews emphasise both implicitly and explicitly the importance of a more substantial and secure role for user assessment in the medical device development process, as well as pointing to major methodological issues and problems that a considered and careful scrutiny of published methods reveals. The three reviews, encompassing as they do, major bodies of literature in different but linked areas as far as medical device development is concerned, give a broad picture of the 'state of the art' in published approaches to user assessment. The review of health care literature complements those in the areas of social science and engineering/ergonomic literature, and focuses particularly on the development of methods in clinical settings. In this respect the reviews cover published literature on many stages of device development, including that of clinical testing and evaluation, in relation to which there are particularly important issues to be addressed.

These substantial reviews constitute the building blocks on which two associated deliverables have been written, that is Deliverable 19, which indicates and analyses methodological 'gaps' and problems in user focused assessment in medical device development, and Deliverable 10 which provides a practice guide indicating the lines on which user focused assessments should be developed and deployed.

Deliverable 6 is also the building block of the next phase of the work of the Project 3 in which specific attention will be paid to the development and deployment of effective targeted methods in relation to particular sets, and particular stages of medical device development. This next stage of the work of Project 3 will be based on more extensive consultation and collaboration with industrial partners, as well as with users themselves, in the context both of current regulatory requirements, and ways in which those regulatory requirements might be influenced in due course to reflect a more significant account being taken of user assessments and evaluations.

PART A EXECUTIVE SUMMARY

Purpose

The purpose of the review of the healthcare literature was to explore existing approaches to capture the differing perspectives of the users of medical devices in formal and measurable ways.

Scope and Methods

The healthcare literature was surveyed to identify, review and summarise the methods and methodological issues used to engage the users in medical device development and evaluation. An established qualitative methodology, 'Framework Analysis', was adopted to analyse the data and elicit relevant thematic issues. This methodology was found to be appropriate to accommodate the diverse nature of the papers in relation to their varying focus, contributing disciplines, format and content.

Summary of Key Issues, Findings and Conclusions

Users and end-users:

- End-users were predominantly perceived to be clinicians rather than patients and were mainly involved in the post-market surveillance stage of device development. The key issue extrapolated in relation to patterns of end-user involvement is the requirement for value to be placed on the individual end-user, their social group, together with healthcare professionals throughout the stages of device development. A cluster of exemplary cases illustrated components of user and end-user engagement including 'locking-in' manufacturers in partnerships with academics, clinicians, engineers and ergonomics.
- Inclusion of both user and end-user information is crucial to the successful outcomes of medical devices in an episode of treatment and care. This suggests that a cluster of methods will be needed for the life cycle of any given device requiring established strategies for sourcing information.
- Sampling strategies also need to be carefully structured to include individuals with complex medical diseases and conditions in order to conduct evaluations that provide meaningful outcome measures. A focus on sampling methodologies and small group sampling techniques may address this gap.

The context of medical device usage:

- Unless devices are examined in the context in which they are used, including the cultural and environmental context, the effectiveness and usage of the devices will be limited. The export of medical devices without regard for local customs, norms and resources including materials and skills, has significant implications for global trade and export of medical devices.

The context of tools used in medical device evaluation:

- There is a need for conceptual clarity in tool development that takes into account key domains of medical device users and the context of device use. This clarity is particularly important for generating meaningful outcome measures of device performance including the definition of end points in health technology assessment.

- Issues were raised regarding the validity, reliability and sensitivity of generic tools, highlighting the need to develop context specific device related tools that generate reliable and robust data.

Major Recommendations

The findings indicate a review of methodologies for medical device evaluation. Specifically there is a need for the following:

- Harmonised methodologies and methods underpinned by valid clinical theories in which the end-user is more prominent in the stages of medical device development and evaluation, including post-market surveillance.
- Methods need to be capable of capturing relevant contextual variables and device performance end-points, taking account of the maturity of device technologies and multiple stakeholder perspectives.
- The methodologies must be usable in the fast paced arena of medical device technologies and commercial interests.
- The onus is on academic researchers, in consultation with key stakeholders including industry, to develop and validate methodologies and tools that represent user and end-user needs to industry, to influence the development of user focused products.
- The recommendation from this report is for collaboration with experts from the social sciences, healthcare, health economics and industry to guide the development of methodologies for medical device evaluation.

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1 INTRODUCTION

1.1 BACKGROUND

Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) is the Engineering and Physical Sciences Research Council (EPSRC)'s Innovative Manufacturing Research Centre (IMRC) for the assessment of medical device technologies. It was established to develop and test methodologies to reduce substantially the time and cost from concept to market acceptance of healthcare devices. MATCH has a further role in continuously improving products, ensuring that technology brings real benefits to device users, healthcare professionals and providers. Project 3, engagement with users, was tasked to devise approaches that capture the differing perspectives of patients/clients, professional users and product developers in formal and measurable ways. This aids the synthesis of these perspectives and leads to successful devices that meet end-user needs.

Project 3 seeks to address the involvement of users in the process of product development and evaluation. It is therefore consistent with current NHS and government policies in the United Kingdom (UK), where public sector funding of devices and services are involved.

1.2 RATIONALE FOR THE SURVEY

The rationale for the survey stems from a core theme of MATCH that users' perspectives must be reflected in metrics and measurements of medical devices, since paying inadequate attention to these perspectives will result in discarded or modified equipment, and in repeated surgical procedures.

Device users are a diverse group that includes professionals and patients/clients with their wider family groups. Project 3 is predicated on evidence that in many cases the perspectives of patients/clients differ substantially from the perspectives of both device producers and professional users. Therefore it is imperative to investigate approaches that capture these differences in formal and measurable ways. To this end, methodologies and assessment processes are needed so that professional and user perspectives are synthesised to aid product development, resulting in successful devices that meet user needs. The methodologies must be linked to the patient/client care trajectory and the product development trajectory, iteratively developed to ensure that user and product effectiveness are continuously monitored.

Therefore the Project 3 team has embarked upon an extensive survey of the engineering, ergonomics, healthcare and the social sciences literature. The task was defined as encompassing a survey of the published literature regarding the user perspective within the medical device sector and other selected relevant sectors to:

- Map, using an explicit search strategy, the range of methods for capturing user requirements linked to the product development trajectory
- Examine the selection, development and application of methods for identification, measurement and communication of user requirements and experience

The strategy utilised was to undertake a structured survey and less formal trawl of other work that does not meet the formal criteria of the standard systematic review. The aim was to perform an extensive survey of abstracts from published studies, identifying and reviewing the studies that offer the richest research potential to Project 3. *The King's College London Project 3 research team focused on surveying the Healthcare literature.*

1.3 SCOPE OF THE SURVEY

The scoping statements of the deliverables:

- A structured survey of published literature on methods to capture user perspectives in medical device development, drawing on engineering, ergonomics, healthcare and the social sciences.
- Methodological issues for the investigation of methods to elicit user perspectives and requirements in medical device development.

1.4 AIMS AND OBJECTIVES

From a Healthcare perspective the aims and objectives of the survey were to:

- Identify, review and summarise the methods used to engage the users of medical devices to ensure that devices meet user and end-user needs.
- Identify methodologies including tools for embedding end-users in medical device design, development and evaluation.
- Map methodological issues for future review and development to ensure robust end-user representation in medical device development.

1.5 TERMINOLOGY USED IN THIS SURVEY

1.5.1 Operational definitions of medical devices

The following operational definitions have been taken from the World Health Organisation (2003) to align the review alongside the extensive work that has been done in this area to harmonise terminology across the vast and rapidly evolving sector of medical devices. The aim of such harmonisation is to ensure parity of meaning across the global environments and to negate where possible the complicated legal technicalities across regulatory systems. This work has created a common framework that integrates the

regulatory systems of the five countries/regions with the most advanced medical device regulations: Australia, Canada, Japan, the European Union and the United States of America.

Medical Devices

The term “medical devices” includes everything from highly sophisticated computerised medical equipment down to simple wooden tongue depressors. The intended primary mode of action of a medical device on the human body, in contrast with that of medicinal products, is not metabolic, immunological, or pharmacological.

“Medical device” means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a
- physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Notes:

An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the ‘parent’ medical device to enable the medical device to achieve its intended purpose, it should be subject to the same procedures and the Global Harmonization Task Force guidance documents (http://www.ghtf.org/) as they apply to the medical device itself.

The definition of a device for in vitro examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an in vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, reagents may be covered by separate regulations.

Products, which are considered to be medical devices in some jurisdictions but for which there is not yet a harmonised approach, are:

- aids for disabled people
- devices for the treatment/diagnosis of diseases and injuries in animals
- spare parts for medical devices
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls

1.5.2 Operational definitions of users and end-users

The following definitions of the "user" have been synthesised from the literature and the authors' knowledge of healthcare, healthcare policy in the UK and health service supply chains.

Users

Medical devices are used by a wide range of individuals within various organisations and settings:

Professional Users - of devices require the necessary qualifications and training in the proper use of the device, so as to be familiar with the indications, contra-indications and operating procedures recommended by the manufacturer. Such users are frequently clinicians operating in an array of care settings. They have a responsibility to share experiences gained in the use of medical devices with other users, the manufacturer and distributors to prevent future problems. This can be performed through formal mechanisms such as the reporting of incidents to a coordinating centre from which warnings can be issued on a national basis. Clinicians, such as medical staff and those within the professions allied to medicine, have the responsibility to employ the medical device only for the intended indications or to assure that any non-indicated use of the medical device does not compromise the safety of the patient and other users. These users also bear the ultimate responsibility for ensuring proper maintenance of medical devices during active use and safe disposal of obsolete medical devices.

Lay Users - are another type of user who predominantly are carers and/or part of an extended family and community group who use devices on behalf of the end-users.

End-users

It is important to distinguish the above two categories of 'users' from end-users. End-users are patients, clients, and consumers who have conditions and disorders that require medical devices. End-users can also be defined as users, when using devices on their own behalf. There is overlap between professional, lay and end-users at the point of care delivery.

1.5.3 Medical device development

Medical device development is an overall term used to describe the various stages in the development of a device/product. For the purposes of this report the following stages of medical device development include:

1. Concept
2. Design
3. Testing and Trials
4. Production
5. Marketing and Use

Other Operational Definitions used in this survey can be found in Part A Appendix A: .

2 METHODS

Please refer to Part A Appendix B: for a comprehensive description of the Methods used in this report. Table 1 *gives an overview of the process undertaken.*

Table 1: Overview of the Search and Review Process

Step 1: Mapping of search terms with expert consultation

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Step 2: Selection of databases

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Step 3: Performance of search with expert consultation

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Step 4: Definition of exclusion criteria

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Step 5: Review of abstracts by researchers

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Step 6: Categorisation of results

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Step 7: Sampling strategy of relevant papers defined

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Step 8: Data extraction performed using a Data Extraction Template (Part A Appendix C:)

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Step 9: Data analysis of the extracted data utilising Framework Analysis to derive issues raised and their consequences (Part A Appendix D:)

The search strategy for the survey was based *flexibly* on the stages advocated by the Cochrane Collaboration (2003): this involves scoping, building and maintaining a structured search. Key words were initially identified that categorise "user", "methodology" or "device" related terms to structure the search. Following this MeSH subject headings were sought to increase the number of relevant hits (refer to Part A Appendix B:). The searches were limited to: papers published after 1980, English language publications and human studies. The searches were divided with researchers searching those databases related to their area of specialism i.e. healthcare, social sciences, engineering and ergonomics.

A data extraction table (Table 2) for the literature survey was used by all the Project 3 researchers across the disciplines to extract relevant data from the papers reviewed. It was derived from analysis of the 13 stages of product development proposed by Cooper & Kleinschmidt (1986), producing a condensed model of 5 stages:

- Concept: involves idea generation, including technical, financial and commercial viability
- Design: involves product design and prototype development
- Testing and trials: involves prototype testing in-house and later trials in the field
- Production: includes production supported by business and commercial rationale
- Marketing and use: includes product launch in the market and its on-going use

Table 2: Data Extraction Template

ID	Ref	Year & Country of study	Objective(s)/ Question(s)	Methods/ Tool/ Approach	Device/ Product	Users / Participants (n=)	Product Development Stage at which users were involved					Findings &/or Conclusion	Researcher's Comments
							Concept	Design	Testing & Trials [including prototype]	Production	Deployment [Marketing/ Launch & Use]		

2.1 SEARCH STRATEGY: HEALTHCARE

The databases selected included: Embase, Medline, CINAHL, PsycINFO, The Cochrane Database of Systematic Reviews (Cochrane Reviews), the Health Technology Assessment (HTA) Database and the National Institute of Clinical Effectiveness (NICE). The search strategy for Embase, Medline, CINAHL and PsycINFO yielded 2226 results (last performed on 21.5.04).

The remaining databases (the Cochrane Database of Systematic Reviews, the Health Technology Assessment Database and the National Institute of Clinical Effectiveness) required a separate search strategy because of the need for less specified search terminology in these databases. Therefore they were searched in the main during July 2004 using the key word "medical device".

2.1.1 Exclusion criteria

The relevance of the 2226 results was assessed by both researchers (NB & MBR) independently by reading the titles of the papers and the abstracts. 1335 studies were excluded against the following criteria:

- Lack of or no outcome assessment
- Lack of or no device e.g. evaluation of a rehabilitation service, procedural evaluation
- Lack of or no user perspective
- Primary focus of regulatory requirements e.g. implant registry information
- Non-article based e.g. letters, comments or book chapters

Where the researchers were unable to reach a decision independently with regard to relevance the abstracts were reviewed by both researchers and a consensus generating process was used. A third reviewer was drawn on where required (TG).

2.1.2 Categorisation and sampling: Embase, Medline, CINAHL & PsycINFO

The 891 relevant papers were categorised by:

- Methodologies and tools of particular value to the remit of Project 3. Thus where the results encompassed "out of the mould" methodological approaches to capture user perspectives regarding medical devices, these were categorised separately. These papers illustrated a myriad of imaginative methods and approaches to ensure that medical devices were fit for purpose for end-user populations
- Where the results had a primary focus on the development, utility and validation of tools these were classified under "tools", regardless of the device area, in order to aid analysis.
- Medical device area e.g. cardiac, orthopaedic, neurological.

All the results from the categories of "tools" and "out of the mould" were reviewed given the focus of Project 3. A 5% sample of each device related category was included. In the main the papers in the device related categories described clinical trials or other interventional studies where similar approaches were used e.g. experimental design and retrospective case-note analysis. A total sample of 115 full papers was obtained and the data were extracted into the data extraction template by the researchers.

2.1.3 Limitations to strategy: Embase, Medline, CINAHL & PsycINFO

The dual categorisation strategy (via methodologies and tools of particular value to the remit of Project 3; and via device area) and the dual sampling strategy from these categories (purposeful sampling of all papers from "tools" and "out of the mould"; and random sampling on a percentage basis from the device categories) have inherent limitations. However both strategies can be justified according to the aims of Project 3, in terms of methodological development, and for pragmatic reasons. The high number of relevant results obtained meant that not all papers could be feasibly reviewed, thus necessitating the use of such a dual sampling strategy. The use of a random sampling strategy for the device area could be justified as providing a potentially representative overview of the literature sampled.

2.1.4 Categorisation and sampling: Cochrane Reviews, HTA & NICE

Hits from searching the Cochrane Database of Systematic Reviews, the Health Technology Assessment (HTA) database and the National Institute of Clinical Effectiveness (NICE) database were purposefully sampled accessing those reviews pertinent to the specific interests of the MATCH industrial partners (Table 5, Part A Appendix B:). Reviews that could be cross-referenced to other works across the databases were also obtained, for example the separate works of the HTA and NICE on wound care debriding agents and vaginal tape were sampled. The publications of these organisations were deemed of importance to MATCH given their influence over the medical device industry particularly in terms of methodologies and perspectives on high

quality data. However, the length and complexity of the above works, with respect to the multiple papers contained within each review, precluded data extraction into the data extraction template in its existing form. Therefore it was agreed that these works would be critically reviewed at a later date in the research process.

3 CRITICAL REVIEW AND SYNTHESIS OF THE EVIDENCE

3.1 PROCESS OF LITERATURE ANALYSIS

The process of analysis of the data was informed by the stages of Framework Analysis (Richie & Spencer 1994). It took the following form (Table 3):

Table 3: The Process of Analysis

Stage 1: Familiarisation - with the range and diversity of the literature, listing key ideas and recurrent themes.

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Stage 2: Identifying a thematic framework - of current research practices, outcomes and pertinent issues in the literature to identify methodologies for user involvement under the following themes:

The users
The medical devices
The tools
The methods

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Stage 3: Indexing - the data according to key issues and concepts relevant to the above themes. This involved making judgements as to the meaning and significance of the data.

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Stage 4: Charting – the annotated data into the appropriate thematic framework sections (users, medical devices, methods and tools) using headings and sub-headings.

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Stage 5: Mapping and Interpretation - the core themes, finding associations, providing explanations and recommending strategies.

3.1.1 Framework analysis: outline and rationale for use

The literature survey required a qualitative approach because of the diverse, non-standardised and difficult to classify papers available. As previously described an appropriate methodology for the literature survey had to be developed. In the absence of clear inclusion and exclusion criteria, such as within a systematic review methodology, the researchers had to develop an explicit and auditable methodology, which included the method of analysis. Having completed the first four stages, analysis moved to the final, integrating stage.

Framework Analysis is an analytic strategy developed in the context of applied policy research (Ritchie & Spencer 1994). Complex evaluations such as social policy provide insights, explanations and theories of social behaviour. 'Framework' is embedded with general principles of analysis of complex data across a wide range of studies. It was adopted in the context of this literature survey to draw out the major themes concerning the involvement of end-users in medical device development and evaluation.

'Framework' facilitated identification of key facets of the model embedded in the exemplary cases (Refer to Part A Appendix E:). These cases have provided empirically validated components and driving principles, in particular valuing the end-user.

Stage 5: mapping and interpretation

The data were sifted and charted according to core themes, and key characteristics of the data were grouped. This stage of the analysis involved interpretation of the dataset as a whole using the following parameters to guide this process:

- Finding associations - in the methodologies used and level of user involvement in medical device development
- Providing explanations - both implicit and explicit
- Providing key exemplars - identifying models of both methodologies and/or user involvement in the stages of medical device development

Finally, the main themes identified via this strategy were interpreted in the context of current policies and developments within the medical device and healthcare industries. This report is therefore a thematic analysis exploring the methods and identifying the issues in terms of a user focus, including the methodological and contextual issues in relation to involving users at various stages in medical device development.

4 THEMATIC ANALYSIS AND FINDINGS

The major themes found in the literature survey are presented here. They are a culmination of the synthesis of the data firstly into the Data Extraction Tables (Part A Appendix C: , p75) and subsequent synthesis into the Framework Analysis Tables (Part A Appendix D: , p196), comprising the categories of users, medical devices, tools and methods. The presentation of the data thus follows these categories.

Additionally, a cluster of exemplary cases (10 papers) from the "out of the mould" category of search results, are reported in detail in Part A Appendix E: (The Exemplary Cases: Model Components p230). Together they illustrate underpinning values, approaches and methods of user and end-user involvement, and were unique out of the 115 papers surveyed, in terms of their respective levels of end-user involvement in the stages of medical device development.

A method of referencing has been used that involves referencing not only the authors of the papers but also the Refworks (database) number to which the papers were assigned. This has been done to enable the reader to follow the chain of reasoning from the Data Extraction Tables to the Framework Analysis Tables and the Exemplary Cases to the synthesis of the findings and conclusions. The reference list is thus sorted numerically.

The discussion of the data proceeds through the following thematic issues:

- Users and End-users
- The Level of Involvement of Users and End-users According to the Stages of Medical Device Development
- The Context of Medical Device Usage
- The Context of Tools Used in Medical Device Evaluation
- Methodological Challenges in Medical Device Evaluation

This literature survey was undertaken against the background of important developments over the last decade in the UK National Health Service (NHS). Particularly relevant to this report is the focus on *patient centred care* and the concept of the *expert patient* that promotes end-user involvement in both service delivery and health services research (Department of Health 2002; Morris 1999 [#1660[1]]). This represents a major shift from a culture that places the clinician at the centre of care, to one where end-users play an active role in making decisions regarding their health and care. Implicit in this is the concept of equality of dialogue and partnership between providers and end-users within the healthcare arena, and in the stages of medical device development.

[1] Respective Refworks reference number of the study. Refer to p62 for a list of the papers reviewed and their Refworks numbers.

Findings from this literature survey of users and end-users in relation to the stages of medical device development will indicate how extensively user perspectives are, or are not, embedded and identify methodologies for engaging with users in the various stages. This will serve as the starting point for the development of new approaches and methodologies that can be integrated into the stages of device development ensuring optimum outcomes for end-users. The onus is on academic researchers, in consultation with key stakeholders including industry, to develop and validate such methodologies and tools.

As stated earlier, the published literature within this field is vast and complex, thus this survey is by no means exhaustive. There are no apparent formalized processes for reporting on the stages of device development and evaluation and therefore no clear criteria for reviewing and critiquing the literature sampled. A decision was made to subject the literature surveyed to a thematic analysis. The major themes arising out of this process include a lack of coherent approaches to embedding users in medical device development and evaluation, which may be resolved with methodological development. In particular questions are raised as to what user information is needed and who is the best placed to provide this information so that end-user needs can be met in relation to a specific device and its context of use.

4.1 USERS AND END-USERS

It is clear from the operational definitions of medical devices given at the start of this report (p2) that devices are used by a wide range of individuals, from within various organisations and settings. Users of devices have been categorised as users and end-users (p4). Users are professionals operating in an array of care settings, and lay individuals both using medical devices on behalf of end-users. The end-users are patients, clients or consumers, who have conditions and disorders that require medical devices. End-users can also be users, using devices on their own behalf.

4.1.1 User and end-user information

Varying forms of user and end-user information were identified in the sampled literature. The nature of the device and its function appeared to determine the primary user and the type of user information generated. A key issue concerns the nature of the user and end-user information required in a given medical device context, characterised here as technical/clinical information and contextual/perceptual information. Both types of information are arguably crucial to the outcomes of device use in a given episode of care, and can be demonstrated in the context of implantable devices. For example, a shared goal between the clinician and the end-user of an implanted intraocular lens will be improved sight. However, the evidence of improved sight from the perspective of the clinician and the end-user is necessarily derived from different methods of data capture. From the clinical perspective the information comprises objective measurements of vision, such as visual acuity, to demonstrate a successful outcome. The subjective end-user reports may however reveal important symptoms of visual disturbance, such as glare at night, which are not necessarily revealed through measures of visual acuity (Davis 1992 [#1126]). Thus, to understand user needs, information should be derived from both users and end-users to enable optimal outcomes.

It was clear from the literature that patient expectations can influence outcome assessment measurement. A significant impact of not sourcing user and end-user information is therefore the failure to understand and reconcile differences between the clinician's predictions of end-points and outcomes, and patient expectations. In one study patients who had undergone Total Hip Arthroplasty were followed up in the post-market surveillance stage (Ragab 2003 [#1391]). The perspectives of both the patients and clinicians were elicited using two questionnaires. One aspect of assessment was related to perceptions of pain. Discrepancies between the clinical evaluation and the patient self-assessment became apparent and were attributed to different interpretations of pain. It was also found that patient expectations had changed during the care process. This highlights the need to understand the patients' perspectives in order to reconcile misunderstandings between the patient and doctor.

4.1.2 Sampling

It is apparent in the literature surveyed that sampling in the medical device sector is problematic because of the vast and complex nature of the field. Numerous devices are used by a wide cross section of the population, where individuals present with co-morbid conditions of varying degrees of severity and dependence. In addition there are contextual and environmental variables that influence needs and patterns of device use. The sampling issues identified have been categorised under the following headings: the heterogeneous nature of device users, inclusion and exclusion criteria, sampling techniques and the use of proxies.

Sampling heterogeneous populations

Two strategies were identified for sampling heterogeneous populations. The first sampled the primary intervention regardless of co-morbid conditions and the second confined the population to the intervention and one co-morbid condition.

The first strategy raises methodological challenges including the difficulties of isolating the impact of co-morbid conditions on the primary intervention, the principal outcome variable. For example, drawing again on the study by Ragab (2003 [#1391]), which evaluated the outcomes of Total Hip Arthroplasty (THA) via a standard posteriolateral approach a number of different co-morbid conditions were identified. The outcome measures comprised a standard scoring system for clinical use (Harris Hip Score, See Part A Appendix F: Glossary of Tools) and a patient administered questionnaire including measures of pain, satisfaction with the procedure and recreational activities. The sample comprised 103 patients with an average age 60.1 years, 67 females and 36 males. Importantly, 84% had a preoperative diagnosis of degenerative joint disease, 3% rheumatoid arthritis, 5% avascular necrosis and 8% other causes. The authors acknowledged that discrepancies were found between the standard scores and the self-administered questionnaire responses, which may have resulted from the co-morbid conditions.

The second strategy appears to overcome the difficulties of isolating the impact of the principal outcome variable, generating meaningful outcome measures that may be generalised to individuals with similar conditions. For example, 25 patients undergoing THA and who had aplastic anaemia were studied and the authors demonstrated the sustained durability of implant fixation and increase in hip function (Kim 2000 [#238]). They were able to conclude that THA can be performed safely in individuals with aplastic anaemia. In a further example of 103 patients undergoing THA with ankylosing spondylitis the authors concluded that THA provides long-term improvement in hip function in individuals with this condition (Joshi et al 2002 [#617]).

Exclusion and inclusion criteria

There was evidence in the literature of tight exclusion criteria, applied to post-marketing surveillance studies, which may fail to include the more needy individuals who use medical devices and arguably are the "real life" end-users.

Some of these studies appeared to exclude clinically complex patients. For example, in a study examining outcomes post THA all individuals that had undergone previous surgery to the hip were excluded (Johanson et al 1992 [#1163]). In another study of changes in the life situation related to an implantable cardioverter defibrillator all patients with psychological and/or medical complications, planned heart transplant or coronary artery bypass grafts and language difficulties, were excluded (Bolse et al 2002 [#1355]). In a further study of age-related differences in functional status of patients undergoing total hip or knee joint arthroplasty it was stated that

"…The patients are considered to represent an average rural population with osteoarthritis in Sweden. None of the patients had serious heart or lung disease, or other diseases of the musculoskeletal system…" (Oberg & Oberg 1996, p97 [#1869]).

A fourth study examining functional progression during hospitalisation after total hip arthroplasty excluded individuals experiencing any condition that interrupted routine physiotherapy or complicated the course of stay, such as a urinary tract infection (Kroll et al 1994 [#1951]).

Conversely, patients who had received revision procedures and those with co-morbidities were not excluded in a study assessing the impact of total hip arthroplasty as a treatment for osteoarthritis (Harwood & Ebrahim 2000 [#231]).

The use of proxies

In some of the studies 'healthy' populations were sampled raising questions regarding the generalisability of findings to real life end-user populations. For example, in one study testing a curb-climbing aid for wheelchairs able-bodied volunteers were used (White, Szeto & Hogan 1980 [#1317]). In another study, healthy volunteers were used to test the effects of lycra support stockings (Jonker et al 2001 [#1514]). The volunteers were screened to exclude those individuals with objective symptoms of chronic venous insufficiency, however support stockings are required in this context. In a third study looking at the development of orthotic devices, a sample of 5 right-handed males with normal neuromuscular function, aged between 34 and 41, was recruited (Ramanathan et al 2000 [#1638]). Their arm trajectories were analysed as they performed "everyday tasks" simultaneously, such as spooning water from a bowl, simulation of hair brushing whilst wearing a baseball cap, and also whilst sitting in a wheelchair with their elbow movement minimised in a "constrained manner". Finally, in a single case study involving a healthy and fit transfemoral amputee a prosthetic limb was tested, with the individual performing six repetitions of each task, such as ascending and descending a slope and

stairs, where she chose to take two stairs at a time when ascending (with her sound leg) and descending (with her prosthetic leg) (Frossard et al 2003 [#29]).

Ethical and safety issues can make it necessary to use appropriate proxies for a sample population in particular situations. This would include using physical models, for example, anthropomorphic test dummies, for testing wheelchair occupant restraint systems (van Roosmalen 2001 [#1511]) or use of mothers as proxies for data collection when studying functional status in toddlers with limb deficiency (Pruitt et al 1999 [#1662]).

Combining users and non-users in the same study

Some of the studies appeared to choose a combined sampling strategy of users and non-users in comparative designs. For example, a study recruited 20 individuals with muscular dystrophy to explore satisfaction and the value placed on electronic aids for daily living (EADL), of which half the sample used such devices and the other half did not (Stickel et al 2002 [#664]). Non-users were the control group, though they were interpreted as having the potential to benefit from using EADLs in the future and were asked to anticipate the potential impact of EADLs on their daily lives. It was found that 70% of users of EADLs lived in apartments either alone or with attendant support, whereas only 25% of the non-users were living similarly. The access to EADLs seems to have an impact on the ability of this group to live on their own.

In a later study both users and non-users of EADLs were recruited to evaluate an assessment tool, the Measure of Control Using Electronic Aids to Daily Living (MCEADL) (Tam et al 2003 [#439]). The tool was designed to detect differences between the two groups and to measure functional performance and satisfaction before and after EADL provision. The authors alluded to the perceived problems in recruiting appropriately sized samples stating that a comparative study design was chosen instead of a prospective study because of the anticipated difficulties with recruiting a large enough population for statistical analysis in a time efficient manner.

Both these studies raise questions as to the validity of combining users and non-users in the same sample, not least the methodological flaws inherent in doing so to achieve a large enough sample for statistical analysis.

The value of sampling experienced users

A model of involving researchers with disabilities has been devised in the US to train and inform disability groups in research methods and conducting research (Blanck et al 2003 [#1406]). This on-going project aims to solicit the participation of researchers, many with disabilities, who are interested in extending knowledge of research methods to the disability community. Researchers will team with disability community organizations to create knowledge rooted in scientific methods relevant to the daily experiences of these individuals.

One particular postal survey, regarding both the utilisation of assistive devices in various social settings and the perceptions around such devices, purposefully sampled scientists and engineers with disabilities (Brooks 1991 [#1202]).

Studies such as these reflect the movement towards engaging expert patients/end-users in health services development and research and suggest the need for core methodologies for embedding users and end-users in research processes.

Self-selected user samples

Some of the studies surveyed recruited their sample populations in a more purposeful manner. Such sampling processes may be criticised in relation to a lack of methodological rigour but they can be very successful in targeting specific user populations. A study that developed a shoulder pain index associated with wheelchair use, recruited wheelchair users at a wheelchair athletic event (Curtis et al 1995 [#1045]). In a further study of the impact of implant-stabilised prostheses on the health status of complete denture wearers, patients who were reporting difficulties with conventional dentures were recruited through hospital departments and dental practitioners (Allen et al 2001 [#208]). In another instance a sample of edentulous patients' was obtained through an advertisement offering replacement of their current prostheses in return for participation in a study (Awad & Feine 1998 [#1716]).

In Summary:

- User and end-user information is crucial to successful outcomes for medical devices in the context of an episode of treatment and care.
- It is apparent from the literature sampled that there is a lack of both established strategies for sourcing information and cogent criteria for sampling the user and end-user.
- It is clear that criteria and methods for embedding end-users together with sampling methodologies are required.

4.2 THE LEVEL OF INVOLVEMENT OF USERS AND END-USERS ACCORDING TO THE STAGES OF MEDICAL DEVICE DEVELOPMENT

A recurring theme in this survey is that assistive technologies are a particular category of medical devices where a user-centred approach appears to be an established methodology for engaging with clients (Burkitt et al 1995 [#326]; Hefzy, Nemunaitis & Hess 1996 [#994]; Sethi 1982 [#1305]; Malassigne et al 2002 [#1482]; Malassigne et al 2000 [#1631]; Mulholland et al 2000 [#1643]). In an example of outdoor mobility devices and services for end-users with impaired mobility, a user-centred approach was developed to assess effectiveness (Jedeloo, De Witte & Schrijvers 2002 [#119]). Indeed, failure to adopt such a user-centred approach was associated with discontinuance of device use. Furthermore, in a study guided by Everett M Rogers theory of diffusion of innovations, which offers a comprehensive philosophy regarding the processes involved in accepting or discontinuing use of technology, end-user involvement was negatively associated with discontinuance (Riemer-Reiss 1999 [#2179]).

4.2.1 Embedding end-users in medical device development

The majority of the studies surveyed demonstrate end-user involvement primarily in the post-marketing stage of the product development. A cluster of exemplary cases (Part A Appendix E: , p230) drawn from assistive technology devices appears to indicate well established models of end-user engagement throughout the stages of medical device development. These exemplary cases may reflect a global shift towards focusing on assessment throughout the stages of medical device development, including the regulatory processes. The predominance of the post-marketing surveillance studies identified may indicate key stakeholder influence on device development for example the existing regulatory frameworks and legal requirements of market listing and usage. Thus a focus is placed on post-marketing surveillance studies or trials by companies, perhaps at the cost of involvement of users at earlier stages of device development. Where this occurs devices may lack user involvement in their development. Consequently, the device may only partially meet user requirements or fail to meet user requirements.

The shift in culture alluded to earlier whereby end-users play an active role in making decisions regarding their health and care needs to be matched by changes in methods, methodologies, regulatory, marketing and purchasing frameworks to embed end-users. In an opinion article the status quo for user involvement was identified as revolving around the clinician, and trends were cited indicating an increasing move towards a more consumer led market where the end-user, the patient, is paramount (Morris 1999 [#1660]).

4.2.2 End-user involvement in the post-market surveillance stage

The following example was exceptional in demonstrating aspects of good practice in end-user involvement within the literature sampled. This exemplar from the US (University of Buffalo Consumer Assessments Study) was a post-market surveillance study which focused on the end-users and identified substantive contextual issues around understanding of the elders' perceptions towards their own disability, assessment of needs, and matching the device to accurately assessed needs and training (Mann et al 1995 [#22]). The study focused on end-user involvement in the assessment of assistive devices, specifically walkers (individuals over the age of 65). Data were captured from a representative sample of end-users, in interviews in subjects' homes by 2 expert clinicians, with no by-proxy information given by others. The findings indicated that 57% of the sample had walking aids that not only did not meet needs but that were potentially dangerous. Recommendations were made for improved assessment of needs as opposed to new designs, although intelligent and advanced technology designs were also proposed. The study indicates that advanced technology solutions were not required to meet needs, and what was needed was appropriate attention to detail at the end-user interface.

Exemplar studies in terms of user and end-user involvement through the stages of medical device development. (Please refer to Part A Appendix E: for the Model Components of the following Exemplary Cases p230)

In a small study a social science method (survey) was used to identify limitations in a first generation device (Peckham et al 2002 [#640]). Users and end-users were subsequently involved in designing a second-generation device. The design criteria for the device was developed from a survey of neuroprosthesis users and therapists to identify how the first generation technology could be improved. The product was then developed and tested functionally on a small sample of participants (n=4). No indication of commercial exploitation was given but the end-users were followed up for 4 years. From a methodological perspective this study appears exemplary in embedding end-users in the design and follow-up stage. The study provides a model of product development, based on neuroprosthesis user and therapist involvement, to generate a second-generation device and evaluate its performance.

The following exemplar represents a holistic model of embedding end-users in the delivery of a service, the context of device use, and in the stages of device development including manufacturing processes that are sensitive to both local materials and skills (Sethi 1982 [#1305]). The model is one of ongoing research and development for service delivery in a geographical population of amputees. An extensive end-user population (rehabilitation service users) was sampled involving over 5000 amputees requiring artificial limbs in rural Northern India. Key aspects of this approach include individually inspired user driven service delivery (orthopaedic clinician), and culturally and environmentally sensitive product development i.e. using local products and artisans.

Another key aspect was the use of methodologies for evaluating product performance, including a double-blind study, to compare the Jaipur design with the Western design. This exemplar represents a strong rebuttal to globalisation and provides lessons for Western exporters of devices. Local end-user needs are required to be embedded in products for export to avoid discontinuation of device use (Healthcare Industries Task Force 2004; Riemer-Reiss 1999 [#2179]).

An exemplar from the US Department of Veteran Affairs (Rehabilitation Research and Development Service) describes a model, which focuses on consumer driven assistive technologies with a method for engaging with industry (Sheredos & Cupo 1997 [#934]). End-users are embedded throughout the stages of medical device development in an iterative process of design and development. Of particular interest is the commercial exploitation of the research outputs via a model of technology transfer employed by the commercial section which engages or “locks in” manufacturers at an early stage in development. The process begins and ends with a clinically defined need and in turn can significantly improve the availability of products and techniques with the potential outcome having a positive impact on the lives of individuals with disabilities. The aim of this technology transfer model is the timely transition of prototype developments into commercially viable products and techniques that can be readily available and accessible to benefit both veterans and non-veterans with disabilities. This is accomplished through the funding of R&D proposals to improve treatment, management and rehabilitation of veterans within the following defined priority areas: prosthetics, amputations, orthotics; spinal cord injury; sensory, cognitive and communication aids; and ageing. The process attempts to bridge the gap with the manufacturing sector by use of procurement contracts to purchase pre-commercial models as an enticement to attract companies. The manufacturer is identified in the early stages and is committed to the future production and marketing of the product/technique. National clinical evaluation of such models is then performed to validate the product or technique's success in meeting the specified clinical need, and defining readiness for commercial production and marketing. The authors conclude that "locking-in" a manufacturer early in the process and utilising clinical evaluation from an objective environment, apart from the developer's lab, are major elements that assist in ensuring the process can affirm market opportunity for the final product.

The above US Department of Veteran Affairs ‘model’ features the involvement of users and end-users at various stages of product development. In this study a range of methods was adopted including social science methods (questionnaires, interviews, informal discussions and visual techniques - photography) (Malassigne et al 2002 [#1482]). The end-users, individuals with spinal cord dysfunction using prone carts, and their carers were involved in an iterative process of product development. During the concept stage of the development an end-user was the concept originator evaluating existing prone carts. In the design stage further end-users generated ideas for both

manual and motorised carts. In the testing and trials stage the end-users tested the developed prototypes. In the production stage the research team collaborated with manufacturers to commercialise the product, to facilitate the final stage of the product development including deployment and use of the product.

Another study of consumer driven assistive technologies from the US Department of Veteran Affairs not only addressed embedding end-users and carers in needs driven device development, but also included the process of embedding commercial companies (Malassigne et al 2000 [#1631]). This process led to the development of three potential products. The methods were again a cluster of social science, ergonomics and engineering methods. The example involves end-users (individuals with spinal cord injuries) and their carers. During the concept stage of device development clinical evaluation was performed to evaluate existing commode-shower chairs. During the design stage safety and performance criteria were defined from the clinical evaluation for two versions of a commode-shower chair, both assisted and self-propelled. In the testing and trials stage prototypes of the chairs were developed and tested by the end-users. In the production stage there was collaboration by the research team with manufacturers, some of whom made the decision to commercialise the product.

This following exemplar represents a UK university research team (Brunel) involved in consumer driven assistive technologies development (Burkitt et al 1995 [#326]). A similar process was used to that of the Veterans Model, but without the commercial “locking in” process. Multi-methods were employed including questionnaires to determine design. End-users (individuals with motor neurone disease) and their carers were visited in the home environment to determine needs. Specifications for the device were agreed with end-users and appropriate care professionals and a hands free liquid feeding device controlled by means of a single switch was developed. An iterative process of prototype testing and evaluation was used with the final product being marketed by a UK company.

An academic and design team exemplar from two countries demonstrated that the combination of perspectives on the device performance from both end-users and their carers provides added value in assessment (Mulholland et al 2000 [#1643]). Furthermore it was observed that involvement of carers and/or family members in assessment might increase device acceptability and usage in a cultural context. Methodologically the challenge is to achieve consensus in a timely fashion. Whereas the methodological processes and methods may be generalisable the specific study findings, regarding the device, may not be. This was an international study between Queens University, Canada and the National Institute of Design, India. A multi-professional team of engineers, ergonomists and designers together with professionals allied to medicine including occupational therapists and physiotherapists was involved. It represents a cultural, environmental and end-user (women with bilateral lower extremity disabilities) driven design, including family and community members. Use of local materials and resources

were included in the contextual assessment of long-term need. Multiple methods were employed including social science methods for reaching consensus with a multi-faceted sample and achieving generalisation from a specific cultural and disability group.

In Summary:

- Apart from a cluster of exemplary cases, the literature revealed that end-users were not embedded in the early design and prototype stages of medical device development. However, they did feature in the post-market surveillance stage.
- In the main users were perceived to be clinicians.
- Various other definitions of end-users were found including healthy non-users, healthy users and specific groups comprising individuals with profiles of a particular medical device related usage and/or associated aetiology.

4.3 THE CONTEXT OF MEDICAL DEVICE USAGE

Exploring the literature from the perspective of the medical device indicates that it is impossible to examine devices in isolation of the context in which they are used. In addition to the vast range of devices and conditions, there is an equally vast range of complex contexts and training requirements around safe usage. The increasing expectations of knowledgeable consumers of medical devices place significant pressure on medical device manufacturers to develop appropriate technologies that facilitate end-user involvement, at the lowest cost.

The overall context of medical device usage, particularly in the West involves a number of pertinent factors that require consideration (Morris 1999 [#1660]):

- Ageing populations
- Increasing healthcare costs
- National healthcare policies that promote user involvement
- Increasing end-user management of their own diseases and conditions
- Increasing consumer expectations

As already indicated in this report assistive technologies are a distinctive class of medical device. It is in this group that models for embedding the end-user that embrace human factors design (See Part A Appendix A: Operational Definitions) in the stages of medical device development, appear to be well developed. As with other classes of medical devices, a vast number of assistive technology devices exist. It is also evident that a single user or end-user may use a significant number and range of devices. For example, in a study of assistive technology use in older adults with cognitive impairments (n=20) an average of 5.35 devices per person were used (Nochajski, Tomita & Mann 1996 [#320]). In a further study of 2002 individuals responding to the Quebec User Evaluation of Satisfaction with Assistive Technology questionnaire as many assistive devices were in use as individuals sampled (i.e. 2002) (Wessels & De Witte 2003 [#541]).

4.3.1 Systems approach to medical device usage

Medical devices are frequently used in a system, with one device necessitating the use of another. For example, in device usage three potential scenarios were identified, either over a period of time or on a single occasion of care delivery:

- Multiple use of the same product
- Multiple use of the same class of device
- Multiple use of varying classes of device

Devices are also used as the primary treatment, for example cardiac pacemakers (Newman et al 1992 [#1157]), or as adjuncts within the overall treatment and care being received by the end-user, for example oesophageal stents for malignant palliation (Mosca et al 2000 [#719]).

In practice devices can be developed and tested in isolation rather than in conjunction with other devices with which they are normally used. In a study examining occupant injury, measures of a fixed vehicle mounted wheelchair occupant restraint system found that the system did not meet the needs of individuals because of poor belt fit, difficulties in use and discomfort. Therefore the authors recommended that restraint systems rather than being solely tested with wheelchairs should be incorporated into wheelchair design (van Roosmalen 2001 [#1511]).

Furthermore, it is not uncommon to find one medical device being used to assess another. This raises questions regarding the relationship between a diagnostic and therapeutic device:

- What effect does the use of a further device have on the assessment of the device under focus?
- Is the evaluation consequently affected by this additional device, for example in terms of its usage and calibration?
- Could the evaluation explain more about the additional device than the device under investigation?

In one example, an optical leg volume meter was required to assess the effects of lycra support stockings (Jonker et al 2001 [#1514]). In another, a transducer was used to measure the forces and moments applied on the socket of an amputee when wearing a transfemoral prosthetic limb. These measurements were recorded at distance using a wireless modem (another device) to transmit the data (Frossard et al 2003 [#29]).

Particular measurement challenges and issues exist in relation to testing of safety and efficacy in highly invasive devices such as implantable anti-tachycardia devices. These devices are designed to detect arrhythmias and deliver the appropriate therapy. However, when testing such a device (implanted defibrillator) in 20 patients with recurrent ventricular arrhythmias, 26% of the shocks given by the devices were found to be inappropriate (Newman et al 1992 [#1157]). This high number of inappropriate shocks may have potentially serious or fatal consequences.

4.3.2 Complex disease variables and care effects, including 'acceptable' complication risks

Methodological issues are raised in relation to a number of factors. Some of these include the profound effects of underlying diseases and conditions on device outcome evaluation and the difficulties of differentiating between care/treatment effects and actual device performance. As medical device performance and outcomes are intertwined with numerous variables (some of which may be clinically unknown) device evaluation requires methodologies that facilitate device assessment within the context of their usage, reflecting and capturing issues of aetiology, co-morbidity, treatment and care.

One study surveyed noted that variables such as age at surgery and pathological diagnoses are highly significant (p=0.0001) in terms of outcomes following knee

arthroplasty (n=355) (Gill & Joshi 2001 [#202]). Another study evaluated revision hip arthroplasty (n=609) in the first year after surgery. It reported dislocation of the new implant occurred in over a quarter of patients who had undergone two or more previous total hip arthroplasties and over a third needed a further operation (Dawson et al 2001 [#144]).

A further paper reported on a series of saddle prostheses (n=17), inserted following resection of pelvic malignant tumours (Cottias et al 2001 [#689]). Complications such as nerve damage and infection were observed in 11 patients and functional results were available for only 9 patients as 6 had died, 1 was lost to follow up, and 1 was excluded because of removal of the prosthesis secondary to deep infection. Despite a complication rate of 65%, the authors' comment quoted below suggests that in such complex cases the outcome standards reported are acceptable:

"…The prosthesis provided in all cases an early pain free weight bearing reconstruction with minimal limb shortening, but the functional results remained fair in most patients due to a limited range of motion and poor abductor strength…" (p90)

Small group-work with inclusive sampling strategies, such as in the above example, suggests that in-depth case study methodologies may be appropriate to maximise understanding in complex cases.

Contextual issues also arise in relation to complications and risk, which in turn raise philosophical and ethical questions. The study cited earlier examining the role of self-expanding stents, endoscopically implanted for the palliative treatment of malignant oesophageal stenosis, raises the issue of what is acceptable in relation to complication rates and outcome measures in palliative care. In this study complications occurred in 9 out of the 37 patients who had stents inserted (Mosca et al 2000 [#719]). In 3 of the 40 patients it was not possible to implant the stent because the guide wire could not be passed through the stenosis. The 9 complications comprised 2 bleedings, 3 neoplastic obstructions, 1 food obstruction and 3 distal dislodgements of the stent. Despite difficulties with the procedure and the device the authors concluded that endoscopic placement of metallic self-expanding stents is safe and to be preferred to plastic stents for easier implantation and lower morbidity in this given context. This study reflects the difficulties in weighing potential risks against the benefits, particularly in palliative care.

There are also questions as to what is acceptable in relation to complication rates and outcome measures in countries where health provision is less harmonised than in the five countries/regions with the most advanced medical device regulations (refer to p3). The two studies described below raise important ethical issues around equity of access and parity of standards within the global healthcare arena.

In a study evaluating the results of extracapsular cataract extraction with posterior chamber intraocular lens implantation (n=49) in an outpatient clinic in Ghana, performed

by 5 American surgeons, biometry was not available therefore intraocular lenses were randomly selected (Egbert & Buchanan 1991 [#1185]). Compared with preoperative status, visual acuity without correction improved in 41 patients (84%), remained the same in 5 (10%), worsened in 3 (6%); with correction, the visual acuity improved in 44 patients (90%), remained the same in 3 (6%) and worsened in 2 (4%). Intra-operative complications included vitreous loss (in 5 patients), posterior capsule astigmatism and iris prolapse. Several postoperative complications were noted. The most serious was diffuse corneal oedema in 4 eyes. Glaucoma developed in 2 of these eyes. Other postoperative complications included 2 cases of updrawn pupil, 1 case of vitrous in the anterior chamber, wound problems, iris prolapse, endophthalmitis and retinal detachment. The intraocular lenses were "well tolerated" except for: 1 anterior chamber device decentred, folding the iris and was removed; 1 posterior chamber device decentred by 2mm; and 1 posterior chamber device was partially anterior to the iris. Despite high complication rates, the authors concluded that outpatient surgery might be a safe and practical alternative to in-patient surgery in developing countries.

Another study reported on the short and medium term outcomes of a prospective series of sutureless manual extracapsular cataract extractions (ECCE) and intraocular lens implantation (n=500) at a high volume surgical centre in Nepal (Hennig et al 2003 [#539]). The mean duration of surgery was 4 minutes and the average cost of the consumables including the lens was less that $10 US. Visual acuity declined in the year post surgery and poor visual outcome of less than 6/60 occurred in approximately 2% and intraocular complications in 9.4%. The authors concluded that rapid recovery of good vision can be achieved with sutureless manual ECCE at low cost in areas where there is a need for high volume cataract surgery though avoidable side effects do occur.

Some might argue that within the given contexts described in these two studies, benefits gained outweigh any associated costs, such as certain side effects. Others would argue that this utilitarian approach sits uncomfortably with the objectives of achieving globalised standards within healthcare.

4.3.3 Transferability of devices across cultures and contexts of usage

Controversial questions arise regarding transferability of devices. A balance is required between both individual requirements for a device and requirements at the group level that will facilitate transferability. This is an issue for the Healthcare Industries Task Force (HITF) agenda, informing the UK export strategy and international trade initiative so that sensitivity to local needs and resources is achieved (HITF 2004).

The inappropriate transfer of designs from one cultural context to another has implications for device use. In the example from Northern India traditional western prostheses were discarded by the end-users, as they were inappropriate for their specific cultural context (Sethi 1982 [#1305]). As a result the Jaipur limb was developed. It was made using durable and readily available vulcanised rubber, enabling end-users to work

in the fields and to sit cross-legged. The method made use of local materials and skills to facilitate low technology designs. This highlights the importance of designing technologies that meet end-user needs, facilitating cultural appropriateness and self-reliance in product development. It has also been noted by some that function and quality of a new device should not get lost or overtaken by mechanical and technical issues (Mulholland et al 2000 [#1643]).

4.3.4 Usability, safety and training in relation to medical device usage

Usability, safety and training are inter-related concepts, which highlight the need for the involvement of both users and end-users in the various stages of medical device development. Failure to involve users and end-users in the device development process can result in an end product that fails in its intended purpose. The following studies suggest that human factors/usability methodologies (See Part A Appendix A: Operational Definitions) are indicated to improve medical device design and usability.

In the study reporting on the design and testing of a curb-climbing aid for wheelchair bound paraplegics, 2 channel shaped ramps were attached to the wheels of the wheelchair and telescopic control rods had to be manipulated into position by the wheelchair user. Thus the end-user had to be able to manipulate the ramps into position across the curb for ascent and descent (White, Szeto & Hogan 1980 [#1317]). This system was designed to increase the independence of the end-user but it appears that it may be cumbersome and problematic to use.

Evaluation of devices within the context of usage is essential for evaluating in-use issues, such as safety for both end-users and their carers. In a study of seating problems in patients with Duchenne's muscular dystrophy 63% (60 out of 95) could not lift their heads by themselves when they were tilted backwards whilst seated in their wheelchairs (Liu et al 2003 [#509]). This could lead to asphyxia if unnoticed and was reported in 2 patients. Of the 60 formal carers, 58% experienced trauma related to the seating systems, such as difficulty in making bodily contact with the patients when lifting them from behind the wheelchair. Involving expert assessment and patient and carer interviews benefited both care management and device usage. The authors suggested practical solutions to the safety issues identified, such as ankle-foot orthoses, trunk support, pressure-relieving cushions, powered wheelchairs and adjustable systems.

It is recognised that the fit and performance of medical devices may be problematic even in healthy population samples and raises issues of patient safety. In an analysis of walker problems encountered by subjects in the University of Buffalo Consumer Assessments Study, high levels of performance problems including non-usage of devices and device failures that impact on safety and usability were found (Mann et al 1996 [#22]). Out of 69 individuals 42 reported problems with their walkers. These 42 individuals reported a total of 46 "problem walkers", with 33 no longer being used but 9 were. 57% of the problems were categorised as "difficult and/or dangerous", highlighting a need for careful

professional assessment and follow up. This study noted that improved designs should go hand-in-hand with professional training in assessment and methods for longitudinal follow-up and post-market surveillance.

In a study evaluating two 1-channel volumetric infusion pumps extensive usability problems were identified related to the pumps. For example pump 1 had 89 usability problems identified and pump 2, 52 problems (Zhang et al 2003 [#470]). A further study examined the possible relationship between temporomandibular joint (TMJ) implants and persistent pain, responses to sensory stimuli, quality of life and systemic immune dysfunction. The authors concluded that TMJ implant surgery for TMJ disorders should not be performed until new compelling evidence for the efficacy of implant surgery is obtained. 25 of 32 implants in the sample were removed because of pain and mandibular dysfunction (Ta et al 2002 [#561]).

In the study investigating the effect of mild compression on the development of swelling of the legs and the effect on subjective complaints in healthy subjects, despite a young healthy sample (mean age 39.3), size adoption of lycra support stockings was required for 58 out of 118 individuals (Jonker et al 2001 [#1514]). This was because the individuals did not fit the regular sizing table of the standard stockings. 43% of the sample complained about the discomfort of the 14mmHg stocking and 84% with the 6mmHg stocking. The authors noted that proper sizing of the stockings was a particular problem.

The provision or lack of device related training may greatly affect device related outcomes and usage. For example, in a study evaluating the experience of men (n=120) with the Dynaflex self-contained inflatable penile prosthesis, patient dissatisfaction because of their inability to work the pump was originally 16.66% but after intensive teaching the dissatisfaction rate dropped to 0.83% (Anafarta, Yaman & Aydos 1998 [#1722]). In another example user satisfaction with physical devices increased with training and support (Nochajski, Tomita & Mann 1996 [#320]). This was a pilot study conducted with individuals with cognitive impairments receiving a comprehensive assessment, individualised interventions, training and follow-up over a six month period.

In Summary:

- The context of medical device usage, including cultural appropriateness, must be the starting point for product development including design and use.
- Models for embedding the end-user in the stages of Medical Device Development appear to be well developed in Assistive Technologies.
- Medical devices should not be seen in isolation but as part of a systematic approach to care delivery, including training in medical device use.
- Failure to differentiate between care/treatment effects and actual device performance has implications for outcome measurement and evaluation.

4.4 THE CONTEXT OF TOOLS USED IN MEDICAL DEVICE EVALUATION

A comprehensive list of the tools used within the studies surveyed, together with a brief description and their original source where available can be found in Part A Appendix F: . Additionally, a description of the tools that were developed within studies can be found in the relevant Data Extraction Table corresponding to the Refworks Number.

Given the plethora of tools available for use within medical device evaluation it is not surprising that issues arise regarding appropriate selection for a given context of use. For example, one study states that since 1945 over 75 instruments have been developed to measure functional limitation and disability alone (Parker, Baker & Allman 2001 [#2155]). Particular problems with tools generally relate to the lack of formalised frameworks for producing device-specific outcome models, which will be applicable to different types of devices and their outcomes. Additionally, because of the lack of internationally standardised clinical outcome measurement systems, there is a need for the development of such standardised systems. For example there has been a call for a standardised hip score (Garellick, Malchau & Herberts 1998 [#875]).

Currently the development of device-specific outcome models is motivated by clinical concerns such as comparing the outcomes of competing devices of different but related types (Fuhrer et al 2003 [#1329]). Such models require careful selection of the variables used, and designation of the user population to which they apply. Nevertheless, well-developed and validated models will facilitate the research agenda for medical device evaluation in terms of, for example, the manner and duration of device usage.

In a study developing a framework for producing assistive device specific outcome tools the following aspects were discussed: procurement of a device-type, introductory use, shorter term outcomes, longer term use, moderating co-factors, longer term outcomes, continued use, and discontinued use (Fuhrer et al 2003 [#1329]). The framework highlighted the need to examine outcomes consistently over time, the need to include the multiple stakeholder perspectives and consideration of all stages of device development. Additionally, the inclusion of multiple methods within the context of device use was indicated.

The recurring theme in the literature surveyed is the lack of harmormised outcome measures. This indicates the need for the development of such measures otherwise problems in evaluating outcomes will remain. For example, different tools used for evaluating the same clinical condition may actually be measuring different outcomes, making comparisons between similar studies problematic. In one study 15 different tools for assessing knee arthroplasty procedures were analysed (Barck 1997 [#930]). The results contradicted the prevalent opinion expressed in the paper that the outcome differences between knee evaluation systems were small. Thus, the notion that different

knee evaluation systems measure different underlying factors was supported. More detailed operative specifications for the different systems were suggested as a first step to decrease the variability among assessment system outcomes. Reasons given for the wide spread of the results were different demarcation of categories, the indices measured different factors, and poor operating instructions.

Another study reported that the SF-36 has been used to establish outcomes following total hip arthroplasty and is perceived as a well-established assessment tool in clinical studies (Harwood & Ebrahim 2000 [#231]). Furthermore it was used as a "benchmark" with which to compare the outcomes of other tools such as the London Handicap Scale and the Nottingham Extended Activities of Daily Living. However in this particular study comparing the size of benefits resulting from a hip replacement using the SF-36, the London Handicap Scale and the Nottingham Extended Activities of Daily Living scale, the three various tools calculated different sizes of benefits. This is another example highlighting the fact that different tools may measure varying sizes of benefits in relation to outcomes because they focus on and measure varying aspects of functional recovery.

Not only may variation in scoring ranges and scales potentially cause confusion in practice but the example below revealed significant differences among the mean total score outcomes causing questions to be raised regarding the reliability of the measures. Four commonly used scoring systems for knee arthroplasty: the Hungerford Score, the Hospital for Special Surgery score, the Knee Society knee and function scores, and the Bristol Knee score revealed considerable differences in outcome scores (Bach et al 2002 [#117]). Using statistical analysis the median total score outcome, as averaged for both observers and for all the knees was 74 points; the median for the Hungerford score was 75, for the Hospital for Special Surgery score 58, for the Knee Society score 50, and for the Bristol score 71. The authors concluded that the results indicated that using different scoring systems makes it difficult to compare results of different studies reporting on outcome of total knee arthroplasty.

4.4.1 Conceptual clarity for tool development

There is value in the development of tools that incorporates a variety of different perspectives in assessing device performance. An abundance of factors that influence the ability to perform activities of daily living, independent of the effectiveness of assistive devices, were identified in one paper (Wessels et al 2001 [#697]). This was an empirical study conducted to support the contention that the Individually Prioritised Problem Assessment (IPPA) is a valid measure of the change attributable to assistive technology service delivery, as perceived by the client/end-user. The assumption was made that the difference between the total IPPA score before and after provision of assistive technology represents the effectiveness, thus indicating the degree to which the perceived inconvenience diminished with respect to problems.

It was noticeable that tools may not focus solely on outcome measures. Tools may aid analysis of a particular product but some of the issues raised may not have known answers within the context of medical device development. The intended use of a developed product may yet to be determined. Even where the use of the product is known and developed, the size of the potential market may be unknown because of a lack of epidemiological data regarding particular conditions for which the device may be beneficial. For example, a conceptual tool, the Rehabilitation Technology Product Taxonomy, was developed as a framework for analysing rehabilitation technology products and extracting demand determinants (Vernardakis, Stephanidis & Akoumianakis 1994 [#1955]). The tool promotes examination of: the economic environment - competitive strategies, prices, level of competition, and intensity of competition; the market structure - size of firms and type of structure (i.e. monopoly, oligopoly, free market conditions etc); the product itself - the type of product (tool versus appliance), the purpose, the form of support a product is associated with (i.e. tangible versus non-tangible), the method of provision (i.e. loan, subsides &/or tariffs), and the intensity of care that the product is aiming to provide; and the underlying technology - type of technology, innovation type and direction, existing versus non-existing technology, enabling versus disabling technology, and technology maturity stage (i.e. technology push versus technology pull). By incorporating different factors in one tool, including the different stakeholder perspectives, greater clarity can be achieved.

4.4.2 Tool development for specified applications

Two categories of tools were identified to assess device performance: generic tools and specific tools. A number of issues are raised regarding the validity, reliability and sensitivity when using either category of tools in a particular application. An additional issue for generic tools is whether they are able to distinguish the end-user's general condition from actual device performance. For example, The Barthel Index, Sickness Impact Profile and Functional Independence Measure have been used to measure general disability levels within studies rather than specific medical device related goals (Wessels et al 2001 [#697]). These issues are expanded below.

The use of tools for specific populations and groups of medical devices suggests that in medical device evaluation the use of generic tools may not yield informative data of device performance and patient outcomes. This raises a number of issues regarding sampling of medical device user populations or groups and the need to generate device and context specific tools. A tool for example has been designed to examine specific populations, such as the self-administered hip-rating questionnaire, for the assessment of patients with arthritis of the hip (Johanson et al 1992 [#1163]). A further tool, the Quebec User Evaluation of Satisfaction with Assistive Technology, addresses specific groups of medical devices such as those used to assess seating and mobility aids, transfer aids (toilet adaptation, toilet seats/chairs and stair lifts), communication devices, lower limb

prostheses and environmental controlled devices (Demers, Weiss-Lambrou & Ska 2000 [#1585]). The Child Amputee Prosthetics Project-Function Status Inventory is specific to toddlers who use protheses (Pruitt et al 1999 [#1662]). It is a standardised instrument designed to assess functional status in toddlers aged 1- 4 years who have either an upper or lower limb deficiency.

Process of Tool Development and Use

There are distinct processes involved in developing tools that will effectively measure user outcomes and capture the end-user experience. The initial formation of items for a tool may involve a process of generation, including a literature review, a review of existing instruments, expert knowledge, consensus generation and end-user review. For example in the development of the Seating Identification Tool, a screening tool designed to identify the need for formal seating and wheelchair intervention among institutionalised elderly, the generation of items was performed by two clinicians, an occupational therapist and a physiotherapist, utilising their clinical experience and a literature review (Miller et al 2004 [#402]).

The complexity involved in developing tools is compounded by the various factors embedded within the tool that can impact on study outcomes. Care needs to be taken to ensure that measurement scales contained within tools provide sufficient meaning when evaluating device performance. In the case of medical device evaluation the commonly used visual analogue scale, for example a 10cm scale anchored from “no difficulty” to “so difficult require help” may be problematic, lacking sufficient meaning at specific points (Curtis et al 1995 [#1045]).

Tool development may often involve extraction of items from existing tools, however this will necessitate a further process of validation. For example, the Wheelchair Users Shoulder Pain Index was developed from the Shoulder Pain and Disability Index (Curtis et al 1995 [#1045]).

Examples displaying thorough tool development processes

A study developing a tool for amputees using prostheses found that piloting of the instrument was essential, increasing the instruments validity and internal reliability (Huber, Medhat & Carter 1988 [#379]). The purpose of the study was to construct a reliable and valid instrument to identify problem areas in the broad range of activities within the capability of lower extremity amputees with prostheses. Maslow's Hierarchy of Needs and Roy's Adaptation Model were used as a conceptual framework in developing this tool, the Prosthesis Problem Inventory Scale. Items were selected from a comprehensive literature review, existing instruments assessing other disabilities, and the clinical experience of the authors. The instrument was assessed by a diverse range of instrument reviewers, and content experts from the fields of nursing, rehabilitation medicine, sex therapy, sports medicine, sports and physical fitness. The suggestions of the content experts were then incorporated in the instrument. A pilot study was

conducted with 26 amputees to develop the content validity of the instrument. The instrument was further revised and then given to the 131 amputees for further validation.

In another study that developed an interactive training programme and interpretive guidelines for professionals administering the Assistive Technology Device Predisposition Assessment consumer form (ATD PA), an iterative user involvement process was used (Scherer & Cushman 2002 [#663]). Professionals (n=22) representing diverse geographical regions, cultural backgrounds, a range of ages and both genders were exposed to the new, pre-pilot, interpretive guidelines. The participating professionals and consumers who were exposed to and used the ATD PA were then asked to complete a survey on their experiences. Members of an advisory committee read summaries of the responses to the survey and identified the essential content for the ATD PA interpretive guidelines and interactive training programme. This information was used by the advisory committee in a modified nominal group technique (See Part A Appendix A: Operational Definitions). All responses were summarised and distributed to the advisory committee members until the group was unable to provide additional responses. Finally, all acceptable topics were redistributed to participants to rank-order the ones they believed were most important in: a) the process of matching person and assistive technology; b) to include in computerised interpretive guidelines; and c) to include in the interactive training programme.

In both studies a diverse range of professionals were used to review the respective tool's content and their feedback was appraised so as to be incorporated systematically into the tools.

The final process of tool development is necessarily validation of the instrument. The nature of disease processes that underpin medical device usage fluctuate over time complicating the validation process. Indeed stability in coding over a period of time could reflect a lack of sensitivity of the particular tool in capturing changes. Thus the issues of validation required for tools used in the context of medical device assessment are inherently complex.

4.4.3 Validity and reliability

As stated previously, there are issues concerning the use of both generic and specific tools. Questions are raised as to how sensitive generic and specific tools are to changes in disease status and device performance (Ragab 2003 [#1391]).

From the literature survey a variety of difficulties and questions were raised which reflect the need for robust validation processes in the application of tools in medical device evaluation:

- Can generic and specific tools be used in one study?
- Are specific tools where available more sensitive to clinical change?
- Is clinical change measurement sensitive to changes related to device performance as opposed to other factors such as the surgical procedure?
- Does a battery of tools yield information about device use?
- Are specific and generic tools sensitive to nuances in device performance and outcomes?

The following examples illustrate some of the challenges to robust validation as mentioned above. From the literature surveyed it is apparent that some studies developed and used tools with no mention of piloting or validation processes. For example in a study examining the experiences of women receiving bilateral breast augmentation, the women completed a 2 page questionnaire designed to assess their reasons or expectations for the surgery and their concerns about perceived risks of both surgery and the implants (Cash, Duel & Perkins 2002 [#1474]). At 6, 12 and 24 months postoperatively the women completed another 2 page questionnaire, rating on a 5 point Likert scale their satisfaction with surgery and its specific psychosocial outcomes, their concerns and their benefits-to-risk appraisals of the augmentation. The questionnaires were adapted from an existing survey instrument and from information obtained from focus group research with women who had sought breast implants. The authors acknowledged that they did not use well-validated instruments.

In a study designed to assess the reliability of the Pain and Function of the Hip Scale (PFH) and its degree of association with other instruments, as well as its ability to measure clinical change (responsiveness) in patients undergoing total hip arthroplasty, it was found that Cronbach's alpha reliability coefficients were 0.81 for the PFH and 0.91 for the Nottingham Health Profile (NHP) (Alonso, Lamarca & Marti-Valls 2000 [#219]). Data presented in this study showed that the PFH is responsive to clinical change. The amount of improvement detected by the PFH (a specific tool) was higher than that of the NHP (a generic tool), indicating the PFH to be more sensitive. Also, the PFH showed a moderate to high level of correlation with patients' perceived health status as measured by the NHP. However, only moderate correlation was observed between the PFH scale and clinical examination.

In another study assessing patients with a primary total hip arthroplasty, the Harris Hip Score and the Nottingham Health Profile was used at 1, 3 and 5 years post surgery to compare the specific and general outcome measures in evaluating total hip replacement. The authors concluded that the tools were not able to detect subtle differences in the

performance of 2 different types of hip replacement at 5 years post operatively (Garellick, Malchau & Herberts 1998 [#875]).

Translation to other areas (validity)

Transferring tools to contexts outside those in which the tool was developed and intended raises questions regarding the validity of such use. For example, the Nottingham Extended Activities of Daily Living scale is a popular outcome measure in stroke research but it has not been validated in other conditions (Harwood & Ebrahim 2002 [#628]). However, in this study it was used in the context of total hip arthroplasty. It was reported that responsiveness was disappointing and it was unsuitable for evaluating interventions outside the setting for which it was designed. The authors stated:

"...The quest for brief generic instruments for measuring outcomes must be viewed with considerable caution..." (p376).

Another study evaluated whether dissatisfaction with the artificial limb and/or body image related to achieved mobility following lower limb amputation in established limb wearers. A questionnaire on body image was used, adapted from an eating disorders instrument (Fisher & Hanspal 1998 [#60]).

The inherent nature of some tools can also preclude their use by varying groups of assessors. For example, OTFACT, an assistive technology outcomes assessment protocol is used by occupational therapists (Smith 2002 [#571]).

There are methodological issues raised in relation to modifications of existing tools. Some of these include:

- Modification of a tool from an assessor administered tool to a patient self-administered one raises issues regarding validation. For example, in a study examining outcomes post Total Hip Arthroplasty (THA) a self-reported version of the Patient-Specific Index was created (Wright, Young & Waddell 2000 [#57]. The original Patient-Specific Index reflects how individual patients weigh concerns in rating the outcome of THA and is administered by an interviewer.
- Issues arise regarding tool validation for particular populations.
- An additional and related point is validation of tools translated into another language.

All the above changes will require further validation of the tool post-modification.

Training of observers (reliability)

Both inter-observer and intra-observer reliability may be of concern in relation to tool usage. Reliability can be affected by the specific professional group using a tool and by the level of clinical skill and experience of individual assessors within that group. For example, a study examining the reliability of the American Knee Society Score found that intra-observer reliability varied according to the experience of the assessor (Liow et al 2000 [#220]). The assessors who evaluated the subjects included: a consultant with an

interest in knee surgery, two registrars with at least 3 years experience in orthopaedics, one senior house officer with 3 months experience in orthopaedics, and two arthroplasty nurse practitioners whose responsibilities occasionally included clinical assessment. The more experienced observers had greater intra-observer reproducibility. Notably, there was moderate agreement between observers in the subjective variables, while the objective variables produced lower levels of agreement. The authors noted high levels of inter- and intra-observer variations in scoring of the tool and concluded that reliable use of the tool would necessitate repeated evaluation by an experienced observer. This study raises pertinent contextual issues with respect to tools being used by varying professionals in order to measure outcomes. These include cross-disciplinary working issues, professional variation in opinion within and between professional groups and the need for robust, observable, single-meanings for components of any tool, with terminology defined.

In a study examining use of the Brooker Classification (1973) used in post hip arthroplasty, physicians with different training backgrounds were assessed for inter and intra-observer reproducibility (Della Valle et al 2002 [#580]). They included: three orthopaedic research fellows who trained in Argentina and Italy to act as observers; and three observers, who were trained in North America, a surgeon, a 4th year orthopaedic resident, and a musculoskeletal radiologist. The study showed that the classification lacked inter-observer consistency which improved with a modified classification (52% to 76%).

The literature surveyed revealed the need for training of assessors in the appropriate use of context specific tools. It has also been found that the mechanism or format of administration of the tool may be pertinent. Multiple sclerosis participants found an interview based format of the Quebec User Evaluation of Satisfaction with Assistive Technology (version 2) to be the most convenient, with robust test-retest stability, when compared to the self-administered questionnaire format (Demers et al 2002 [#2153]).

User and end-user rating variations

Just as reliability is an issue for tool use within and between professional groups, discrepancies and variations between clinicians and end-users may be highlighted when completing tools. These variations require acknowledgement. Essentially differences in perceptions between clinicians and end-users need to be understood and the context of the end-users needs to be taken into account. For example the Functional Independence Measure and Instrumental Activity Measure have been found not to cover all aspects of care that are significant to young adults living in the community who have cerebral palsy or spina bifida (Andren & Grimby (2000) [#782]). It was found that these tools exclude aspects that individuals with potentially high levels of need consider to be of importance such as personal care and occupational and leisure domains.

Differences have been observed in tool ratings between patients and clinicians. In a tool assessing function post total hip arthroplasty, patients rated themselves more favourably than physiotherapists, with the patients perceiving that they did not require “assistance” while the physiotherapists assessed that they did (Kroll et al 1994 [#1951]). The authors concluded that this disagreement might reflect variation in individual definitions of the word “assist”.

In Summary:

- The literature surveyed reflects a need for standards in tool development for medical device evaluation including:
  - Conceptual clarity for tool development
  - Development of device and context specific tools
  - Embedding end-users in the process of tool development and validation
  - Validation of the transfer of tools from one context/device to another
  - Training of observers
- The approach to tool usage whereby multiple tools and data triangulation (different sources of data) are adopted can still miss the goal of generating valid and reliable outcome measures of medical device use, unless the tools are ‘fit for purpose’.

4.5 METHODOLOGICAL CHALLENGES IN MEDICAL DEVICE EVALUATION

A cluster of recurring themes were identified in the literature, which are relevant to the specific context of medical device evaluation, and raise procedural and methodological challenges to research in this area. They include the fast paced nature of technological development, ethical approval and research governance processes, commercially funded research, and lack of device performance outcome measures and methods.

4.5.1 The fast paced nature of technological development

Traditionally, clinical trials take a matter of years from the beginning of the research process until the publishing of results. This model is not however suited to the evaluation of devices that are continually evolving through technological developments. This suggests that methodologies that take account of new iterations of existing devices, such as 'Tracker Trials', are called for to determine the implications of new devices and their value against existing ones (Lilford et al 2000).

4.5.2 Ethical and research governance procedures

There were indications in the literature surveyed that ethical approval for studies involving devices for vulnerable subjects, such as children with physical disabilities, may influence the researchers' ability to access these subjects directly. For example, in a study, conducted in a seating clinic, assessing seating and mobility devices for children with physical disabilities, parents and caregivers were used as proxies for children even those up to the age of seventeen (McComas, Kosseim & Macintosh 1995 [#1912]). This suggests that once careful consideration has been given to identifying who the end-users are, the researchers need to make a robust case to ethics committees to sample these users with governance processes in place to protect vulnerable subjects. In the UK ethical approval and research governance procedures are being thoroughly overhauled. It is well recognised that because of high profile cases such as Alder Hey (Royal Liverpool Children's Hospital 1999) the current processes of gaining access to research subjects have been tightened up to the point where they have become barriers to research.

The dangers of over-regulation in this respect are to drive research into communities and countries where ethical approval procedures are not required. There were indications in the literature that western trained clinicians have performed procedures and interventions abroad where standardised protocols are lacking. For example, in a study examining the results of extracapsular cataract extraction with posterior chamber intraocular lens implantation in an outpatient clinic in Ghana, performed by 5 US trained clinicians, the authors stated that:

"…Preoperative refractions could not be performed because of the dense cataracts, and biometry was not available therefore intraocular lenses were randomly selected…." (Egbert & Buchanan 1991 p1765 [#1185]).

The recipients in this study underwent treatment they may not have otherwise received but the lack of protocol and assessment tools suggest a lack of global standards. Current initiatives in the UK and globally are addressing these issues. It is to be hoped that on-going revisions in UK ethical and research governance procedures, together with the global initiatives on standards, will reach a balance between protecting the vulnerable and allowing sound research and innovation to proceed, for the benefit of medical device users and end-users (HITF, World Health Organisation, Global Harmonisation Task Force and the European Union's New Approach Directives).

4.5.3 The influence of commercial funding on research outcomes

Controversially, commercial funding may be associated with a bias towards reporting of positive outcomes. For example, it may be more likely that a single manufacturer's device is evaluated without cohort groups of other manufacturers' devices or comparators.

The following paper raises the additional issue of the inability to analyse the frequency of failures to disclose commercial relationships. In a review of the prevalence of corporate funding in hip and knee arthroplasty 603 consecutive studies reviewed. Commercial funding was found to be present in 50% of the studies (Ezzet 2003 [#1321]). The authors found that in adult lower extremity orthopaedic research upward of 90% of studies reported positive outcomes when carried out by commercial industry, and 30-60% of studies reported bad results or cause for caution when carried out by independent researchers. In the US information on the performance of implants is primarily via research literature. Surgeons funded by commercial companies may provide the available literature, and because the criterion for disclosure varies from one format to the next, the same investigator presenting the same research may fail to disclose a relationship in another format.

Overall engagement with industry is problematic if commercial values and needs are given priority over user and end-user needs. This suggests more equitable partnerships with industry for medical device evaluation, possibly following the US Veterans Model of 'locking-in' manufacturers at an early stage of medical device development and evaluation, may be of great value (Sheredos & Cupo 1997 [#934]).

4.5.4 Lack of harmonised outcome measures and methods

There is a lack of clarity and consensus on what constitutes appropriate outcome measures for medical devices. It has been argued for example, that the results obtained with physical status measures including goniometry, muscle force measurement and radiographic examination, commonly used for orthopaedic device evaluation to reflect relevant aspects of quality of life, should also be related to the physical and social ability of the patient (Oberg, Oberg & Oberg 1994 [#1086]). Uniform outcome measures and defined end-points for specific device areas require on-going development, incorporating consensus generation so that measures are comprehensively accepted across studies.

This lack of clarity with outcome measures is further complicated by issues of appropriateness regarding outcome measures for particular settings. For example, visual acuity may be appropriately used as the sole outcome measure following intraocular lens implantation in Nepal (Hennig et al 2003 [#539]). The author stated that:

"In developing countries there has been a shift to surgery with an intraocular lens, but phacoemulsification has had a limited role, owing to the expense of equipment and consumables, and the high proportion of eyes with dense nuclei and mature cataracts. In order to obtain the advantages of a self sealing suture-less incision at low cost, developing world ophthalmologists are considering alternatives to phacoemulsification." (p266)

In contrast, in the developed world more complex outcome measures may be utilised within this context such as best corrected Snellen distance acuity and Miller-Nadler glare testing (Davis 1992 [#1126]). In this example pharcoemulsification was already being used in Canada in the early 1990s. Thus, outcome measures may require defining to be appropriate to the country, cultures and population of the study. Consequently, the differences also raise questions regarding the need for global harmonised methods.

Varying data collection time points will affect study results and outcomes particularly in the post-intervention follow-up period. The following three studies highlight the need for robust protocols in post-market surveillance studies. The first study raises a pertinent question as to whether 3 months as the last data collection point is satisfactory in terms of assessing patients with both conventional dentures and implant stabilised prostheses (Allen, McMillan & Walshaw 2001 [#208]). Another study evaluated patient satisfaction and quality of life after bone-anchored hearing aid implantation. Patient benefits were found to be significantly improved following implantation and when the participants were asked about the success of their bone-anchored hearing aid the response was extremely positive. However, no baseline data prior to implantation were collected, so assessment relied on retrospective recollection by the participants (Dutt et al 2002 [#611]). Lastly, in a single study, post pacemaker implantation assessment (n = 93, 56 Swedish patients & 37 US patients) was performed at 3 months in a Swedish sample and at 6 months in a US sample, with comparisons being made between the two different time points (Bolse et al 2002 [#1355]).

Technical/Clinical and Contextual/Perceptual Information

Within the literature questions are raised as to the importance of the concept of satisfaction in assessing device performance and usage. In a study of 70 upper limb amputees in Australia, 56% wore their limbs "once in a while" or "never" (Davidson 2002 [#1489]). The amount of time amputees wore their prostheses was only moderately associated with their level of satisfaction with their prostheses. The association between the amount of time amputees wore their prostheses and their level of satisfaction with their functional abilities was very low. In addition this example raises other important

issues: What do high levels of non-usage of devices inform about device performance? Were the high levels of non-usage related to the experiences of pain and sweating? 40% stated pain interfered with their ability to wear a prosthesis and 55% rated sweating as "not acceptable" whilst wearing the device. A further study is required to explore sub-optimal outcomes.

The following studies raise a number of issues in relation to the use of satisfaction as an outcome measure. Where the device is implantable and part of a surgical intervention end-user satisfaction may only be measurable on the parameters of the process of care rather than the actual device (Mancuso & Salvati 2003 [#52]; Ragab 2003 [#1391]).

In the study examining the experiences of women (n=360) receiving bilateral breast augmentation very high levels of satisfaction were found in 90% of the sample (Cash, Duel & Perkins 2002 [#1474]). Even where significant capsular contraction occurred 71% of those women remained satisfied with the outcomes. Thus, obvious signs of procedural failure (related to muscular contraction) did not correlate with outcome satisfaction. This example also illustrates that without the 'right tool', measuring constructs such as satisfaction, and relating these to clinical and technical outcomes, gives rise to conflicting findings that are difficult to interpret.

In a study assessing patients satisfaction with the process of total hip arthroplasty (n=336) older individuals and those who did not live alone tended to be more satisfied suggesting that living alone may significantly influence measures of satisfaction (Mancuso & Salvati 2003 [#52]).

Other difficulties with satisfaction measures:

In practice it can be problematic for individuals to distinguish satisfaction levels related specifically to the performance of their device from their overall satisfaction levels with the care and services they have received, thus raising issues of validity. For example, studies may question participants regarding "what is the overall level of satisfaction with your device?" and "what is your overall satisfaction of service delivery as a whole?" (Wessels & De Witte 2003 [#541]).

There may be difficulties with measuring device satisfaction using different products with similar end-points. For example a postal questionnaire was used, which relied on retrospective recall of one contraceptive implant compared with other forms of contraception previously used by the participants (Reuter & Smith 2003 [#1388]). This type of post-market surveillance relies heavily on memory and lacks accuracy of measurement. Respondents in the study (n=75) compared the implant favourably, "better" or "the same", with their experiences of other methods of contraception, despite the fact that only 17% of the sample experienced no side effects. Bleeding irregularities were experienced by 41% followed by weight gain, moods and headaches. 19% had

their implant removed during the study period mainly for bleeding problems, and the wish for pregnancy was not stated as a reason for removal.

Other measurement issues:

Outcome measures that capture psychological domains were used in some studies. Psychological issues may not be related to device performance. Additionally, issues may be raised regarding the measurement sensitivity of these outcomes and whether individuals find such measures inappropriate or intrusive. In a study seeking to establish whether dissatisfaction with the artificial limb and/or body image related to achieved mobility following lower limb amputation in established limb wearers (n=107), body image disruption, anxiety and depression were measured (Fisher & Hanspal 1998 [#60]). The authors concluded that these measures were not common in established limb wearers.

Both response rates and sample attrition raise questions regarding non-response bias. It is possible that those individuals who do not respond are indicative of those who are frustrated by their treatment or device outcomes. In a study following patients for up to 12 months after total hip arthroplasty, the initial patient population was 98, by 6 months this had fallen to 62 and 42 patients remained at 12 months (Johanson et al 1992 [#1163]). In a study evaluating total hip arthroplasty the authors concluded that care must be taken in interpreting results of intervention studies where the response rate is less than 100% (Harwood & Ebrahim 2000 [#231]). They stated that patients least pleased with their results may also be the least likely to respond to requests to complete questionnaires, with an additional element of acquiescence bias also possible, where patients grateful for any help that they get are reluctant to declare poor outcomes.

4.5.5 Methodological challenges

Methodological development

Disparate, and at times flawed methods and tools are used across numerous and diverse contexts of medical device usage. Methodological development is therefore clearly needed. Defining and validating methods that can be used systematically within specific device related groups and populations would facilitate comprehensive mapping of device performance.

Successful use of any method requires careful selection dependent upon the medical device under evaluation, the context of its use and the populations under study. Additionally it is predicated on the actual implementation of the method. Studies illustrate that contextual detail is all important, as is carrying out tests and feedback for device development in real life environments that are related to everyday tasks. A range of methods are indicated, for example, clinical imaging and engineering (Wuisman et al 2001 [#738]), social science methods (McCreadie et al 2002 [#564]; Bauer et al 1998 [#878]) comprising focus group and consensus building methods, and ergonomics methods (Hefzy, Nemunaitis & Hess 1996 [#994]).

Data capture methods (pre-market)

A number of studies highlighted a variety of methods to capture data that facilitated device development. For example, home visits were made to individuals with motor neurone disease to discover what items of equipment would enable them to live more independent lives (Burkitt et al 1995 [#326]). These visits produced a list of over 30 items that were then prioritised via the use of a questionnaire. One item was chosen from the list and the Autosip device was designed. This device was designed to assist individuals with motor neurone disease who have minimal sucking ability and/or arm strength to have a drink. It removes the need for assistance from a carer. Consultations were held with potential end-users, and the appropriate care professionals, in various stages in the development of the Autosip. Prototypes were frequently tested with end-users which ensured that the desired device was produced. However, the paper indicates that only sixty of these devices were adopted which raises issues regarding successful commercialisation of products developed through research initiatives.

The value of obtaining user feedback is illustrated in a case with older people in a research programme with gerontologists and engineers. Focus groups (See Part A Appendix A: Operational Definitions) and informal/user trials were used to identify problems and solutions with respect to their indoor mobility difficulties (McCreadie et al 2002 [#564]). Their views were then incorporated into making the proposals to design the products. Both methods (focus groups and informal trials) addressed the issues identified and provided innovative assistive devices and highlighted the value of using these methods before attempting to design solutions.

Other methods of capturing data include the use of case study and usability test designs (See Part A Appendix A: Operational Definitions) incorporated in the product design criteria (Hefzy, Nemunaitis & Hess 1996 [#994]). The device is an affordable pressure-relieving device that is adaptable for wheelchairs which allows individuals with quadriplegia to relieve the pressure from their ischial tuberosities. First and second generation prototypes were developed which highlighted simplicity of design, and included real life observation and testing. This resulted in a pressure relief system that functions without the assistance of another individual (carer).

Data capture methods (post-market)

There is a need for methodologies for reporting outcomes with evolving devices within the post-marketing surveillance stage in medical device development. In a previously mentioned study, outcome data between 1993 and 1999 were reported for metallic self-expanding oesophageal stents used in palliative care using three different manufacturers' stents (Mosca et al 2000 [#719]). The way in which this study was performed made it problematic to draw conclusions between the performance of one stent and another. This suggests the need for a protocol for reporting changing technologies for the benefit of

manufacturers and providers, as well as the need for a more rigorous and universal post-market surveillance methodology.

Methods for predicting possible device related hazards and events also require development. This is of particular importance because reporting of actual events and hazards by users may be based on voluntary systems, for example the Medicines and Healthcare products Regulatory Agency (MHRA) Adverse Incident Report Forms system for users and manufacturers (http://www.mhra.gov.uk). In a study that sought to determine whether computer-based surveillance can reliably identify medical device-related hazards (no known harm to patient) and adverse medical device events (patient experienced harm) with alternative methods of detection of device-related problems, two pertinent issues were highlighted: currently there are poor predictive detection strategies; and potential hazards or events are not regularly assessed (Samore et al 2004 [#1349]).

There is an overall need for combined and triangulated data collection methods. The use of a combination of data collection methods, such as clinical evaluation by expert clinicians, radiographic evaluation and patient completed questionnaires to combine perspectives of outcomes may facilitate comprehensive assessment. In additional, there is value in using comprehensive interventional methods. In appropriately designed studies interventional methods may be particularly beneficial in revealing the value of specific devices and the associated requirements for individualised assessment and training. A study assessing the impact of professional intervention amongst older adults with cognitive impairments (n=20) who use assistive devices, used satisfaction as a measure (Nochajski, Tomita & Mann 1996 [#320]). Based on assessment results and interviews with the participant and care provider, assistive devices and environmental interventions were provided or existing assistive devices were adapted to meet specific individual needs. The participants received individualised training on the use of the devices by an occupational therapist. Further support was provided by telephone follow up at 2 week, 4 week, 2 month, 4 month and 6 month intervals.

Longitudinal studies have value in ascertaining the impact of medical device usage over sustained periods of time. In a study examining satisfaction of 3 treatment modalities in resolving lower denture related complaints, patients (n=90) were followed for ten years post-treatment (Raghoebar et al 2003 [#1337]). Such length of follow-up however was infrequently found.

Data capture for the testing & trials and post-market stages

Outcome measures that are both specific and appropriate in assessing device performance are required. Such outcome measures need to be observable and objective, but may vary widely according to the device and setting. For example, heart rate may be an appropriate measure of physiological strain when using an arm propelled 3-wheeled chair in the context of the developing world (Mukherjee & Samanta 2000 [#772]).

However, heart rate may not be an outcome measure for a person who uses an electric wheelchair.

Methods are indicated for systematically transforming end-user requirements into a form that is useful and accessible to product designers and manufacturers. For example one study described the use of a focus group, based on the Kano Focus Group Model and a consensus generation model, based on the Quality Function Deployment Model (Bauer et al 1998 [#878]). The method was used to examine battery chargers for wheelchairs. It identified low cost improvements that could be made which would possibly provide companies with a competitive advantage in the market place. It also highlighted issues that were important to end-users which are not normally considered in product evaluations of battery chargers such as warranty lengths.

Multidisciplinary working for the purposes of methodological development and device design can facilitate novel development and beneficial insights through collaboration that would not develop by single disciplines alone (Mulholland et al 2000 [#1643]; Sethi 1982 [#1305]; Burkitt et al 1995 [#326]; Malassigne et al 2002 [#1482]; Sheredos 1997 [#934]; Barrett, Laurin & Bloom 2003 [#1389]). The examples given here can be found in Part A Appendix E: (Exemplary Cases). In addition, the multi-disciplinary process lends itself to multiple methods and can involve industrial expertise. For example, a custom made sacral prosthesis was developed using extensive clinical analysis, CT and MRI imaging, 3D modelling and wax models, in conjunction with engineers from a manufacturing company (Wuisman et al 2001 [#738]).

There is also a need for methodologies for testing the theoretical risk of two devices where one could have an influence on the vital functioning of the other and on patient safety. For example warnings regarding a heart rate monitor affecting pacemaker function stimulated the respective manufacturer to part-fund a study conducted by a clinical and academic collaboration (Joglar et al 1999 [#846]). They investigated whether any interactions occur between a heart monitor and the implanted pacemaker that might affect the function of the pacemaker or the accuracy of the monitor. The theoretical risk was not substantiated in this case. A practical approach was demonstrated involving the investigation of interactions between devices leading to safe practice with implications for a number of contextual uses.

There is a profound need for routine data capture in healthcare practice regarding medical device performance. Such data capture would create comprehensive clinical databases that could facilitate mapping of device performance, and would be of benefit to national regulators and providers. The use of systematic data regarding devices and their performance could also be used to inform study design and sampling methodologies. In a previously mentioned study it was found that in Sweden, where there is National Hip Registry, there was a lower rate of revision total hip replacement (8%) when compared to the US (17%) where there was no such registry in place (Ezzet 2003 [#1321]). The author

concluded that it was possible that the registry allowed dissemination of objective implant information to all surgeons in Sweden, which led to improved implant selection.

Small group designs with experienced users and end-users

It is possible to transfer some methods across diverse groups of devices, populations, settings and cultures. Methods such as case studies, interviews, photo documentation and observation may demonstrate transferability. For example, these methods were used to obtain the opinions of potential wheeled mobility device users who were Gujarati women with physical (bilateral lower extremity) disabilities (Mulholland et al 2000 [#1643]). They were aged 13 to 28 (n=8) and their levels of formal education varied. The methods were used at an early stage in the design process to ensure the development of technology, which would meet the end-users functional needs.

There is potential value in the use of experiential knowledge of both the user and end-user. Involvement of experienced clinicians and end-users is essential to the appropriate and successful use of methods and device development. One paper outlined a clinician's 24 years of experience providing rehabilitation aids such as artificial limbs and callipers for individuals in Northern India, highlighting appropriate identification of population needs and device design to the extent that

"…Our rural amputees now no longer are required to migrate to urban areas, seeking and learning sedentary occupations…" (Sethi 1982 p37 [#1305]).

A crucial factor to consider is who is best placed to assess medical devices. It may be possible that "naïve" evaluators are more beneficial than "experienced" evaluators because they may not have expectations regarding the device and may be more likely to think of out-of-the box solutions and approaches to design. They may also increase the simplicity of the design for example, preventing the use of medical jargon in monitoring and drug delivery systems. Conversely, non-clinical evaluators may not be aware of the context of device use, for example the possibility of patients tampering with infusion devices, and may not consider these implications fully. In a study using non-clinical evaluators in assessing medical devices, inspections were conducted which highlighted a large number of usability problems (Zhang et al 2003 [#470]). However, it was acknowledged that the evaluators' level of domain knowledge had an influence on findings.

There are potential benefits of university related educational programmes in promoting methodological awareness. For example, an engineering course at the University of Wyoming educates students as to the special needs of community members with disabilities (Barrett, Laurin & Bloom 2003 [#1389]). Such programmes can facilitate the production of well-tested prototypes, engagement with users and end-users and an awareness and sensitivity to the requirements of designing medical devices for specific groups.

The value of advanced methods and technologies

The novel application of theory to medical device development can assist in creating coherent definitions of device function and evaluation. For example heuristic theory was applied to the study of medical devices, which enabled the identification of extensive usability problems including discontinuance (Zhang et al 2003 [#470]). Usability Heuristics, a modified version of the Nielson-Shniederman Heuristics, was applied to the evaluation of volumetric infusion pumps. Of two pumps, Pump 1 heuristics were violated a total of 192 times for 89 usability problems. Consistency & Standards and Visibility were the two most frequently violated heuristics, with Feedback and Match the next most common. These four heuristics accounted for 64% of the violations. With Pump 2 heuristics were violated a total of 121 times for 52 usability problems. Visibility was the most frequently violated heuristic, with Memory and Consistency & Standards being the next most common. These three heuristics comprised 54% of the violations. The authors concluded that heuristic evaluation could be used to identify the great proportion of major usability problems with a product in a timely manner at reasonable cost.

In another study, a diffusion of innovations theory (E M Rogers), underpinned work illuminating the factors that are associated with discontinuance of assistive technology by individuals with disabilities (Riemer-Reiss 1999 [#2179]). It offers a comprehensive philosophy regarding the processes involved in accepting or discontinuing use of technology.

Enhanced methods, for example predictive algorithms, which capture data that inform patient diagnosis can guide the decision making process while concurrently informing device performance. For example, enhanced telemetry in the newer anti-tachycardia devices, with stored or real time patient data, can be used to assess device efficacy as well as provide information on device use and function (Newman et al 1992 [#1157]). The devices are designed to detect arrhythmias and deliver the appropriate therapy, which may range from anti-tachycardia pacing to low-energy cardioversion to high-energy direct current shock. In the above study, such a device was used in 11 of 20 patients during follow-up. In the entire group anti-tachycardia pacing was activated on a mean of 44 occasions per patient with shock delivery occurring on 8 occasions (mean) per patient. 26% of shocks were not appropriate and were due to atrial arrhythmias in 2 patients and dysfunction of the sensing lead in 3. Anti-tachycardia pace acceleration occurred in 5.3% of cases, and 7% of attempts at pacing were unsuccessful and needed shock therapy. The authors concluded that enhanced telemetry in newer devices enabled more accurate assessment of device use and enhanced diagnosis of inappropriate therapy delivery.

New technologies and methodologies are needed to prevent the necessity for using invasive procedures as a method of assessing clinical outcomes. Currently the objective assessment of clinical outcomes without the use of invasive procedures is difficult. For example, the outcome of re-narrowing post coronary artery stenting may arguably only be

assessed with precision via angiogram. Development work proposing alternative outcome measures such as sensitive imaging are required to prevent additional invasive interventions. One study reported the use of statistical methodologies to produce a methodology for evaluating new coronary artery stents (O'Malley, Normand & Kuntz 2003 [#1418]). The methodology offers a flexible solution to estimation of restenosis outcomes under conditions of varying reference populations and samples. This can allow manufacturers and clinicians to assess the utility and cost-effectiveness of a device.

Some methodologies facilitate device development and therefore raise issues of their potential value. The following example demonstrates the utility of a flexible user-focused methodology that enables different elements of the framework to be applied at different times in the stages of product development. This study outlines how the concepts of user centred design and usability engineering, have been applied to develop a methodology called USERfit (Poulson & Richardson 1998 [#858]). This tool was designed to ensure that human issues are adequately considered through the development process of an assistive device. The techniques that can be used in gathering information include brainstorming, task analysis, interview techniques and user trials. A key aspect of the methodology is that it forces design issues to be made explicit and developers need to justify any design assumptions they have made, either about technology or users. Some of the elements of USERfit include: environmental context, product environment, user analysis, user activities, product analysis, product attribute matrix, requirements summary, design summary, and usability evaluation. It includes the selection of methods for evaluation as well as establishing suitable evaluation criteria. The documentation of the results of such evaluation activities is supported, along with action points for the necessary improvement of the product before full commercial release. Interestingly a low response rate was found in a survey on usability of the handbook for the USERfit method, which could be indicative of its length. Out of 114 UK developers and academics who requested the USERfit manual 25 responded to a postal questionnaire, 16 of whom had read some part of it, with only 5 making use of the methodology.

There is a tension between the prevailing paradigm embracing statistical methodologies and alternative ways of judging effectiveness of medical devices, for example universal design (See Part A Appendix A: Operational Definitions). Where methodological development is performed the utility and value of the methods have to be demonstrated to medical device stakeholders before findings and outcomes are accepted. Issues are raised regarding medical device evaluation within the device industry as a whole. In particular, manufacturers and regulators need to be convinced of the value of specific methods before they adopt the concepts of research findings and/or possibly change the way in which the industry operates. For example, it has been noted that traditionally industry needs statistical justification for practicing universal design as a method and that they also need a set of universal design performance indicators against which to judge their designs for use by a diverse consumer base (Story 1998 [#292]).

Throughout this survey there has been an overarching emphasis on valuing both user and end-user perspectives through methodologies for device development and evaluation. Crucially such methodologies need to be practical and usable in the fast paced nature of medical device technologies and commercial interest.

In Summary:

- Device specific outcome methods require careful selection and application to the user population, enabling capture of relevant variables. Such outcome methods will facilitate the research base of medical device evaluation in terms of, for example, the manner and duration of device usage.
- There is a need to examine outcomes over time, including multiple stakeholder perspectives and consideration of all the stages of medical device development.
- The problems identified in the literature in relation to the lack of conceptual clarity/frameworks to derive coherent methods causes a cascade of effects on medical device evaluation.
- The resulting lack of harmonised methodologies and methods underpinned by valid clinical theories renders ethical approval procedures and industrial processes regarding medical device development and evaluation extremely problematic.
- The overall finding that end-users are under-represented in the methods is not therefore surprising.
- The emphasis on valuing users and end-users through methodologies for device development and evaluation needs to include the usability of such methodologies in the fast paced arena of medical device technologies and commercial interests.

5 CONCLUSIONS AND RECOMMENDATIONS

Currently, medical devices are recognised as one of the fastest growing industries yet, many end-users lack access to high quality devices that are appropriate to their specific needs. However, this literature survey has revealed a lack of coherent approaches in product development, where product development encompasses all the stages of medical device development identified in the data extraction template (Table 2, p7).

The user focus in MATCH, together with other UK funded projects such as:

- The EPSRC funded Woundcare Research for Appropriate Products study (WRAP) (Cowley et al 2004 (http://www.wrap/kcl)
- The Design for Patient Safety study comprising a research team from the Universities of Cambridge and Surrey and the Royal College of Art (Department of Health 2003)
- The Helen Hamlyn Research Centre (http://www.hhrc.rca.ac.uk) dedicated to the study and practice of socially inclusive design for people with disabilities

are just some examples of the contemporary movement towards client-centred health and social services, including medical devices.

In addition, the growing movement towards harmonised systems including regulatory processes is an acknowledgement of the problems generated by the proliferation of different national systems and regulations, in relation to medical device development and evaluation. Some of the problems include increased costs and hindered access to healthcare technologies, which can unintentionally jeopardize the safety of the patient (World Health Organisation 2003).

The following section comprises a synthesis of the findings in terms of a lack of coherent approaches to user and end-user representation in the stages of medical device development.

The core findings from this aspect of the survey are clustered around five major headings: users and end-users; their level of involvement in the stages of medical device development; the context of medical device usage; the context of tools used in medical device evaluation; and the context of methodologies for medical device evaluation. Key recommendations are included for methodological development to embed users and end-users in health technology development and assessment.

5.1 USERS AND END-USERS

The inclusion of user and end-user information is crucial to the successful outcomes of medical devices in the context of an episode of treatment and care. In practice this means sourcing clinical and technical information from professional users, which includes physical and physiological data derived from end-users. Contextual information is also required in the form of environmental and cultural data from lay users and end-users, together with personal experience and perceptual information. This suggests that a cluster of methods will be needed for the life cycle of any given device.

It is apparent however from the literature sampled that there is a lack of established strategies for sourcing information, which includes cogent criteria for sampling the users and end-users. Ideally, epidemiological data should be available to define end-user populations. In addition given that end-users of medical devices can have more than one medical condition, sampling strategies need to be carefully structured so as not to exclude individuals with complex needs. However, in order to understand complex needs and to conduct meaningful evaluations sampling techniques are required that can provide meaningful outcome measures of device performance within the context of complex conditions and lifestyles. Closing the gap therefore requires a particular focus on sampling methodologies and may require small group sampling techniques and legitimate methods of generalisation. These are profound methodological issues requiring expert review and methodological development from a number of disciplines including social sciences, healthcare, ergonomics, engineering, health economics and industry.

5.2 THE LEVEL OF INVOLVEMENT OF USERS AND END-USERS IN MEDICAL DEVICE DEVELOPMENT

In the published literature end-users were predominantly perceived to be clinicians rather than patients. Apart from a cluster of exemplary cases, the literature also revealed that end-users featured predominantly in the post-market surveillance stage and were not embedded in the different design and prototype development stages. As the survey of the literature was not exhaustive and clearly confined to the published literature, it is possible that there may therefore be sources of unexplored literature that features end-users in design and development such as in filed patent applications.

In addition, various other definitions of end-users were found including healthy non-users, healthy users and specific groups comprising individuals with particular profiles of a

medical device related intervention and aetiology. The overall lack of clarity and consensus for defining users and end-users highlights an obvious gap in the gathering of meaningful data.

5.3 THE CONTEXT OF MEDICAL DEVICE USAGE

From the perspective of the medical device it is clear from the literature surveyed that unless devices are examined in the context in which they are used including the cultural and environmental contexts the effectiveness and usage of the devices will be limited. This is particularly evident when devices from one part of the world are exported to another without regard for local customs, norms and resources including materials and skills. This has significant implications for global trade and export of medical devices. In addition, medical devices were substantially viewed in isolation of the associated episode of treatment and care. From a methodological perspective this created problems in separating outcome measures pertinent to the device from the more general aspects of treatment and care.

The contexts within which medical devices are used must therefore be the starting point for product development including design, use, and evaluation of effectiveness and cost-effectiveness. It is crucial that users and end-users should be skilled in medical device usage indicating that training must become an integral, formal and standardised process. The proposal here is that training in medical device use should be an embedded activity.

The literature revealed that models for embedding the users and end-users in the stages of medical device development appear to be well developed in Assistive Technologies and Human Factors Design as evidenced in the cluster of Exemplary Cases (Part A Appendix E:). The recommendation from this report is for collaboration with experts in the methodologies adopted by these disciplines to guide medical device development and evaluation more generally.

5.4 THE CONTEXT OF TOOLS USED IN MEDICAL DEVICE EVALUATION

The literature surveyed reflected a number of issues in relation to rigour in the development of tools. A need for conceptual clarity for tool development was identified to include key domains of medical device users in general, and the context of device use. This clarity is particularly important to generate meaningful outcome measures of device performance including the definition of end-points in health technology assessment.

Related to the sampling issue reported above was the need for specific device and context related tools. The application of a generic tool for the evaluation of a specific medical device is limited in its ability to generate robust and relevant data for the device in question. The conclusions are drawn that it is essential to embed users and end-users in the process of tool development and validation. Where tools were transferred from one context and device to another, validation of the tool in its new application did not appear

to feature and is clearly a substantive omission in either the reporting of the usage of such tools or indeed their actual use.

Training of the users and end-users of medical devices is a recurring theme in this report. Training was an evident issue in relation to inter-observer reliability and tool use when the observers were drawn from a number of disciplines and levels of skill. In order to reach the goal of harmonised processes in healthcare technologies training in assessment is imperative.

In what seemed to be a strategy for overcoming the limitations of using a single tool to evaluate medical devices, multiple tools and data triangulation were adopted. However loading a battery of tools into a single study can still miss the goal of generating valid and reliable outcome measures of medical device use, unless the tools are 'fit for purpose'. Overall, a need was identified for conceptual clarity and device and context specific tool development.

5.5 THE CONTEXT OF METHODOLOGIES FOR MEDICAL DEVICE EVALUATION

The problems identified in the literature in relation to the lack of conceptual clarity/frameworks to derive coherent methods causes a cascade of effects on key stakeholders and processes in the medical device world. The resulting lack of harmonised methodologies and methods underpinned by valid clinical theories renders ethical approval procedures and industrial processes regarding the parallel and interactive activities of medical device development and evaluation extremely problematic.

Device specific outcome methods require careful selection and application to the end-user population, enabling capture of relevant variables. Such outcome methods will facilitate the research base of medical device evaluation in terms of, for example, the manner and duration of device usage. There is also a need to examine outcomes over time, including multiple stakeholder perspectives and consideration of the maturity of medical devices in the context of device development. The emphasis on valuing users and end-users through methodologies for device development and evaluation needs to take account of the usability of such methodologies in the fast paced arena of medical device technologies and commercial interests.

5.6 FUTURE DEVELOPMENTS

5.6.1 Mapping of user and end-user involvement in medical device development and evaluation

In the conclusions to the literature survey a lack of coherent approaches were identified in the stages of medical device development and it was argued that they may be resolved with cogent methodologies. The onus is on academic researchers, in consultation with key stakeholders including industry, to develop and validate methodologies and tools that

represent user and end-user needs to industry, to influence the development of user focused products.

Four distinct but inter-related frameworks for medical device development and evaluation were used to map areas for methodological review for the explicit involvement of users and end-users in medical device development (Table 4). The reason for drawing on these frameworks was to locate recommendations for methodological review and development in established processes in medical device development and evaluation. This mapping process identifies key stakeholder groups in the medical device sector who need to be consulted and possibly participate in the development of novel methodologies. The process can also extend to facilitating dissemination and uptake of the methodologies once they have been validated.

The first of the frameworks focuses on the stages of product development from a manufacturing perspective and is drawn from Cooper & Kleinschmidt (1986). This framework formed the basis of our data extraction template, to which the other three frameworks have been aligned. The second framework, identified in the literature surveyed, demonstrates a method of end-user engagement with manufacturers in a 'locking in' process during the early stages of device development (Sheredos & Cupo 1997). It is evident from further searches that this model is in use by the American Department of Veterans Affairs - Technology Transfer Section. The process results in the manufacture and marketing of end-user driven products, usually by the companies involved in the research and development process who at an early stage are also preferentially 'locked in' to procurement contracts. The third framework comprises the stages of health technology assessment, adapted from the UK Medical Research Council (MRC) framework (2000), which is recommended as good practice for complex clinical evaluations. The fourth framework comprises a model of economic evaluation proposed by Sculpher, Drummond & Buxton (1997), which provides a clear strategy for aligning economic evaluation with device development and clinical effectiveness, thereby providing a mechanism for assessing the value of new and revised technologies through the stages of their development.

5.6.2 Mapping the areas for review and methodological development

From Table 4 the following methodological aspects have been identified for particular scrutiny and development.

- Theoretical and conceptual frameworks
  - Relevant theories for product development e.g. clinical, ergonomics, engineering
  - Identifying the users and end-users
- Sampling of users and end-users to accrue information of needs and experiences in the context of medical device usage
  - Methods e.g. interviews, observations
  - Early expert opinion
- Methods and tools development and validation, including device specific outcome measures and end-points
- Methodological strategies for sampling of user and end-user groups for health technology assessment and generalisation
- Embedded training of users, end-users and evaluators

Table 4: Mapping Existing Frameworks in Medical Device Development and Evaluation

	Product Development	***Technology Transfer***	***MRC Framework***	***Economic & Clinical Effectiveness***
Phases	**Concept:** Involves idea generation, including technical, financial and commercial viability	**Research:** End-user need identification, ideas, concepts, design goals, computer simulation and basic scientific information	**Theory** (Pre-clinical): Explore relevant theory for hypothesis development and to predict major confounders and design issues	
	Design: Involves product design and prototype development	**Development:** Start development (decision point), working prototype (decision point), alpha test completion, successful laboratory and limited consumer use data	**Modelling** (Phase I): Identify components of interventions, underlying mechanisms that influence outcomes, predictive evidence of how they relate and interact	**Stage I:** Systematic review of evidence relating to cost and effectiveness of existing practice; use of informal clinical opinion to assess the potential value of the new technology
	Testing and trials: Involves prototype testing in-house and later trials in the field	**Gateway Selection:** Decision point, device meets user need, fit for use, manufacturable and marketable; 'Locking-in' of the manufacturer through procurement contracts	**Exploratory Trial** (Phase II): Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the device to an appropriate alternative	**Stage II:** Modelling studies using data from existing clinical studies; pilot studies of economic data collection alongside trials
	Production: Includes production supported by business and commercial rationale	**Technology Transfer:** Initiate technology transfer – manufacture beta models, pilot evaluation (1 or 2 sites); Design changes from beta test (decision point) – freeze design, modify or construct new beta models if required; Field evaluation (decision point) – design changes, freeze design, first commercial production run; Marketing strategy – training and education of marketing staff, field support	**Methods of Clinical Evaluation** (Phase III): Evaluate a device using a theoretically defensible protocol	**Stage III:** Economic data collection alongside trials; refined modelling studies using systematic overviews of clinical data
	Marketing and use: Includes product launch in the market and its on-going use, post-marketing surveillance	**Commercialisation:** Decision point, multiple product changes as a result of consumer feedback throughout the life cycle of the device, end-user needs met	**Long-term Implementation** (Phase IV): Determine replication of device performance and results, in uncontrolled settings longitudinally	**Stage IV:** Economic data collection alongside pragmatic trials; modelling studies to generalise results to other settings, or to extrapolate to the long term
Refs	**Adapted from** Cooper & Kleinschmidt (1986) producing a condensed model of 5 stages	Sheredos S J & Cupo M E (1997) The Department of Veterans Affairs Rehabilitation Research and Development Service's Technology Transfer Process	Adapted from MRC Health Services and Public Health Research Board (2000)	Sculpher M, Drummond M & Buxton M (1997) The iterative use of economic evaluation as part of the process of health technology assessment

These methodological aspects have been synthesised into the following table (Table 5).

Table 5: Mapping the areas for review and methodological development

Phases	**Theory and Context:** Explore the relevance of theory in medical device development drawing on the following disciplines: healthcare, ergonomics, engineering and health economics. Explore the nature of user and end-user information and respective levels of engagement in the stages of medical device development. Map types of relevant contextual issues in particular user and end-user culture and environment, components of health technology and economic analysis.
	Modelling: Identify advanced technologies that provide mechanisms for translating qualitative user and end-user information into objective design criteria and comparable information of prototype performance.
	Data Sources for Methods of Clinical and Economic Evaluation: Identify appropriate strategies for sampling medical device user and end-user populations and for generalizing outcomes. Identify new models of medical device evaluation including experimental designs and post-market surveillance in uncontrolled settings. Review approaches to embedding training requirements of users, end-users and evaluators in device use and evaluation.
	Implementation of New Methodologies: Review methodologies for time, manpower, costs of involving and not involving users and end-users in the stages of medical device development. Review the novel nature of proposals emanating from the review from key stakeholder perspectives: Health Technology Assessment (HTA), Regulatory Groups (e.g. MHRA, FDA), Health Service Procurement Processes (e.g. DoH, National and Private Health Services).

Figure 1 maps the essential components of the four existing frameworks for medical device development and evaluation and includes a fifth framework to scope areas of methodological review and development for embedding users and end-users.

In conclusion, this survey of the healthcare literature has revealed important limitations in the approaches to including users and end-users in medical device development and evaluation. These limitations will be integrated with the findings of the Ergonomics & Engineering and Social Science surveys in order to make recommendations for methodological review within MATCH.

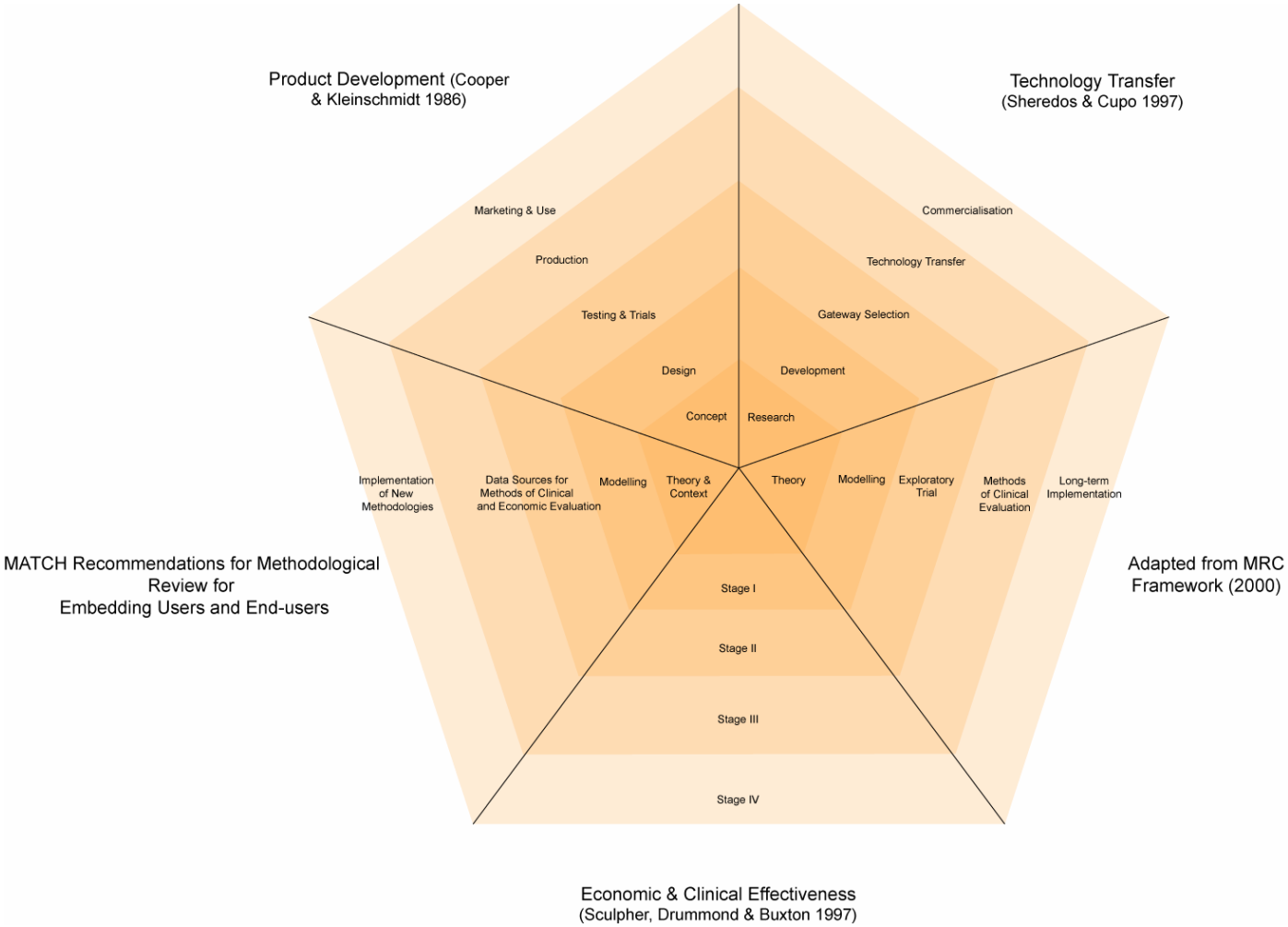

Figure 1: Mapping Areas for Methodological Review for User and End-user Involvement in Medical Device Development

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PART A APPENDIX A: OPERATIONAL DEFINITIONS USED IN RESEARCH TERMINOLOGY

The following definitions have been synthesized from the literature and relevant research programmes.

Action Research

Aims to contribute both to the practical concerns of people in an immediate problematic situation and simultaneously to further social knowledge. Thus, there is a dual commitment in action research to study a system and concurrently to collaborate with members of the system in changing it in what is together regarded as a desirable direction. Accomplishing these goals requires the active collaboration of both researcher and client, and thus it stresses the importance of co-learning as a primary aspect of the research process.

Adverse Event

A problem that can or does result in permanent impairment, injury or death to the patient or the user.

Case Studies

Refer to the collection and presentation of detailed information about a particular participant or group, frequently including the accounts of subjects themselves. A form of qualitative descriptive research, the case study looks intensely at an individual or participant pool, with an emphasis placed on exploration and description to draw conclusions relative to the specific case.

Case Series

Report of a number of cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients (National Institute of Clinical Excellence 2004).

Cohort Study

A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure to an intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the intervention (National Institute of Clinical Excellence 2004).

Consensus Methods

Techniques that aim to reach an agreement on a particular issue. Formal consensus methods include Delphi and nominal group techniques, and consensus development conferences.

Expert consensus methods will aim to reach agreement between experts in a particular field (National Institute of Clinical Excellence 2004).

Data Extraction Tables

Tabulated presentation of data collected from individual studies (National Institute of Clinical Excellence 2004).

Effectiveness

A device is clinically effective when it produces the effect intended by the manufacturer relative to the medical conditions. For example, if a device is intended for pain relief, it is expected that the device will relieve the pain. It is also expected that the manufacturer possesses objective evidence, such as clinical test results, that the device does in fact relieve pain.

Epidemiological Study

The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences and interventions (National Institute of Clinical Excellence 2004).

Exclusion Criteria (clinical study)

Criteria that define who is not eligible to participate in a clinical study (National Institute of Clinical Excellence 2004).

Generalisability

The extent to which the results of a study based on the measurement in a particular patient population and/or a specific context hold true for another population and/or in a different context (National Institute of Clinical Excellence 2004).

Human Factors

Discovers and applies information about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, systems, tasks, jobs, and environments for productive, safe, comfortable, and effective human use.

Incident

An unusual, unexpected event associated with the use of a medical device. Such an incident may lead to problems and all incidents should be investigated for potential problems.

Interviews

A method of data collection involving an interviewer asking questions of another person (a respondent) either face to face or over the telephone, with verbal communication between the researcher and subject being performed either in a structured or unstructured format.

Manufacturer

Any person who produces medical devices. The manufacturer, as the creator of the device, must ensure that it is manufactured to meet or exceed the required standards of safety and performance. This includes the stages, design/development/testing, manufacturing, packaging and labelling, that lead to a product being ready for the market.

Nominal Group Technique

This technique takes advantage of pooled judgments, allowing the judgments of a variety of people with varied knowledge and skills to be combined. The nominal group technique is a generic name for face-to-face group techniques in which instructions are given to group members not to interact with each other except at specific steps in the process. The steps in the process are: 1) silent idea generation; 2) round-robin sharing of ideas; 3) feedback to the group; 4) explanatory group discussion; 5) individual re-assessment; and 6) mathematical aggregation of revised judgments.

Performance

Technical performance plus effectiveness.

Placing on-market

“Pre-market” and “post-market” are established regulatory terms. “Post-market” refers to when the products are on the market. “Placing on-market” aims to distinguish the regulations governing the commercial aspects.

Post-market surveillance and vigilance

The different terms in post-market surveillance are currently used by different countries with varying meanings. Post-market surveillance is a broad term that covers any and all monitoring activities including the vigilance system for medical devices in use. In Europe, vigilance concerns the responsibility of the manufacturer to inform the competent authority of incidents, according to national/European legislation.

Quality of Life

In its most general context, quality of life is a concept incorporating all the factors that might impact on an individual’s life (Billingham, Abrams & Jones 1999). In health service research it is more usual to consider health-related quality of life (HRQoL) which refers to an individual’s perceived physical, mental and social well-being; not merely the absence of disease (National Institute of Clinical Excellence 2004).

Questionnaires

The term questionnaire has been used to describe a variety of data collection instruments. McColl et al (2001) define them as “structured schedules used to elicit predominantly

quantitative information, by means of direct questions, from informants, either by self-completion or via interview" (p3-4).

Randomised Controlled Trials

In healthcare evaluation, these are designed for particular measurements; in particular relative treatment effects that are potentially subject to selection bias, such as a hazard ratio. Selection bias is minimised by randomly assigning people to one or two or more treatment groups and, where possible, blinding them and the investigators to the treatment that they are receiving. The outcome of interest is then compared between the treatment groups. Such studies are designed to minimise the possibility of an association due to confounding and remove sources of bias present in other study designs (Philips et al 2004).

Reliability

The degree to which the results obtained by a measurement procedure can be replicated (National Institute of Clinical Excellence 2004).

Surveys

Approaches designed to collect systematically descriptions of existing phenomena in order to describe or explain what is occurring. Data are obtained from a sample of participants often using questionnaires or personal interviews.

Universal Design

The design of products and environments to be usable by all people, to the greatest extent possible, without the need for adaptation or specialised design. The intent of universal design is to simplify life for all by making products, communications and the built environment more usable at little or no extra cost.

Usability Tests

A way of finding out how users react to a product by observing them using it. These tests can be done formally, in a laboratory with video cameras, or informally, with mock-ups of an application, where users are asked to perform certain tasks in an effort to measure for example the product's ease-of-use, task time, and the user's perception of the experience. Whether the test is formal or informal, usability test participants are encouraged to think aloud and voice their opinions, helping to find design problems and resolve design decisions.

User Error

An act that has a different result than that intended by the manufacturer or expected by the operator. User error may result from a mismatch between variables, for example the operator, device, task, or environment. By incorporating human factor engineering principles in design, and appropriate training for users, the risk of user errors can be minimised.

User Trials

Investigations that are carried out in order to evaluate products. It is common for such investigations to take place in the laboratory, where it is possible to control the range of tasks performed, observing and recording performance. In addition the trial setting allows the investigator to ask the users questions in order to clarify any observations made.

Validity

Internal validity refers to the degree to which the results of a study are likely to approximate the 'truth' for the participants recruited in a study, that is the results are free from bias. It refers to the integrity of the design and is a prerequisite for applicability, external validity of a study's findings (National Institute of Clinical Excellence 2004).

PART A APPENDIX B: METHODS

The search strategy for the survey was based *flexibly* on the stages advocated by the Cochrane Collaboration (2003): involving scoping, building and maintaining a structured search. 79 key words were identified that categorise "user", "methodology" or "device" related terms to structure the search with Boolean operators (Table1).

Table1: Grouped Search Terms

Medical device	**Methodology**	**User**
Assistive technology	Anthropotechnics	Consumer
Classification	Bayes theorem	Daily life activity
Development	Clinical trials	Disability
Device	Consensus methods	Disabled
Device approval	Consumer satisfaction	Health care delivery
Disposable equipment	Cost-benefit analysis	Health care need
Emerging technologies	Design for all	Health care system
Equipment and supplies	Engineering psychology	Healthcare professional
Equipment design	Ergonomics	Human
Equipment failure	Ethnography	Nurse
Equipment safety	Evaluation	Patient
Health care	Focus group	Patient care
Human factors	Functional assessment	Physical activity
Medical devices	Health technology assessment	Physical disability
Medical technology	Human engineering	Rehabilitation
Monitoring	Human factors engineering	Terminology
Orthopaedic fixation devices	Human performance Engineering	Treatment planning
Performance	Human-system interface	Users
Prostheses and implants	Inclusive design	
Prosthesis	Interview	
Safety	Man-machine systems	
Standards	Medical errors	
Technical aid	Methodology	
Technology	Methods	
Terminology	Observation	
	Outcome assessment	
	Outcomes research	
	Participant observation	
	Participatory design	
	Patient attitude	
	Patient satisfaction	
	Post marketing	
	Product surveillance	
	Quality of life	
	Questionnaire	
	Research design	
	Structured observation	
	Technology assessment	
	Universal design	
	Usability	
	User assessment	
	User centred design	
	User focus	
	User requirements	
	Video analysis	

The searches were limited to: papers from 1980 onwards, English language, and human. In addition search terms were truncated where applicable e.g. ergono$.mp. The searches were divided along the lines of the databases with researchers searching those databases related to their area of specialism i.e. healthcare, social sciences, engineering and ergonomics.

A data extraction table for the literature survey was developed by the social sciences team of Project 3 at Brunel University (Table 2). It was derived from analysis of the 13 stages of product development proposed by Cooper & Kleinschmidt (1986), producing a condensed model of 5 stages:

- Concept: involves idea generation, including technical, financial and commercial viability
- Design: involves product design and prototype development
- Testing and trials: involves prototype testing in-house and later trials in the field
- Production: includes production supported by business and commercial rationale
- Marketing and use: includes product launch in the market and its on-going use

The template, representing an initial level of data analysis, was used by all the Project 3 researchers across the disciplines to extract relevant data from the surveyed papers.

Table 2: Data Extraction Table

ID	Ref	Year & Country of study	Objective(s) / Question(s)	Device/ Product	Methods/ Tool/ Approach	Users / Participants (n=)	Product Development Stage at which users were involved					Findings &/or Conclusion	Researcher's Comments
							Concept	Design	Testing & Trials [including prototype]	Production	Deployment [Marketing/ Launch & Use]		

Search strategy: Healthcare

Databases, Keywords and MeSH Subject Headings

All the databases that were originally selected in the scope and strategy for the literature survey were retained: Embase, Medline, CINAHL, PsycINFO, The Cochrane Database of Systematic Reviews (Cochrane Reviews), the Health Technology Assessment (HTA) Database and the National Institute of Clinical Effectiveness (NICE). However an unmanageable number of results were obtained when using key words and MeSH subject headings related to all the 79 key words initially identified by Project 3 (Table1). For example the MeSH subject heading of clinical trials resulted in 112,213 hits in Medline alone and the subject heading of methods resulted in 231,141 hits. Consequently from a purely pragmatic viewpoint the initial search strategy needed to be modified so as to perform the search in the healthcare databases. Two experts in the area of literature reviewing were consulted independently and the decision was taken as advised to exclude the "user" related terms because they would be implicit in the search area and results, and the search results were limited to those related to humans. In consultation with one of the experts the scope notes for MeSH subject headings were

thoroughly examined and those that were too broad were removed, for example classification and safety. However MeSH headings for devices that were of particular interest to the research partners were included, thus a particular focus was placed upon self-help devices, wheelchairs, implants and wound dressings. The search strategy (for Embase, Medline, CINAHL and PsycINFO), outlined in Table 3, was the outcome of the consultation process and 2226 results were obtained (last performed on 21.5.04).

The remaining databases (the Cochrane Database of Systematic Reviews, the Health Technology Assessment Database and the National Institute of Clinical Effectiveness) required a separate search strategy because of the need for less specified search terminology in these databases. Therefore they were searched in the main during July 2004 using the key word "medical device".

Table 3: Electronic Search Strategy and Results

#	**Search History**	**Results**
1	assistive technology$.mp	2916
2	medical device$.mp	5039
3	Self-Help Devices/	3142
4	Wheelchairs/	5161
5	Artificial Limbs/	2770
6	Joint Prosthesis/	29789
7	Hip Prosthesis/	11999
8	Knee Prosthesis/	5506
9	Occlusive Dressings/	2289
10	Bandages/	4837
11	implant$.mp	248719
12	Cost-Benefit Analysis/	6685
13	Evaluation Studies/	5481
14	Product Surveillance, Postmarketing/	1416
15	Device Approval/	3666
16	functional assessment$.mp	28279
17	Outcome Assessment (Health Care)/	10007
18	Patient Satisfaction/	14578
19	Activities of Daily Living/	11644
20	Rehabilitation/	22294
21	usability.mp	2044
22	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	295243
23	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	103434
24	22 and 23	3120
25	limit 24 to english language	2819
26	limit 25 to human	2579
27	limit 26 to yr=1980-2004	2489
28	remove duplicates from 27	2226

Notes:

CINAHL: 1982-2004, EMBASE: 1980-2004, MEDLINE: 1980-2004, PsycINFO: 1980-2004

/ Denotes database MeSH subject heading

.mp Denotes key words

Theoretical and Methodological Issues

The inherent nature of the medical device sector led to methodological difficulties because of the wide range of both users and devices. Overall a high recall rate (2226 potentially relevant studies from Embase, Medline, CINAHL and PsycINFO) was obtained with a higher precision rate (actual relevant studies) than had been expected (Shaw et al 2004). This was attributed to the wide range of users and devices, the often complicated contextual usage of medical devices both in conjunction with drug administration and in conjunction with underlying complicating pathologies. Furthermore it was recognised that devices are frequently used in combination, with the device as the key therapeutic intervention or at the opposite end of the spectrum as an adjuvant, supportive of but secondary to medical treatment.

In traditional systematic reviews the quality of relevant papers is assessed using a hierarchy of evidence that classifies methodologies. For example the gold standard is classified as high-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias (National Institute of Clinical Excellence 2004). Such a model was thought problematic by Project 3 for the medical device research arena given a lack of RCTs. The readership of the report can refer to the data extracted from the various studies to draw their own conclusions on individual papers based on the data provided in the template, such as the methods and findings.

Exclusion Criteria

The relevance of the 2226 results was assessed by both researchers (NB & MBR) independently by reading the titles of the papers and the abstracts, the initial part of the literature analysis process. 1335 results were excluded against the following criteria:

- Lack of or no outcome assessment
- Lack of or no device e.g. evaluation of a rehabilitation service, procedural evaluation
- Lack of or no user perspective
- Primary focus of regulatory requirements e.g. implant registry information
- Non-article based e.g. letters, comments or book chapters

Where the researchers were unable to reach a decision independently with regard to relevance the abstracts were reviewed by both researchers and a consensus generating process was used. A third reviewer was drawn on where required (TG).

Categorisation and Sampling: Embase, Medline, CINAHL & PsycINFO

891 relevant results were obtained from Embase, Medline, CINAHL and PsycINFO against the exclusion criteria. These results were categorised by:

- Methodologies and tools of particular value to the remit of Project 3. Thus where the results encompassed “out of the mould” methodological approaches, to capture user

perspectives regarding medical devices these were categorised separately, to aid the identification of research methods of richest potential to Project 3.

- Where the results had a primary focus on the development, utility and validation of tools these were classified under "tools", regardless of the device area, in order to aid analysis.
- Medical device area

The above categorisation was used to define the criteria for sampling the results within these categories (Table 4). The researchers together categorised the results in a process of consensus generation. By this stage of the process the abstracts of the papers had been read at least twice. The categories were determined, with the number of results in the separate categories totalled for illustrative purposes.

The results from the categories of "tools" and "out of the mould" were purposefully sampled in their totality given the focus of Project 3. A 5% sample of all device related categories was included. In the main these papers describe clinical trials or other interventional studies where similar approaches are used e.g. experimental design and retrospective case-note analysis. A total sample of 115 full papers was obtained and the data extracted into the literature extraction template by the researchers. Each researcher reviewed papers and data extracted by the other as a validation check. It was found appropriate to reclassify some of the papers following analysis and this is reflected in Part A Appendix C:

Table 4: Categorisation of References for Review

Category		Number of results	Number of full papers obtained
Methodologically orientated papers	"Out of the mould"	34	34
	Tools	36	36
Device orientated papers	Auditory, Ophthalmic & Orbital	75	4
	Breast	28	1
	Cardiac	71	4
	Dental & Oral	54	3
	Digestive & Excretory	30	2
	Hormonal & Contraceptive	25	1
	Imaging devices	4	1
	Infusion devices & intravenous catheters	6	1
	Neurological	33	2
	Orthopaedic	303	15
	Prostheses: limb, facial & pelvic	52	3
	Skin related	6	1
	Assistive devices: mobility aids	92	5
	Assistive devices: others	29	2
Irrelevant		1335	n/a
Total		2226	115

Categorisation and Sampling: Cochrane Reviews, HTA & NICE

Hits from searching the Cochrane Database of Systematic Reviews, the Health Technology Assessment database and the National Institute of Clinical Effectiveness database were

purposefully sampled accessing those reviews pertinent to the specific interests of the MATCH industrial partners (Table 5). Reviews that could be cross-referenced to other works across the databases were also obtained, for example the separate works of the HTA and NICE on wound care debriding agents and vaginal tape were sampled. The publications of these organisations were deemed of particular importance to MATCH given their influence over the medical device industry particularly in terms of methodologies and perspectives on high quality data. However, the length and complexity of the above works, with respect to the multiple papers contained within each review, precluded data extraction into the literature extraction template in its existing form. Therefore it was agreed that these works would be critically reviewed at a later date in the research process.

Table 5: Sampled Cochrane Reviews, HTA Reports & NICE Guidelines and Appraisals

The Cochrane Database of Systematic Reviews (Cochrane Reviews)
Complete reviews:
Absorbent products for containing urinary and/or faecal incontinence in adults
Elastic compression stockings for prevention of deep vein thrombosis
Frameless versus classical intrauterine device for contraception
Splints and orthosis for treating rheumatoid arthritis

Health Technology Assessment Database (HTA)
A systematic review of the effectiveness and cost-effectiveness of metal on metal hip resurfacing arthroplasty for treatment of hip disease
Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature
Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review
Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model
Primary total hip replacement surgery: a structured review of outcomes and modelling of cost effectiveness associated with different prostheses
Systematic review of the clinical effectiveness and cost effectiveness of tension free vaginal tape for treatment of urinary stress incontinence
The clinical effectiveness and cost effectiveness of inhaler devices used in the routine management of chronic asthma in older children: a systematic review and economic evaluation
The debridement of chronic wounds: a systematic review

National Institute of Clinical Excellence (NICE)
Clinical guidelines:
Pressure relieving devices (CG7)
Technology appraisals:
Coronary artery stents (No. 71)
Hip resurfacing: metal on metal (No. 44)
Hips: prostheses for primary total hip replacement (No.2)
Stress incontinence: tension-free vaginal tape (No. 56)
Wound care: debriding agents (No.24)

Limitations to Strategy: Embase, Medline, CINAHL & PsycINFO

The search strategy involved simultaneous searching of multiple databases, Medline, EMBASE, PsycINFO and CINAHL via OVID. MeSH subject headings were identified which are suitable for EMBASE and Medline. However this was not the case for PsycINFO and CINAHL. Therefore CINAHL did not generate results for: bandages, product surveillance/post marketing, device approval and outcome assessment. PsycINFO did not generate results for: self-help devices, joint prosthesis, hip prosthesis, knee prosthesis, occlusive dressings, bandages, cost-

benefit analysis, evaluation studies, product surveillance/post marketing, device approval, and outcome assessment. To summarise, the key word search strategy resulted in hits across all the databases however the MeSH subject heading strategy applied in EMBASE and Medline only. This reduced the recall rate but the precision rate using keywords and subject headings in combination was high. Such combined searching was recommended by Shaw et al (2004) who advocated the use of more than one search strategy, using subject headings and key words, including free text and broad based terms.

The dual categorisation strategy (via methodologies and tools of particular value to the remit of Project 3; and via device area) and the dual sampling strategy from these categories (purposeful sampling of all papers from “tools” and “out of the mould”; and random sampling on a percentage basis from the device categories) have inherent limitations. However both strategies can be justified according to the aims of Project 3, in terms of methodological development, and for pragmatic reasons. The high number of relevant results obtained meant that not all papers could be feasibly reviewed and thus necessitated the use of such a dual sampling strategy. The use of a random sampling strategy for the device area categories could be criticised in the light of the fact that a truly comprehensive perspective on the following areas could not be gained: users, methodologies and medical device development. Nevertheless this component of the sampling could be justified as providing an overview of the literature, potentially representative of the greater body of research literature. Table 6 summarises the steps taken in the search and review process.

Table 6: Overview of the search and review process

Step 1: Mapping of search terms with expert consultation (Table1)
↓
Step 2: Selection of databases
↓
Step 3: Performance of search with expert consultation (Table 3)
↓
Step 4: Definition of exclusion criteria
↓
Step 5: Review of abstracts by researchers
↓
Step 6: Categorisation of results (Table 4)
↓
Step 7: Sampling strategy of relevant papers defined
↓
Step 8: Data extraction performed using a Data Extraction Template (Part A Appendix A:)
↓
Step 9: Data analysis using Framework Analysis to derive issues raised and consequences (Part A Appendix D:)

PART A APPENDIX C: DATA EXTRACTION TABLES

RefWorks Number: 5 [TOOLS]		Year/County: 2003 - UK
Reference		**Berry C, Kennedy P. A psychometric analysis of the Needs Assessment Checklist (NAC). Spinal Cord 2003; 41(9):490-501.**
Objective/Questions		The Objective of this paper is to evaluate the psychometric reliability and validity of a clinically focused measure of rehabilitation outcome, the Needs Assessment Checklist [NAC, 1999] (which has not been performed previously). The NAC is a rehabilitation outcome measure, specifically developed for patients with spinal cord injury [SCI].
Device/Product		Assistive Technology Devices.
Users		n = 43 consecutive SCI in-patients [38 males & 5 females] selected from a series of 55 consecutive patients between Dec 2001 and Jun 2002. 28 patients had recently completed their first NAC & 15 patients had recently completed their second NAC. Mean age 42.19 years. Sample included 13.9% with complete tetraplegia, 37.2% with incomplete tetraplegia, 23.3% with complete paraplegia, and 25.6% with incomplete paraplegia. Mean time between date of injury and completion of first NAC was 17.5 weeks, and with second NAC mean time was 38.6 weeks. A multi-disciplinary team carried out the clinical assessment and included: physiotherapist, occupational therapist, named nurse, or psychologist.
Method/Tool/Approach		The NAC has been implemented and developed at the National Spinal Injuries Centre [NSIC] as part of a structured multi-disciplinary rehabilitation framework that provides a way of assessing and ensuring that rehabilitation programmes are geared toward each patient. The NAC was developed to incorporate patient perceptions and each patient rates his/her own level of independence for each task/item by means of an interview, lasting Approximately 1 hour. Each item receives a score from 0 to 3. The Spinal Cord Independence Measure [SCIM, Version 2, 1997] and Hospital Anxiety and Depression Scale [HADS] were also employed as comparable benchmark assessment measures with established psychometric properties. Clinical assessment [routine administration of the NAC used to build profiles of individual patients' needs and for goal planning] was carried out by a representative from the multi-disciplinary team: physiotherapist, occupational therapist, named nurse, or psychologist. In order to evaluate the consistency of this current 'clinical' assessment utilising the NAC, a test-retest cut-of period of one week was adhered to. At this time point retest assessments were not carried out. In one session, a single person [an assistant psychologist, not professionally related with the patient] administered the NAC, HADS, and SCIM. In order to limit errors completing the SCIM with limited patient knowledge, this measure was completed with the assistance of both the patient and nursing staff- regarding respiration and sphincter management. All staff administering the NAC had been trained in its use via a 1-day training workshop. As an integral part of this study, further comments from patients were also gained during the assessment session. Each participant was asked to rate the NAC (0 to 10) based on its usefulness, clarity and personal relevance, and were asked whether they found any aspects of the NAC particularly helpful or unhelpful, and to provide additional comments. All the assessments used in this study were carried out during the participants' first admission for rehabilitation.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Reliability analyses yielded high internal consistency coefficients. All subscales performed above the specified level. The mean item-internal validity correlation for NAC subscales was 0.5921. Test-retest correlations ranged between 0.694 [Bladder Management] and 0.904 [Skin Management]. The mean test-retest assessment over all NAC subscales was 75.5%. Concurrent validity analyses correlating individual subscale scores with SCIM and HADS subscales produced high correlations. Significant differences were identified between injury categories within NAC subscales; however, this was not consistent. The NAC achieved high patient ratings, attaining mean ratings of seven out of ten for usefulness, and eight for its clarity and personal relevance. The findings from this study indicate that the NAC is a psychometrically reliable and valid clinical measure of rehabilitation outcome. Further study may examine the NAC's adaptability to use with other populations and evaluate whether this measure maintains its psychometric validity across physical rehabilitation. The Needs Assessment has undergone consumer review by the Spinal Injuries Association. The NAC is also regularly reviewed by the NSIC and had been modified throughout its implementation based on current research, multidisciplinary standards of practice, and organisational and legal developments.
Researcher's Comments		Funding not addressed.

KEY: X – Absence of users and or end-users

RefWorks Number: 19	**["OUT OF THE MOULD"]**	Year/County: 1996 - Netherlands
Reference		**Wessels RD, Willems CG, de Witte LP. Technical note. How to select a method to evaluate usability of assistive devices. J Rehabil Sci 1996; 9(2):53-7.**
Objective/Questions		A report on the approaches that can be used to assess usability aspects of assistive devices. The scope and outcome of individual approaches are given, together with a guide to select the preferential approach taking into account the major aims of the usability evaluation to be performed.
Device/Product		Assistive Technology Devices.
Users		n = 0
Method/Tool/Approach		Methods identified for the design of a study by (combining or adjusting the following available approaches) include: evaluation by experts, evaluation of use, evaluation by users, case study and simulation of use. A set of 11 criteria was presented with which to assist evaluators to select the most suitable method to evaluate usability in a particular situation.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Due to the subjectivity and dynamic concept of usability, as well as having different people/parties involved in the various stages of the device development, a universal approach to evaluation of usability is impossible. Using Batavia and Hammer's criteria for evaluation of assistive devices, evaluation by users was the most suitable method to evaluate most of the features of usability, with limitations to evaluating products that have been in use for some time. One method or a combination of methods need to be selected and adjusted to a specific research aim e.g. complexity of device, the amount of time and finance available. The cost of an evaluation project was identified as an important factor, where evaluation by users is more expensive than evaluation by experts. The use of expert panels even in the early stages of product design is being used more frequently. The values attached to the different approaches were highlighted by the authors as their personal opinion, which they saw as being valid in a 'general sense'.
Researcher's Comments		Funding not addressed.

RefWorks Number: 22	**["OUT OF THE MOULD"]**	Year/County: 1995 - USA
Reference		**Mann WC, Hurren D, Tomita M, Charvat B. An analysis of problems with walkers encountered by elderly persons. Phys Occup Ther Geriatr 1995; 13(1/2):1-23.**
Objective/Questions		To provide an overview of walker designs and a review of the literature on walkers and walker use, and an analysis of walker problems encountered by subjects in the University of Buffalo Consumer Assessments Study.
Device/Product		Assistive devices: walkers (no specific devices named).
Users		n = 42 (13 men & 29 women).
Method/Tool/Approach		The sample was gained from 333 subjects who were in the Consumer Assessments Study at the time of analysis, 69 of whom used a walker, 42 of whom reported problems with their walkers. The Consumer Assessments Study sample was compared to results from the 1986 National Health Interview Survey and the 1987 National Medical Expenditure Survey and it was determined that the subjects represented elders with disabilities. The Consumer Assessments Study data were collected in personal interviews in subjects' homes by 1 of 2 project interviewers. Functional status instruments included the Functional Independence Measure (FIM) and a section of the Older Americans Resources and Service Center Instrument (OARS). Psycho-social dimensions were captured with the Center for Epidemiologic Studies Depression Scale (CESD) to measure depression and the Mini Mental State Exam to measure mental status and the Rosenberg Self Esteem Scale to measure self-esteem. The final instrument used was the Consumer Assessments Assistive Technology Used (CAATU). This study analysed the open-ended responses of the subjects who had a walker with which they were not satisfied.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The subjects reported a total of 46 "problem walkers", 33 were no longer being used and 9 were in use. 57% of the problems were categorised as "difficult and/or dangerous" to use, pointing to the need for careful professional assessment and follow up. Complaints in this category frequently included the terms "heavy" "awkward" and "bulky" particularly for folding walkers. Other problems related to difficulty in gripping the walker and in pain associated with its use. Need for maintenance was another problem, and inability to function well on sidewalks was reported by another individual. The authors conclude that despite the importance of safety and prevention of falls it appears that a large percentage of elderly persons own walkers which are potentially dangerous for them. 8 subjects owned walkers that they no longer used because their physical and or mental status had declined. 7 subjects no longer used their walker because their status had improved; the majority of these individuals had a hip fracture. 1 subject was not trained in the use of the walker and stated this as the reason for not using it. Another was given the walker by a friend and did not feel the need for it. A relatively small percentage (4%) of walker owners cited stigma as a problem. The authors argue that the development of a "better" walker appears less important than ensuring individuals with mobility impairments are properly assessed and that if they receive a mobility aid then that aid is appropriate and that they receive continued follow up and training. However they suggest that an intelligent walker could include sensors to monitor gait and adjust to the walker's speed, a lifting mechanism, ability to monitor the users' vital signs and command of the device by voice for example.
Researcher's Comments		Supported through funding from the National Institute on Disability and Rehabilitation Research of the US Department of Education and the Administration on Aging of the Department of Health and Human Services.

RefWorks Number: 29 [PROSTHESES: LIMB, FACIAL & PELVIC]		Year/County: 2003 - Australia
Reference		**Frossard L, Beck J, Dillon M, Evans J. Development and preliminary testing of a device for the direct measurement of forces and moments in the prosthetic limb of transfemoral amputees during activities of daily living. Journal of Prosthetics and Orthotics 2003; 15(4):135-42.**
Objective/Questions		To provide an extensive description of the direct measurement of the forces and moments applied to the socket of a transfemoral amputee with prosthetic limb/s during daily living activities.
Device/Product		Transfemoral prosthetic limb & a low-profile commercial transducer with wireless modem. The prosthesis used was composed of an ischial containment socket, the transducer, an Otto-Block safety knee (Vienna, Austria), a solid ankle, and cushion heel (SACH) foot.
Users		n = 1 female transfemoral amputee, age 36, 62.65kg. The subject was selected because of her high functional levels since the initial testing was going to be significantly demanding with respect to distances to be walked and length of time.
Method/Tool/Approach		Case Study: The forces and moments applied on the socket of the subject were measured with a commercial transducer and recorded at distance using a wireless modem to transmit the data. The subject was asked to walk in a straight line and around a circle as well as to ascend and descend a slope and stairs. She was instructed to perform each activity at her natural pace and as she would usually perform it during daily life [not stated where the testing took place]. Occasionally she used the handrail when ascending and descending the slope and the stairs, and also chose to take two stairs at a time when ascending [with her sound leg] and descending [with her prosthetic leg]. Although the apparatus used allowed recording of an unlimited number of trials and gait cycles, the subject was asked to repeat each activity six times. The subject was free to take a sufficient resting period between each trial and activity, if necessary, to avoid a fatigue effect. The wireless modem was used to transmit the data from the transducer to a laptop composed of a transmitter and receiver with operating range outdoors greater than 700m. The 200g transmitter was connected to the transducer by a serial cable and was carried in a waist pack.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The article claims that its proposed apparatus was an improvement on the current method of using a gait laboratory to assess the load applied on the residuum and the knee of transfemoral amputees. The superiority of this technique was said to rest on the combination of the direct measurement of the loading, the discreet sized transducer and the absence of cables to transmit the data. These three major assets enabled the measurement of the true loading on the residuum during real, every-day situation. The apparatus presented here can be used at this stage of development by engineers and biomechanics, to refine the design of conventional prosthetic and direct skeletal fixation components. Future directions could include having user friendly sensors to be used by clinical teams including prosthetists, orthopaedic surgeons, physiotherapists etc. This proposed method could aid the decision making process by providing quantitative feedback about the rehabilitation program and fitting of lower limb amputees.
Researcher's Comments		Funding not addressed.

RefWorks Number: 31	**[ORTHOPAEDIC]**	Year/County: 2002 - UK
Reference		**O'Brien S. An outcome study on average length of stay following total hip and knee replacement. J Orthop Nurs 2002; 6(3):161-9.**
Objective/Questions		To establish whether variation in the inpatient length of stay for total joint replacement patients is associated with variation in the short term outcome obtained, the problem and complication rates encountered and the variation in the care inputs received by patients in the immediate post discharge period.
Device/Product		Hip and Knee Prostheses (no specific devices named).
Users		n = 400 patients (150 men & 250 women): 265 having total hip replacement and 135 having total knee replacement; n = 18 orthopaedic surgeons.
Method/Tool/Approach		Prospective observational study carried out in a single unit. Patients undergoing unilateral primary total hip or knee replacement surgery were recruited. Outcome measures used were Oxford hip and knee scores at 3-12 months post surgery, SF-36 at 12 months post-surgery, EuroQol, Barthel's activities of daily living index and use of post discharge resources, readmission and complication rates. The intervals of patient contact were: preoperatively on admission, prior to discharge, day 10 post discharge by telephone, day 90 post discharge by telephone and in person at clinics, 1 year post surgery by telephone and at routine clinics.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The primary diagnosis was osteoarthritis in 92% of cases and rheumatoid arthritis in 8%. The sample included 247 short stay patients and 153 long stay. Both long and short stay hips achieved greater than 70% success in terms of achieving their target discharge date. Short and long stay knees were less successful in achieving their target discharge date (36% of short stay and 51% of long stay knees). In the majority of cases (16.25%) discharge was delayed for medical reasons. When patients were asked if their length of stay was "just right" 96% said that it was. The SF-36 showed improvements in all but one area for all patients (social functioning). The principal benefit of a hip or knee replacement appeared to be a reduction in bodily pain and an improvement in physical functioning, but substantial improvements in emotional and mental health were also found. At 3 months post discharge a majority reported relying on informal carers for shopping (69%) and housework (58%). 77% of patients were still taking analgesia by day 10 post discharge. Overall 97.75% had no concerns about their ability to manage at home post discharge. Patients in all groups experienced general infections but there were no major wound infections. There was a very significant difference in terms of improvements in scores for patients comparing pre and post surgery outcomes. Improvements were noted for all groups. There was no significant difference in outcome between short and long stay thus the author concludes that there is scope for making reductions in the average length of stay without significant negative impact on outcomes or post discharge care needs.
Researcher's Comments		Funding not addressed.

RefWorks Number: 32 [TOOLS]		Year/County: 2003 - UK/US/Australia
Reference		**Whitehouse SL, Lingard EA, Katz JN, Learmonth ID. Development and testing of a reduced WOMAC function scale. J Bone Joint Surg (Br) 2003; 85B (5):706-11.**
Objective/Questions		The development and testing of the reduced Western Ontario and McMasters Universities Osteoarthritis Index [WOMAC] functional scale.
Device/Product		Hip & Knee Prostheses -Kinemax Plus.
Users		The Kinemax Outcomes Study is a multinational, prospective cohort study of Primary Knee Replacement for patients with osteoarthritis. Patients were recruited between Sep 1997 and Dec 1998 and all surgeons used the Kinemax Plus [Stryker Howmedica Osteonics, Mahwah New Jersey] prosthesis. Dataset: n=716 random Medicare patients in the USA who had primary THA for osteoarthritis in 1995.
Method/Tool/Approach		Data was gathered before and at 3 and 12 months after the operation by physical examination and self-completion of a questionnaire. Trained research assistants collected the data from the history and physical examination, and the questionnaire included specific questions on function including walking distance, the use of a walking aid and the ability to climb stairs. WOMAC is a self-assessment, disease specific measure for patients with osteoarthritis in the hip and knee. The original version has 24 items in three dimensions: pain [5 items], function [17 items] and stiffness [2 items]. In order to reduce the WOMAC score successfully, several factors were considered: the stiffness score is largely redundant and is commonly excluded from the questionnaire. The pain scale has only five items and no reduction is deemed necessary, reducing the scale to 17 items. The reduction of items was initiated by a clinically driven process. A poll of orthopaedic and rheumatology personnel in the UK and USA was conducted. 36 responded. Respondents were requested to indicate which 5 items from the scale they would keep according to three given criteria. The data was then analysed to confirm that the selected items represented a range of difficulties, were clinically sensitive to detecting change, had few missing values and were applicable to patients with hip and knee symptoms. The scaled was tested for validity, reliability and responsiveness from data gathered prospectively from a multinational study [US/UK/AUS]. The scale was further validated at three years on a random sample of the 716 Total Hip Arthroplasty patients. These data included three year postoperative WOMAC, Harris Hip Scores and SF-12 (An abbreviated 12 item version SF-36; [SF-12] has previously been developed and validated.)
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		DATA SOURCES- 1 Clinical Opinion of Orthopaedic Personnel: n=24 from the UK and n=12 from the USA - 21 surgeons, 6 researchers, 5 nurses, and 4 physiotherapists. The complete dataset contained 862 primary TKR patients, with 94% having a valid WOMAC at 3 months review, and 88% at 12 months. Their mean age was 70 years, 38-90. 50% from the UK, 31% from USA, and 19% from Australia. The 716 THR patients had a mean age of 73.6 years, 65-93, with 665 having valid WOMAC function scores for this dataset. From the clinical opinion 4 of the top 7 items were kept in the reduced scale [i.e. 7 items were kept in total] - ascending stairs; rising from sitting; walking on flat; getting in or out of a car; putting on socks; rising from bed; and sitting. From the data-driven analysis using Spearman's correlation coefficient the scale was validated using both THR and TKR data: Criterion Validity- to compare the full scale against the reduced scale, a very strong correlation [0.96-0.97] existed and high agreement in the scores support the hypothesis that the reduced scale captures functional status as well as the original version. The Convergent Construct Validity- was assessed by determining whether the reduced scale has similar strength of correlation to other scales- the Harris Hip Scores, SF-12 physical component scores for THR. For the TKR data both the full and reduced scales were correlated to SF-36 physical component scores and physical function scores, the Knee Society's function score and the Oxford Knee Score. All Spearman's rank correlation coefficients are significant at the level of 1% level, and for the reduced scale, are a mean of only .035 less than those of the full scale, support the hypothesis that a reduced scale is valid. Reliability- Spearman's non-parametric rank were calculated to assess the association between the changes in scale scores and the patient's perceived change in functional status. Similar values were obtained for both scales. Since the reduced scale is a subset of the full scale, it will be relatively simple to compare results across studies using either form, especially as the WOMAC is a recommended disease-specific outcome measure. This will increase its acceptability and usefulness within orthopaedics. The other shortened measures of outcome- Oxford hip and knee scores and Bristol knee scores have disadvantages. The authors acknowledge that further work needs to be done to validate the reduced scale with patients treated non-operatively or those undergoing revision, as well as investigating compliance and missing values.
Researcher's Comments		Supported by the Stryker Howmedica Osteonics and NIH Grants. "Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article…"

RefWorks Number: 52	**[ORTHOPAEDIC]**	Year/County: 2003 - USA
Reference		**Mancuso CA, Salvati EA. Patients' satisfaction with the process of total hip arthroplasty. J Healthc Qual 2003 25(2):12-9.**
Objective/Questions		To assess patients' satisfaction with the process of total hip arthroplasty.
Device/Product		Hip Prostheses (no specific devices named).
Users		n = 336 patients (60% women); n = 1 orthopaedic surgeon.
Method/Tool/Approach		Patients were eligible to participate if they had total hip arthroplasty between 1998 and 2000 with the same surgical staff, were fluent in English and had completed a self-administered satisfaction survey at discharge. The survey asked patients to rate their satisfaction with the quality of care received for major services before and during hospitalisation on a scale of 0-10, with higher ratings indicating more satisfaction. It included the following 16 major items: preoperative testing, preoperative radiographs, autologus blood donation, arrangements for hospital admission, preoperative hip arthroplasty educational class, hospital admission, care from surgical, anesthiology, medical and nursing staff, recovery room care, postoperative pain control, physical therapy, social services, discharge planning and billing. Patients were also asked a global question about their overall satisfaction with the quality of care they received throughout the entire process. Patient demographic and medical data were obtained from office and hospital charts. Information included diagnosis, body mass index, patient reported symptoms, type of total hip arthroplasty, postoperative complications, length of stay, and discharge destination. The surgeon assessed preoperative orthopaedic status using the Hospital for Special Surgery Hip Scale.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean age of the patients was 67 years (28-90). Osteoarthritis was the most common diagnosis (89%). Before surgery nearly 90% of patients had severe hip pain and took pain medications and more than 90% considered their hip condition to be unacceptable. A total of 16% had postoperative complications, which included cardiac events (2%), deep vein thrombosis (2%) and anaemia (5%). Mean length of stay was 5.5 days (3-53). In general patients were very satisfied with the quality of care surrounding hip arthroplasty, with mean ratings above 9 for all items, which may reflect ceiling effects. Provider characteristics considered reflected attributes of reliability, responsiveness, communication and interpersonal care. Among patient characteristics considered the most marked finding was that older individuals and those who did not live alone tended to be more satisfied. The authors conclude that total hip arthroplasty in addition to being an effective treatment for hip arthritis is also a desirable option from the perspective of patient satisfaction with the process of care.
Researcher's Comments		Supported by the Center for Clinical Outcome Research at the Hospital for Special Surgery in New York, and the Center for Aging Research and Clinical Care at the Weill Medical College of Cornell University.

RefWorks Number: 57 [TOOLS]		Year/County: 2000 - USA
Reference		**Wright JG, Young NL, Waddell JP. The reliability and validity of the Self-Reported Patient-Specific Index for total hip arthroplasty. J Bone Joint Surg (Am) 2000; 82A (6):829-37.**
Objective/Questions		The Patient-Specific Index [1997] reflects how individual patients weigh concerns in rating the outcome of total hip arthroplasty [THA], which is administered by an interviewer. The purposes of the present study were: 1 To create a self-reported version of the Patient-Specific Index. 2 To determine the reliability of this new self-reported version. 3 To determine the relationship between the scores on the new self-reported version and those on the original interviewer-administered version.
Device/Product		Total Hip Prostheses.
Users		n = 10 patients arbitrarily chosen for pilot study before they had their surgery. n = 55 patients enrolled. They had consecutive elective primary or revision THA performed by same surgeon at one hospital.
Method/Tool/Approach		In a prior study the authors established the test-retest reliability and validity of an interviewer-administered questionnaire. The Patient Specific Index is intended to evaluate the concerns of individual patients before and after THA. A pilot of the self-administered version was performed after minor changes to the wording were made. The patients were debriefed after completing the questionnaire. They reported that they understood all of the individual questions, and minor changes in the wording of a few questions were required to reflect the post-operative period. Patients rate 24 concerns [and any additional ones] with regard to severity and importance, with each concern having 7 response categories from 'not important at all' to 'extremely important'. From a previous study by two of the authors, it was decided that the simplest way to provide a summary score was to add ratings for severity and importance. In order to determine Reliability, the self-administered version was completed by the patient twice at home, two weeks apart. Both questionnaires were mailed. The interval of two weeks was chosen because the clinical status of the patients was not expected to change substantially during this time and the time that patients would recall similar responses was minimized. Criterion Validity was assessed by comparison of the two versions- self administered and interviewer administered. The reason to do the interviewer administration version last was so that potential teaching would not falsely elevate the result of the self-reported Patient Specific Index reliability testing. 25 patients were interviewed pre-operatively and 30 post-operatively. Upon return of the second self reported Patient Specific Index, subjects were contacted in order to schedule a time for interviewer administration of the Index, either in their home, at St Michael's Hospital or by telephone.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance
Conclusions		Mean age of the 55 patients was 65.6 years range 28-84 years. 23 were male and 47 had a primary THA. 25 patients in the preoperative group were interviewed at a mean of 2.6 months before operation, and the postoperative group at 9.5 months after operation. The patients were asked about any change in their clinical status between the administration of the questionnaires to determine test-retest reliability. 34 reported no change in their condition, 10 slightly better, and 11 slightly worse. The test-retest reliability of the self-reported Patient-Specific Index was 0.79 [> 0.75 represents excellent reliability, using the random-effects intra-class correlation test-retest coefficient]. The mean difference between both the interviewer and self-administered versions were found to be small and not significant. The concordance of the two methods of administration was 0.78 suggesting excellent agreement. The Patient-Specific Index is a method of outcome assessment that addresses the concerns of individuals. The two main disadvantages of interviewer-administered questionnaires are a decreased feasibility of utilization [getting personnel to conduct interviews in patients homes, patients moving away etc] and a concern about how the interviewer may affect the patient's responses to the questions [patients may want to please their surgeons and thus underrate their concerns]. The main limitation of the study is the generalisability of the results obtained from the patients of a single surgeon. The study should be repeated in other contexts to ensure the generalisability. Also, the questionnaire is appropriate only for patients who are fluent in written English. The questionnaire would need to be translated before being used for patients who speak other languages.
Researcher's Comments		"…Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article, benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non-profit organisation with which one or more of the authors are associated..."

RefWorks Number: 60 [PROSTHESES: LIMB, FACIAL & PELVIC]		Year/County: 1998 - UK
Reference		**Fisher K, Hanspal R. Body image and patients with amputations: does the prosthesis maintain the balance? Int J Rehabil Res 1998; 21(4):355-63.**
Objective/Questions		To establish whether dissatisfaction with the artificial limb and or body image relate to achieved mobility following lower limb amputation in established limb wearers.
Device/Product		Lower limb Prostheses (no specific devices named).
Users		n = 107 amputees (67 men & 40 women).
Method/Tool/Approach		Patients attending limb fitting clinics participated, who were established limb wearers at least 1 year from amputation. The measures used were a specially designed (for this study) Attitude to Artificial Limbs Questionnaire (to measure attitudes to their artificial limb, consisting of 10 questions with responses on a 5 point Likert scale from "not at all" to "completely", total range of scores 0-50, examining satisfaction with the leg overall, comfort, shape, colour and material, how well the respondents felt able to walk, how they were treated by others, whether they felt the leg was part of them, whether they felt their body image had been restored or the leg improved), a body image questionnaire adapted from an eating disorders instrument including reference to body shape, the Hospital Anxiety and Depression Scale and the Harold Wood Stanmore Mobility Scale. The rehabilitation physician rated satisfaction with the prosthesis on a numerical rating scale from 1 (indicated satisfaction with the prosthesis) to 4 (indicated that the prosthesis was unsatisfactory cosmetically, though was preferred by the patient for perceived functional advantage).
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean time from amputation was 13.9 years (1-54). The results showed patients were moderately satisfied with their artificial limb, had little experience of body image disruption or distress and there was no overall relationship between these variables and mobility. However those with a more negative body image were more anxious and in younger patients who sustained more traumatic than vascular amputations, the correlation between body image and mobility was significant, anxiety was higher and physician satisfaction with the prosthesis was lower. The authors conclude that body image disruption, anxiety and depression are not common in established limb wearers except in young people with traumatic amputations.
Researcher's Comments		Funding not addressed.

RefWorks Number: 97	**[ORTHODAEDIC]**	Year/County: 2002 - Australia
Reference		**McGee MA, Howie DW, Ryan P, Moss JR, Holubowycz OT. Comparison of patient and doctor responses to a total hip arthroplasty clinical evaluation questionnaire. J Bone Joint Surg (Am) 2002; 84A (10):1745-52.**
Objective/Questions		To compare patient and doctor responses to a total hip arthroplasty clinical evaluation questionnaire.
Device/Product		Hip Prostheses (no specific devices named).
Users		n = 1117 patients (516 men & 757 women).
Method/Tool/Approach		The data were obtained during 2934 clinical assessments (all clinical assessments performed from 05/1991-11/1996), including 839 preoperative assessments and 2095 postoperative assessments. The postoperative assessments were performed 3 months to more than 10 years after the procedure. Questionnaire data were obtained at 1 or more clinical assessments of the patients who underwent a total of 1273 total hip arthroplasty procedures. Consultant and trainee doctors performed similar total numbers of assessments. 2 consultants performed 57% of the assessments that were undertaken by consultants. Through a consensus process involving committees of 3 international orthopaedic groups, key outcome parameters for hip arthroplasty were identified. This total hip arthroplasty evaluation system was described by Johnson et al (1990) and its recommended parameters and terminology were used in this study. A clinical evaluation questionnaire was developed in 2 formats, 1 to be completed by the patient and the other by the doctor. The questionnaire had 2 components: a clinical evaluation component and a patient satisfaction component. The clinical evaluation part comprised 11 items, 2 on activity, 2 on pain, 3 on function and 4 on gait. The patient satisfaction part was completed at postoperative assessments only and included 5 items related to satisfaction after hip arthroplasty. The questionnaire was completed by both patient and doctor as part of the routine clinical assessment both preoperatively and postoperatively. Additional information was collected on comorbid joint problems and other health problems, strength, mobility of the hip joint and limb length. Radiographic review of the hip joint was also undertaken.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		For 12 of the 16 items the patient responses had acceptable agreement with the doctor responses. Some important differences between patient derived and doctor derived data were found. If the patient had other joint or health problems, had a revision total hip arthroplasty or reported mild or moderate pain, there was a greater chance of reduced agreement on the pain items. Where there was disagreement the patient often reported a greater degree and frequency of hip pain compared to those reported by the doctor. Younger patients demonstrated better agreement with doctors than older patients did. The authors conclude that patients' perceptions of symptoms and outcomes after total hip arthroplasty are relatively similar to those of their doctor. They argue that the selective use of patient completed questionnaires has the potential to substantially reduce the costs of outcomes evaluation programmes by minimising doctor input and pending revision of some of the items the use if this patient completed questionnaire is advocated.
Researcher's Comments		In support of the research or the preparation of the manuscript 1 or more of the authors received grants or outside funding from Australian Medicare Initiative, Royal Adelaide Hospital, Adelaide University, and Adelaide Bone and Joint Research Foundation. No commercial funding received.

RefWorks Number: 117 [TOOLS]		Year/County: 2002 - Austria
Reference		**Bach CM, Nogler M, Steingruber IE, Ogon M, Wimmer C, Gobel G, et al. Scoring systems in total knee arthroplasty. Clin Orthop 2002; (399): 184-96.**
Objective/Questions		To evaluate four commonly used scoring systems for Knee Arthroplasty: the Hungerford Score, the Hospital for Special Surgery score, the Knee Society knee and function scores, and the Bristol Knee score.
Device/Product		Total Knee Prostheses.
Users		n = 92 patients with 118 Total Knee Arthroplasties, 58 women and 34 men, who had follow-up of their Total Knee Arthroplasty at the authors institution. The average age of follow-up was 70 years, range 43-87 years. The average follow-up was 9.8 years, 2-17 years range. n = 2 experienced orthopaedic surgeons who evaluated the patients [CMB and MN].
Method/Tool/Approach		All patients were evaluated by the two orthopaedic surgeons, using the 4 knee scoring systems [scope of instruments not defined]. Each observer [surgeon] completed all 4 scores on the patient's follow-up visit independently. All data were recorded in a database and statistical calculations were used. The individual results were not discussed before completion of the patient examination forms. Total score outcome was computed in points using the individual numerical scale, which ranged from 50 for the Bristol score to 200 for the Knee Society score. Statistical analysis included the global Friedmann Test to compare total point outcome. The individual scores were compared pair wise by the Wilcoxon test and post hoc Bonferroni correction. The results for the Bristol score were doubled and the function and knee scores of the Knee Society score were analysed independently to achieve a maximum of 100 points. Additionally, the results were categorized as excellent or good by both observers and the total number of cases rated fair or poor by both observers were summarised. All 4 scores were divided additionally into 3 subscores: pain, knee and function. The sub score pain consisted only of the variable pain in all four scores. The sub score knee contained variables such as mediolateral and anteroposterior stability, knee alignment, flexion contracture, extension lag, and range of motion. The sub score function included variables such as muscle strength, walking distance, ability to climb stairs, use of walking aids, transfer activity, chair and giving way. The inter-observer correlation was calculated for all variables using the Kendell Tau correlation coefficient.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The median total score outcome, as averaged for both observers and for all the knees was 74 points [range 15-100 points]. Hungerford score - 75 [range 23-97points]; Hospital for Special Surgery score - 58 [range -17-92 points]; the Knee Society score - 50 [range -10-100 points]; and Bristol score - 71 [range 21-98 points]. The global Friedmann test revealed significant differences among the mean total score outcomes. Both components of the Knee Society rating system revealed significantly lower total score outcomes [$p<0.05$, each]. The mean point differences in points between Observer 1 & 2 of the total score outcome were 14.1 points-knee score of the Knee Society, 8.8 points-Hungerford score, 7.2 points- function score of the Knee Society, 4.2 points- Bristol score, and 3.9 points- Hospital for Special Surgery. Evaluation of the scores capability to distinguish an excellent or good result from a fair or poor result showed agreement [between observer 1 and 2] in: 112 cases for the Hospital for Special Surgery score; 109 cases for the Bristol score; 96 cases for the Hungerford score; 103 cases for the Knee Society function score; 90 cases for the Knee Society knee score. Evaluation of inter-observer correlation for the sub score pain revealed an interobserver correlation coefficient of 0.88 -Bristol score, 0.84 -Hospital for Special Surgery score, 0.74 -Hungerford score, and 0.62 -Knee Society score. The four knee scores revealed considerable differences of total outcome. The median total score outcome ranged from 50 points [knee society function score] to 75 points [hospital for special surgery score]. These results indicate that using different scoring systems makes it difficult to compare results of different studies reporting on outcome of total knee arthroplasty. For clinical assessment of total knee arthroplasty, pain should be measured on a four-step system, the knee should be assessed by measurement of range of motion, extension lag, and flexion contracture, and function should be measured on a separate score assessing walking distance and walking aids.
Researcher's Comments		Funding not addressed.

RefWorks Number: 119	**[TOOLS]**	Year/County: 2002 - Netherlands
Reference		**Jedeloo S, De Witte L, Schrijvers G. A user-centred approach to assess the effectiveness of outdoor mobility devices and services. Int J Rehabil Res 2002; 25(2):137-41.**
Objective/Questions		The use of an instrument- the Individually Prioritised Problem Assessment [IPPA] which was developed [see Refworks #697, 2000] to assess the extent to which the problems in daily activities, identified by the client, have been diminished as a result of the provision of a mobility device and/or transportation service.
Device/Product		Mobility Devices: electric driven wheelchairs, electric scooters, special bicycles or three wheelers & Mobility Services: collective shared taxi system, financial support for organising individual transportation.
Users		n = 3 Providers [2 were municipalities and 1 a mandated regional local authority representing 3 municipalities] from which the n = 67 subjects were recruited over a 5 month period. All clients were 18 and over an applying for a new mobility device or alternative transportation service through one of the participating providers. Three quarters were female and half lived alone, and the reported health status was poor. They were included in the study on the condition that a medical needs assessment was requested. In all cases these were requests to the largest national medical needs assessment company, Argonaut-ZVN Advies. People with serious cognitive impairments were excluded from the study.
Method/Tool/Approach		Clients were either recruited directly by the provider or indirectly by a needs assessment company. A baseline interview was carried out during the early stages of the service delivery process, before the medical need assessment. A follow-up interview, which was performed by telephone, took place after 3 months of provision use. No second interview was performed with clients who did not receive a provision. The IPPA was applied as follows: clients were asked to identify the mobility problems that they experienced in daily life and they hoped to be eliminated or diminished as a result of the mobility device or service. For each of the major problems [maximum 7], clients had to assign scores to both in respect of the importance of the problem and the level of difficulty associated with performing it. Scores were rated on a 7-point scale. The 'difficulty scores' were added up, using the 'importance scores' as weighting factors, and divided by the number of problems. This gave a basic IPPA score between 1 and 49, and represents the total average inconvenience experienced by the client. At the 3 month interview the client was asked to assign new 'difficulty' scores to the same activities. The difference between the follow-up and basic IPPA is considered to represent the effectiveness, indicating the degree to which the perceived inconvenience with respect to the problems diminished. The Quebec User Evaluation of Satisfaction with assistive Technology [QUEST 2.0] was used to measure device satisfaction. SIP68 questionnaire completed at baseline to evaluate the effect on participation in daily life. To quantify the amount of change measured, effect sizes were calculated for IPPA and SIP68.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing&Trials	X
	Production	X
	Deployment	X
Conclusions		69 clients [mean age 75 years, 87% over 65 years] were interviewed at baseline, two did not fit the criteria and were removed from the study, resulting in 67. With 49 [73%] of the 67 participants, a second interview was performed. 39 received a service provision and 13 received a device: electrical scooter, manual wheelchairs, electrical wheelchairs, push wheelchair, motor for a bicycle. The total average perceived inconvenience experienced, IPPA score at baseline, was 37.7; on follow up this was 36.8. With a mean change in IPPA score of 17.5, at group level the impact of the mobility problems diminished significantly. The authors found that generally there was a decline in mobility problems and functional health status improvements. However, those who did not participate could have affected results. The group not wanting to participate [n=32] tended to be much older and possibly had worse health status. It was noted that the subjects were elderly and that younger disabled persons who suffer from lifelong disabilities are likely to evaluate they mobility problems differently. Also, it is possible the older subjects may have given responses that they thought the researchers may have wanted. With an SIP68 baseline score of 17.2 and a size effect of 0.4 this indicated that the improvement was small. Improvement was especially seen for the function areas Mobility Range and Somatic Autonomy. When looking at the IPPA effect, when there was no effect for IPPA the SIP68 did not also improve. Thus the IPPA was shown to be a different construct to the SIP68. SIP68 is an objective, universal measure, IPPA is an individual, subjective measure. It is suggested that the IPPA could be incorporated into daily practice and used for needs re-assessment. The elderly population from the Service for the Disabled Act [SDA] users is over-represented in this study. Younger adults were not included in this study. They tend to suffer from life-long disabilities and differ in personal capabilities and demands, are likely to evaluate their mobility problems differently, have different experiences and needs compared to the majority of elderly users, who mostly suffer from late life disabilities. Thus, the satisfaction scores could be influenced by age and it is possible that social desirability biased the result.
Researcher's Comments		Argonaut-ZVN Advies [the largest medical needs assessment company] co-financed the study.

RefWorks Number: 144	**[TOOLS]**	Year/County: 2001 - UK
Reference		**Dawson J, Fitzpatrick R, Frost S, Gundle R, McLardy-Smith P, Murray D. Evidence for the validity of a patient-based instrument for assessment of outcome after revision hip replacement. J Bone Joint Surg (Br) 2001; 83B (8):1125-9.**
Objective/Questions		Assessment of the Oxford Hip Score [OHS] as an instrument to evaluate outcome assessment after revision hip replacement [RHR]. Issues examined include: 1 OHS validity compared with EuroQol 5D [EQ5D]. 2 Sensitivity to change in both instruments is examined- especially important in RHR where improvement may be marginal. 3 The sensitivity to change of both instruments is examined among sub-groups characterised by the number of previous RHRs which had been undertaken.
Device/Product		Revision Hip Prostheses.
Users		n = 609 patients who had RHR, between Sep 1996 and Apr 1999, and had filled in questionnaires. Mean age 68.1 years, 260 males.
Method/Tool/Approach		The OHS is a 12-item patient based questionnaire developed and validated specifically to assess function and pain after THR. Two weeks before surgery and one year after surgery patients completed the OHS and EQ5D [Postal Questionnaires]. Other questionnaires completed by surgeons [details of the implant and surgical technique and their grade], anaesthetists [patient's weight and physical status], and one by an outpatient clinician on post-operative complications. Before completing the one year questionnaires patients were asked if they had undergone any operations since their RHR, whether they were very pleased, fairly pleased, not very pleased or very disappointed with their operation, and whether their hip was much improved, unchanged, slightly worse, or much worse than before surgery. For each instrument change scores [pre-operative and post-operative] and effect sizes were calculated. The latter measures the extent of change in a standardised way which allows comparison between instruments. SPSS and statistical tests were used to analyse the data.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Of the 609 RHR, 20 hips had missing data, leaving 589 hips for which 72% had RHR because of aseptic loosening, 9.8% had sepsis, 6.8% had dislocation, and a further 11% had replacement of prosthesis for other reasons including fracture and pain. 496 patients completed follow-up questionnaires. There was a high level of agreement between OHS and EQ5D pre-operative, post-operative and change scores. For both instruments the effect sizes were large, but the greater effect size of the OHS suggests that it is particularly sensitive to improvements after RHR. One year after RHR the OHS and EQ5D scores were compared with patient responses about post-operative satisfaction and changes in pain levels. There was a high level of agreement reported in all four measures. At one year pain was reported to be much improved in 75% of hips. In the first year after surgery, dislocation of the new implant occurred in over a quarter of patients who had undergone two or more previous THRs and over a third needed a further operation. The OHS postoperative scores at one year deteriorated progressively in line with the number of previous RHRs. The sensitivity of the OHS to marginal change was examined by analysing the results of subgroups of patients who had previously undergone RHR. Despite overall improvement, OHS post-operative and change scores progressively deteriorated with the number of previous RHRs. The EQ5D showed less sensitivity to change.
Researcher's Comments		Funding not addressed.

RefWorks Number: 202	**[OTHOPAEDIC]**	Year/County: 2001 - USA
Reference		**Gill GS, Joshi AB. Long-term results of kinematic condylar knee replacement: an analysis of 404 knees. J Bone Joint Surg (Br) 2001; 83B (3):355-8.**
Objective/Questions		To assess the long-term results of the Kinematic Condylar Knee Arthroplasty.
Device/Product		Knee Prostheses: Kinematic Condylar Knee Arthroplasty (Howmedica, Rutherford, New Jersey) designed to preserve the posterior cruciate ligament and give metal backing to the tibial.
Users		n = 335 patients (states 120 men, 208 women), 1 surgeon.
Method/Tool/Approach		Prospective study between 10/1982-03/1988 of 404 consecutive replacement arthroplasties. Of the 335 patients 268 (80% were reviewed by one of the authors as part of a prospective study within the last 2 years of the study period. The remaining 67 (20%) were assessed by a research secretary using telephone questioning. Clinical examination was made at 2 and 6 weeks, 6 months and 1 year and at variable intervals until the final follow up (the minimum follow up for all living patients was 10 years, range 10-17). Clinical evaluation used the Knee Society clinical rating system. For radiological assessment the radiological criteria and scoring system of the Knee Society was used. Survivorship analysis used the Kaplan-Meier method carried out on all 404 knees, with an end-point defined as removal or revision for any reason, with a second end-point defined as a pain score of less than 21.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		354 knees had osteoarthritis, 45 rheumatoid arthritis, and 5 other diagnoses. The mean age for surgery was 68 years (30-92). There were 7 complications (1.7%), 4 knees suffered a wound dehiscence and 2 had patellar problems (not stated what happened to the 7th). 16 knees were revised (3.9%), 4 because of infection. Survivorship was 99.4% at 5 years, 98.2% at 10 years and 92.6% at 17 years. Before surgery the mean score was 36 which improved to 90 after surgery. An excellent result was achieved by 362 knees (89.6%) and 29 (7.2%) were considered to have a poor result. Age at surgery and pathological diagnoses were found to be significant. The most common cause of failure was loosening of the tibial component. It is concluded that the device provides good long-term clinical results.
Researcher's Comments		No commercial funding.

RefWorks Number: 203 [TOOLS]		Year/County: 2001 - Sweden
Reference		Dunbar MJ, Robertsson O, Ryd L, Lidgren L. Appropriate questionnaires for knee arthroplasty: results of a survey of 3600 patients from the Swedish Knee Arthroplasty Registry. J Bone Joint Surg (Br) 2001; 83B (3):339-44.
Objective/Questions		The authors tested various outcome questionnaires in order to determine which is the best for patients who have had knee arthroplasty.
Device/Product		Knee Prostheses.
Users		n = 3600 randomly selected patients from the SKAR and used to test the instruments. (The Swedish Knee Arthroplasty Registry [SKAR] has over 70,000 prospectively collected knee replacement data.) The patients had a diagnosis of primary osteoarthritis, age >=55 years at surgery and >=95 years at the time of mail-out. Some had either a unicompartmental, lateral unicompartmental, bilateral unicompartmental or total knee arthroplasty. 69.8% female at the time of mail-out.
Method/Tool/Approach		Questionnaires Selected by means of a literature review include [scope of instruments not defined here]. Four general health questionnaires: Nottingham Health Profile - NHP; 12 item Short Form health survey - SF-12; 36 item Short Form health surgery - SF-36; and Sickness Impact Profile- SIP. And three disease/site specific questionnaires: Algofunctional Index for the Knee [Lequesne]; the Oxford 12 item Knee Score [Oxford-12] and Western Ontario and McMasters Universities Osteoarthritis Index [WOMAC]. The patients were randomly divided into 12 groups of 300, each being sent a combination of one general health and one disease/site specific questionnaire [4 general health x 3 disease/site specific = 12]. A covering letter with instructions was included with a postage-paid return envelope and a third questionnaire enquiring about the length of time required and the need for assistance to complete the questionnaires. A reminder letter was sent two weeks later to non-responders. Three weeks after the first mailing n = 420 patients were randomly selected from those who responded to the first mail out and were sent one repeat questionnaire [generic or disease/site specific] to test reproducibility of each questionnaire. A low questionnaire score usually reflects a patient's favourable impression of their health status, while a high score is the opposite. The exception is SF-12 and SF-36. For this study they were inverted. The Oxford-12 and Lequesne produce single scores with the other questionnaires yield a number of subscores, these were calculated by averaging. SPSS and ANOVA were used to analyse the data.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance
Conclusions		The only outcome measure available to date had been revision status. While questionnaires on health outcome may function as more comprehensive endpoints, it is unclear which are the most appropriate. The authors did not aim to compare the construct validity of the questionnaires because there is no established standard for knee arthroplasty. By validating one questionnaire against another involves circuitous logic and the use of 'objective' ratings by surgeons which introduce bias, so that content validity was focused on in this paper. For the general health questionnaires the SF-12 had the highest percentage of completed questionnaires, and the Oxford-12 also had the highest percentage for disease/site specific questionnaires. SF-12 took the least amount of time [7.7 minutes] to be completed in the general health questionnaires. Lequesne took 8.2 minutes followed by Oxford-12 with 9.6 minutes to complete in the disease specific questionnaires. Overall, the SF-12 ranked best for the general health questionnaires and Oxford-12 for the disease/site specific questionnaires, when the mean individual ranks for each parameter were considered. The authors recommend these for use in a cross-sectional discriminative application. Comparisons of the responsiveness of the questions tested were avoided, since the purpose of our study was to define questionnaires which would be appropriate for a cross-sectional, discriminative postal survey.
Researcher's Comments		Funded by grants from the Arthritis Society of Canada, the Medical Research Council of Sweden, Stiftelsen for bistand at vanfora I Skane, the Medical Faculty of the University of Lund, and Socialstyrelsen [The National Board for Health and Welfare]. "..No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article…"

RefWorks Number: 208	**[DENTAL & ORAL]**	Year/County: 2001 - UK
Reference		Allen PF, McMillan AS, Walshaw D. A patient-based assessment of implant-stabilized and conventional complete dentures. J Prosthet Dent 2001; 85(2):141-7.
Objective/Questions		1 The impact of implant-stabilized prostheses on the health status of complete denture wearers using patient-based, oral-specific health status measures. 2 The influence of preoperative expectations on outcome.
Device/Product		Dental Prostheses.
Users		3 GROUPS used in the study and consisted of edentulous patients who each requested implants to stabilize a complete oral prosthesis in the mandible. n = 20 IG [Implant Group]- they were offered and received treatment of an implant stabilized prosthesis; 17 women/3 men; mean age 55.79 years; edentulous for mean time of 23.1 years [3-40 years]. 2 CONTROL GROUPS: n = 20 CDG1 [Conventional Denture Group 1]- requested an implant-stabilized prosthesis but did not receive one; 11 women/9 men; mean age 60.15 years; edentulous for mean time of 19.9 years [2-35 years] n = 20 CDG2 [Conventional Denture Group 2]- comprised edentulous patients who requested replacement of complete dentures by conventional means. They did not request implants and were not given information on implants; 26 women/9 men; mean age 65.06 years; edentulous for a mean time of 27.1 years [3-40 years]. All Subjects recruited from the interdisciplinary implant clinic at Newcastle Dental Hospital, UK. They were referred from general dental practitioners and from other hospital departments, all reported difficulties wearing conventional complete dentures.
Method/Tool/Approach		At the initial examination, subjects were invited to participate in the study by research workers not involved in their treatment. After a clinical and radiographic examination, these subjects were offered treatment to provide an implant-stabilised prosthesis in the mandible. G1 [Implant Group] after placement of implants, 14 subjects received a mandibular removable overdenture, and 6 subjects received a mandibular implant-supported and retained fixed partial denture. CDG1 [Conventional Denture/Control Group1] subjects received conventional complete dentures. CDG2 [Conventional Denture/Control Group2] subjects received conventional complete denture therapy. A prospective longitudinal study. Baseline data were collected before active treatment and, in the case of IG and CDG1 subjects, before deciding which treatment [implant-stabilized or conventional dentures] the patients would receive. All subjects completed the Oral Health Impact Profile [OHIP], an oral-specific health status measure, and a 'self-reported denture satisfaction scale' validated by Feine et al [1994]. IG and CDG1 subjects also completed a scale based on their expectations of implant therapy outcomes. The denture satisfaction and expectations scale uses a Likert response format that ranged from 1-5: 'totally satisfied' to 'not at all satisfied' respectively. For both mandibular and maxillary dentures, the variables assessed were general satisfaction, retention, comfort, stability, speech, appearance, and occlusion. After completion of treatment [3 months after the insertion of prostheses] all subjects once again completed OHIP and denture satisfaction scale.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		At baseline, the 3 groups presented with similar clinical complaints, namely, dissatisfaction with their existing conventional dentures. Although IG and CDG1 subjects were more dissatisfied than CDG2 patients with their mandibular dentures, differences were not striking. This may be due to the 'checklist' nature of the denture satisfaction questionnaire. However, the manner in which tooth loss and consequent conventional denture wearing affected individuals differently is shown in the OHIP subscores. Subjects requesting implants, IG and CDG1, had high expectations for implant-stabilized prostheses, it was also found that with these 2 groups oral problems had psychological, social, and functional consequences. This finding has clinical significance, as conventional prosthodontic treatment may not adequately overcome these severe problems. Furthermore, such problems may not be detected by objective assessment alone. These results demonstrate the potential benefit of using an appropriate health status measure, such as the OHIP, as part of pre-treatment. Improvements in denture satisfaction and OHIP scores were reported by all 3 groups after treatment. Subjects who received their preferred treatment, IG and CDG2, reported a much greater improvement than CDG1 subjects. Pre-operative expectation did not appear to influence satisfaction with the outcomes of implant therapy in IG subjects. Non-significant variables included age, gender, length of time edentulous, number of sets of complete dentures received in the past, and height of edentulous ridges. Moreover, preoperative expectation variables were not associated with change in satisfaction scores. After stepwise regression procedure, the only variable retained in the statistical model was satisfaction with the occlusion of the new prosthesis [Chewing Surface Plane]. After treatment, subjects in all 3 experimental groups reported an improvement in denture satisfaction and oral health status. Biases identified by the authors include: the possibility of selection bias in IG and CDG1 was reduced by inviting all edentulous patients who attended the implant clinic to participate in the study before knowing whether they would receive implants. Another potential bias was the possibility that subjects would try to avoid offending the clinician by indicating a greater degree of satisfaction with their treatment than they actually felt. To minimise this bias, data were collected by research workers not involved in the treatment of the subjects. OHIP helped identify the degree of impairment, disability, and handicap experienced by edentulous patients. Such information may be useful in targeting patients most likely to benefit from implant-related procedures. Conventional dentures can be as effective as implant-stabilized prostheses in improving the health-related quality of life of certain patients.
Researcher's Comments		Funding not addressed.

RefWorks Number: 210	**[ORTHOPAEDIC]**	Year/County: 1998 - Australia
Reference		Van Essen GJ. Chipchase LS. O'Connor D. Krishnan J. Primary total knee replacement: short-term outcomes in an Australian population. J Qual Clin Pract 1998; 18(2):135-42.
Objective/Questions		To evaluate the short-term outcome of primary total knee replacement, using standard and reliable outcome measures, for osteoarthritis in an Australian population.
Device/Product		Knee Prostheses (no specific devices named).
Users		n = 73 patients (33 men, 40 women).
Method/Tool/Approach		Comparison of pre-operative health status of the patient population with population norms using a quality of life questionnaire. All patients completed a self-administered SF-36 questionnaire. Physical evaluation of the knee utilised the Knee Society score, performed pre-admission and post-operatively at a mean follow up of 3 months by a research therapist. Patients with rheumatoid arthritis or those requiring revision were excluded.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The average age was 73 years (54-88). Using the SF-36 there was a statistically significant improvement in physical functioning and bodily pain in males; and bodily pain, vitality, role-emotional and mental health in females. A statistically significant improvement was also seen in Knee Society Scores following surgery for both males and females. Comparison of pre-operative SF-36 data to age-matched Australian normative values demonstrated that female patients requiring total knee replacement were significantly below the norms in virtually all health dimensions whilst males were significantly below the norms in mainly physical health dimensions. Stated limitation: these results were self-reported and males are perhaps less prone to report their mental health. Overall the results demonstrate significant short-term improvement in quality of life following total knee replacement with consequent relief of pain and improved function in an Australian population. However the 3 month post-operative scores despite being significantly better than the pre-operative scores were still below the age matched normative data set. The authors suggest this could be due to the co-morbidities of the patients or the post-operative recovery time.
Researcher's Comments		Funding not addressed.

RefWorks Number: 219	**[TOOLS]**	Year/County: 2000 - Spain
Reference		Alonso J, Lamarca R, Marti-Valls J. The Pain and Function of the Hip (PFH) Scale: a patient-based instrument for measuring outcome after total hip replacement. Orthopedics 2000; 23(12):1273-8.
Objective/Questions		This study was designed to assess the reliability of the Pain and Function of the Hip Scale [PFH] and its degree of association with other instruments as well as its ability to measure clinical change (responsiveness) in patients undergoing Total Hip Replacement [THR].
Device/Product		Total Hip Prostheses.
Users		A total of 131 patients undergoing THR from Jan 1992 to Jun 1993 were eligible. 108 were evaluated at 3 months [2 died and 21 were lost to follow up because they were attending rehabilitation programs or were living outside of the study area]. Of the 90 patients with complete valid data at 3 months, 79 had a complete evaluation at 12 months postoperatively.
Method/Tool/Approach		In 1991, the authors developed the PFH. It was designed to address three major concerns when assessing THR patients: 1) Pain should be measured more carefully and given more relative weight since it is the main reason for hip surgery 2) The scale should be based solely on reports by the patient rather than clinical examination 3) It should be simple enough to be used routinely in clinical practice. Patients were assessed pre-operatively, and at 3 months and 12 months post-operatively. The PFH was administered by a health professional. Scores were obtained by assessing the patient's status for three different subscales: pain [range: 0-40], function [range: 0-25] and mobility/strength [range: 0-20]. An overall score was obtained by adding all three subscales. In addition to the PFH scale, information on clinical status, functional capacity and health status was obtained. A generic perceived health instrument, the Nottingham Health Profile [NHP-Spanish Version, 1990], also was administered pre-operatively, 3 months and 12 months post-operatively. Scores for each of the NHP dimensions [energy, pain, emotional, and physical mobility] were calculated as the percentage of positive responses. Contrary to the PFH, the higher the NHP score, the worse the health status of the patient. General health was assessed by the question- 'In general, how would you rate you health? 1= very good, 2= good, 3=fair, 4=poor, 5=very poor. In follow up patients were asked to rate their health compared to baseline as much better, somewhat better, about the same, somewhat worse, or much worse.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The PFH scale was based on the consensus of Societe Internationale de Chirurgie Orthopedique et Traumatologie, The American Academy of Orthopaedic Surgeon, and the American Hip Society. Mean age of patients was 63 years, 75% of patients in the study population had uncemented prostheses, 16% cemented and 4% hybrid. The most frequent diagnosis was osteoarthritis, followed by avascular necrosis. Pre-operatively, 3 months and 12 months post-operatively the mean PFH scores were 26.5, 63.9 & 69.8 respectively, with an overall improvement of 43.1 points. Correlation with the NHP was high (-0.64), and magnitude of improvement [effect size] as assessed by the PFH scale was large [3.6 compared with 1.7 for the NHP]. Cronbach's alpha reliability coefficients were 0.81 for the overall PFH and 0.91 for the NHP. Data presented in this study show the PFH scale is responsive to clinical change and thus useful for assessing the effectiveness of THR therapies. The difference in pre-operative and post-operative PFH scores is high and statistically significant, with the effect size for surgery being well beyond the threshold suggested for the identification of a large change. The amount of improvement detected by the PFH scale was higher than that of the NHP, indicating the PFH is more sensitive than these other measures. Also, the PFH showed a moderate to high level of correlation with patients perceived health status as measured by the NHP. Only moderate correlation was observed between the PFH scale and clinical examination. This finding demonstrates, once again, the difficulty of mixing patient-based and clinical data in the same instrument for evaluating the effectiveness of THR. At the same time it underscores that both types on instruments are needed for a thorough evaluation of hip replacement. The PFH scale's usefulness for individual patient monitoring deserves further research. Reliability of the overall PFH was 0.81. This value may be considered appropriate for group comparisons similar to those presented here. Nevertheless, the use of this information for individual comparisons (i.e. when indicating surgery or when monitoring an individual patient over time) requires a higher level of reliability. A level of >=0.9 has been suggested [McHorney 1995, Nunnally 1994]. Data on the reliability of previous hip scales are scarce, and comparisons with the study data are difficult to make. One of the reasons for the relative low reliability of the PFH scale might be that reliability depends largely on the number of items in the scale (i.e. the longer the instrument, the higher the reliability). The brevity of the PFH is an advantage for its use in clinical settings, but it may not be completely free of measurement error. Before results of more research on test-retest and inter-observer reproducibility of the PFH are available, the overall PFH score should be preferred to the dimension specific scores, in terms of measurement error.
Researcher's Comments		Funding not addressed.

RefWorks Number: 220 [TOOLS]		Year/County: 2000 - UK
Reference		Liow RYL, Walker K, Wajid MA, Bedi G, Lennox CME. The reliability of the American Knee Society Score. Acta Orthop Scand; 71(6):603-8.
Objective/Questions		The purpose of this paper is to determine the reliability of the American Knee Society Score [AKS] developed in 1989. Specifically the degree to which the AKS produces consistent results between different observers [inter-observer reliability], as well as with repeated examination by the same individual [intra-observer reproducibility].
Device/Product		Knee Prostheses.
Users		n = 29 subjects who were patients awaiting primary or revision knee arthroplasty and patients who have received knee replacements at least 6 months prior to the study. n = 6 observers who evaluated the subjects, and included 1 consultant with an interest in knee surgery, 2 registrars with at least 3 years experience in orthopaedics, 1 senior house officer with 3 months experience in orthopaedics, and 2 arthroplasty nurse practitioners whose responsibilities occasionally include clinical assessment. The nurse and senior house officer were instructed on the examination of the knee and were familiar with the AKS prior to the study.
Method/Tool/Approach		The subjects were evaluated in a random order. Each observer scored the same patient twice, at least 2 hours apart. The observers scores were compared with each other to estimate the inter-observer reliability, and a single observer's 2 scores for each subject were compared for intra-observer reproducibility. Scores were recorded on a standardised chart. Appropriately sized goniometers were provided to estimate the ranges of knee motion and deformities. Range of motion was recorded in the chart by each observer and the entry converted into points by RL. The Knee and Function Scores have a range of 1-100 and thus, the data were statistically analyzed as continuous variables.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The inter-observer variance for the Knee Score was 64. This gave a 95% reference interval that a single observer measuring a single subject will obtain a score within 16 points of the true score, likewise a 95% reference interval for the Function Score yielded 21 points. The more experienced observers had greater intra-observer reproducibility. Notably, there was moderate agreement between observers in the subjective variables, while the objective variables produced lower levels of agreement. The high inter- and intra-observer variations of the AKS make estimation of score change questionable. Reliable use of the AKS would necessitate repeated evaluation by an experienced observer.
Researcher's Comments		Funding not addressed. Definitions: Arthrosis: a degenerative disease of the joint.

RefWorks Number: 231	**[TOOLS]**	Year/County: 2000 - UK
Reference		Harwood RH, Ebrahim S. A comparison of the responsiveness of the Nottingham extended activities of daily living scale, London handicap scale and SF-36. Disabil Rehabil 2000; 22(17):786-93.
Objective/Questions		Hip replacement is an effective treatment for osteoarthritis of the hip joint in appropriately selected patients, although not all patients benefit equally or in the same ways. This study aimed to compare the size of benefits resulting from a hip replacement using a multi-dimensional health profile - the SF36, the London Handicap Scale and the Nottingham Extended Activities of Daily Living [ADL] scale, a measure of disability. The sensitivity to change in the disability and handicap scales has not been assessed previously, and was compared with the 'benchmark' performance of the well-established SF-36.
Device/Product		Hip Prostheses.
Users		Patients about to be admitted to hospital for hip replacement were identified via the hospital's surgical admissions office. They were included regardless of whether their operation was primary or revision, and irrespective of co-morbidity. Patients being admitted twice for sequential replacement of two joints were included in the study only once, being re-measured only after the second procedure.
Method/Tool/Approach		The intention was to assess and compare the measurement scales. The surgeon's clinical decision that operation was likely to be beneficial was taken as the criterion for expecting an improvement in health status. A questionnaire booklet, comprising the London Handicap Scale, Nottingham Extended Activities of Daily Living scale, and the SF-36 was sent by post along with a letter of explanation. All the scales were in self-completion format, and were returned on admission to hospital [for surgery]. Follow-up questionnaires were sent three months after the operation, comprising the same three scales, and asking for an overall assessment of the effect of their operation on a four-point, ordinal scale from 'marvellous to no improvement or worse'. This 'global impression' assessment was included to provide an independent criterion against which changes in the scale scores could be compared. Patients failing to reply were sent a single remainder, then telephoned to offer help. Three months was chosen as the time for reassessment on the basis of orthopaedic opinion, and because this time period had been used in a previous study. Responses from patients and subsequent discussion with surgeons suggested that post-operative improvement continues for at least six months. Therefore, a further questionnaire was sent to patients between six months and a year after the operation [to enable re-survey within the fixed time limits of the study]. A sample size of 50 was calculated to be sufficient to detect a 10% difference in the handicap score after surgery compared with pre-operatively.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Of 129 patients being called for operation, 81[63%] returned the questionnaires, 75 [93%] completed the follow up questionnaires after three months, 58 [79%] of the 73 [two patients died] completed questionnaires sent 6-12months postoperatively. Mean age was 72 years with a range of 40-97 years, 55 female & 26 males. 37 [46%] lived alone, 62% owned their own home and 70% were in non-manual occupations. Arthroplasty was studied as an example of a dramatic intervention which reduces impairment and clearly improves functional ability over a relatively short period of time. The results confirm this functional improvement, but demonstrate that there is considerable variation in the size of benefits depending on exactly what aspect is measured. Overall, the largest improvements were measured on the SF-36 pain, physical function and role limitation dimensions. These benefits are evident 3 months after surgery and were maintained or increased after 6-12 months. For each of these dimensions effect size was in excess of one, a magnitude rarely found in 'medical' interventions. The London Handicap Scale also showed good responsiveness overall, and small improvements between 3 and 6-12 months. It also measured large effect sizes. The extended ADL scale, whilst the simplest of the scales to complete, proved disappointing. This scale was insensitive to change with small effect sizes. Care must be taken in interpreting results of intervention studies where the response rate is less than 100%. Patients least pleased with their results may also be the least likely to respond to requests to complete questionnaires. An element of acquiescence bias is possible, with patients grateful for any help that they get being reluctant to declare poor outcomes. Uncontrolled before and after comparisons are subject to well-known limitations, but the approach is useful in evaluating the performance of scales. If a scale is to be used to demonstrate the marginal benefit of one treatment over another, one would expect it to be able to measure reasonably large changes in a before and after study. Further work is required to establish the validity of using health status measurements to make comparisons between rehabilitation outcomes and other types of health care activities. It is, however, reassuring that the London Handicap Scale, which was designed with rehabilitation in mind, shows at least reasonable responsiveness. Hip replacement aims to reduce pain and improve mobility, and it appears that most patients achieve these outcomes. Attempting to translate these benefits into estimated gains in utility is difficult, because there is no consensus on the outcomes used in trails of effectiveness [Coast, 1992].
Researcher's Comments		Funding not addressed.

RefWorks Number: 238	**[ORTHOPAEDIC]**	Year/County: 2000 - Korea
Reference		Kim YS, Callaghan JJ, Kwon SY, Kim KW, Han CH, Woo YK. Arthroplasty of the hip in patients with aplastic anemia. J Bone Joint Surg (Am) 2000; 82A (9):1231-9.
Objective/Questions		To evaluate the results of arthroplasty of the hip in patients with aplastic anaemia.
Device/Product		Hip Prostheses: 1) bipolar prosthesis fixed with cement, 2) bipolar prostheses fixed without cement, 3) hybrid total hip prostheses, and 22 total hip replacements fixed without cement.
Users		n = 19 patients (14 men, 5 women).
Method/Tool/Approach		Prospective study, 26 primary hip prostheses were implanted between 03/1990 - 05/1992 in patients with aplastic anaemia. Preoperative and serial postoperative Harris Hip ratings and radiographs. Cemented hip prostheses were evaluated for loosening according to the criteria of Harris & McGann (1986) and uncemented prostheses according to the criteria of Callaghan et al (1988). A specific protocol was followed for the perioperative transfusion of blood and platelets.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		25 hips were replaced because of osteonecrosis of the femoral head, and 1 was replaced because of a femoral neck fracture. No patient had excessive peri-operative bleeding or a postoperative infection. There were 3 orthopaedic complications; all were intra-operative fractures. Mean age at surgery was 40 years (20-66). After a mean duration of follow up of 79 months (72-95) 2 patients had died with the original implant in place (1 of pneumonia at 75 months and the other of sepsis at 77 months). The mean Harris Hip score was 55 points (42-68) preoperatively and 87 points (56-95) at the time of the latest follow up. No hip had been revised at the time of publication but 1 patient with a bipolar prosthesis had radiographic evidence of femoral loosening and according to the authors would require future revision. A second patient had some medial protrusion of the bipolar prosthesis with mild symptoms. The authors conclude that top hip arthroplasty can be performed safely in patients with aplastic anaemia. The durability of implant fixation was maintained and the clinical results demonstrated a sustained increase in the function of the hip.
Researcher's Comments		No funding was received.

RefWorks Number: 273 [TOOLS]		Year/County: 1999 - USA
Reference		Loebl D. A decision-making model for the provision of adaptive technology. Am J Occup Ther 1999; 53(4):387-91.
Objective/Questions		A model developed to systematically evaluate the specific functional needs of the person with disabilities, as these needs relate to technological interventions.
Device/Product		Assistive Technology Devices.
Users		Disabled clients - users of the technological interventions. Occupational Therapists - will use the tool.
Method/Tool/Approach		To identify the skills that need to be compensated through technology, three interrelated analyses need to be performed: 1 Task analysis to identify the performance components of the required task 2 Functional analysis to identify the skills that hinder the client from performing the same task 3 Technological intervention(s) that addresses the specific skills that affect the task performance. The model uses 4 steps in its analytical process: (1) identification of an area of activity that needs intervention; (2) identification of the tasks that comprise this activity; (3) analysis of the task to identify the functions that comprise it; (4) each task analysed to ascertain the sensory-motor of cognitive performance components. Procedure: The client is observed while performing a task, the performance components which were identified in the task analysis, and his/her performance is recorded on the grid. A completed grid provides a visual representation of the client's strengths and weaknesses in performing a specific task. The grid requires the occupational therapist to insert individualised information about the task, the function, and the performance of the task. Hence, each completed grid reflects the goals that were identified by the occupational therapist and the client as areas of intervention. After identification of the client's skills/ability to complete a given task has been identified decisions need to be made on what type of intervention-whether assistive technology or adaptation is required. Sixteen steps for application of the model have been summarised here.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		This model has been used since 1976 to guide the selection of technological solutions for functional disabilities. From 1992-1995 the model was applied by an interdisciplinary team comprising of OTs, Physical Therapists, Electrical Engineers, and Specialists in biomechanics and ergonomics working with persons with severe developmental disabilities. The model was implemented and refined as part of a research and demonstration [1997-1998] performed by an interdisciplinary team from New York University, under contract for Mental Retardation and Developmental Disabilities and directed by the author. Four clients with severe developmental disabilities received various technological aids to assist them with daily activities, as determined by application of the model. The team met weekly to discuss the cases and reflect on the evaluation process. They found that quantification of the data was impossible because the different members of the interdisciplinary team interpreted the components differently. It was concluded that although the grid could not quantify the client's abilities and disabilities, it was valuable as a checklist of the client's skills. Furthermore, the need to summarise the client's disabilities as they relate to the task helped the team identify the attribute of a technology that would address the client's needs. Being able to 'spelling out' the attributes of a device helped the team filter out in appropriate devices that may have appeared to provide solutions but that, in fact, lacked crucial features needed to augment the client's skills. This filtering system made the process of locating a suitable technological intervention more focused and timely.
Researcher's Comments		Funding not addressed.

RefWorks Number: 292 [TOOLS]		Year/County: 1998 - USA
Reference		Story MF. Maximizing usability: the principles of universal design. Assist Technol 1998; 10(1):4-12.
Objective/Questions		The development of a set of seven principles of Universal Design used to: guide the design process, evaluate existing or new designs and teach both students [university] and practitioners.
Device/Product		Assistive Technology Devices.
Users		Individuals with disabilities.
Method/Tool/Approach		Between '94 & '97 the Center for Universal Design at North Carolina State University conducted a series of evaluations of consumer products, architectural spaces and building elements. The evaluations involved site visits, focus groups, observations and personal interviews. The purpose of the evaluations was to determine optimal performance characteristics and use features that make products and environments usable by the greatest diversity of people. Project staff then convened a working group of architects, product designers, engineers, and environmental design researchers from other research facilities to assemble a set of principles of universal design. The principles were independently reviewed by a second group of practitioners to critique, validate and refine them. The seven principles include: equitable use, flexibility in use, simple and intuitive use, perceptible information, tolerance for error, low physical effort, and size and space for approach and use.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Each principle has 4/5 guidelines that elaborates on the concept embodied in it. This is work in progress and 2 additional levels of information are planned that must be broken down by design discipline. The authors suggest that this method, with future developments, could be used to assess all types of products and environments. It is suggested that if products are designed with a universal design approach the need for AT may be reduced. Also, AT should be designed to be universally usable. The paper identified that Industry needed to be convinced to change the way that it operates and to accept and adopt the concept of universal design. Some points are mentioned on this aspect e.g. industry needs statistical justification for practicing universal design, they also need a set of universal design performance indicators against which to judge their designs for use by a diverse consumer base, and industry needs guidance to market their products appropriately.
Researcher's Comments		This work was supported by the National Institute on Disability and Rehabilitation Research, U.S Department of Education Grant.

RefWorks Number: 320	**["OUT OF THE MOULD"]**	Year/County: 1996 - USA
Reference		Nochajski SM, Tomita MR, Mann WC. The use and satisfaction with assistive devices by older persons with cognitive impairments: a pilot intervention study. Top Geriatr Rehabil 1996 Dec; 12(2):40-53.
Objective/Questions		To identify reasons for device dissatisfaction among older adults with cognitive impairments and to assess the impact of professional intervention on the use of, satisfaction with and effectiveness of assistive devices.
Device/Product		Assistive Technology Devices: physical, sensory and cognitive devices.
Users		n = 20 (10 men & 10 women).
Method/Tool/Approach		A pilot intervention study: individuals with cognitive impairments received a comprehensive assessment, individualised interventions, training and follow up over a 6 month period. Participants meeting the study criteria (of a score of between 10 and 23 on the Mini Mental Status Exam) were randomly selected from the Consumer Assessments Study sample pool at the Rehabilitation Engineering and Research Center on Aging at the State University of New York at Buffalo and from referrals from the Alzheimer's Disease Assistance Center of Western New York. Data were collected by an occupational therapist who assessed participants and their care providers in their homes. The average length of time of the assessments was 2 hours 29 minutes. The tools used were: the Mini Mental Status Exam, Functional Independence Measure, OARS Multidimensional Functional Assessment of Older Adults, Care Provider Burden Scale, Environment Survey and 2 instruments developed for this study: Activity Performance Worksheet (used to summarise the types and probable causes of problems experienced by the participant and care provider in daily activities and routines) and the Assistive Device User Survey (based on the assistive device survey in the Consumer Assessment Study, used to measure the participants' and care providers' level of satisfaction with the assistive devices they used and the reasons for their satisfaction or dissatisfaction, devices rated on a 5 point Likert scale for satisfaction, effectiveness, ease of use, physical discomfort, compatibility with other devices, durability and maintenance). Based on assessment results and interviews with the participant and care provider, assistive devices and environmental interventions were provided or existing assistive devices were adapted to meet individual, specific needs. The participants received individualised specific training on the use of the devices by an occupational therapist. Support was provided by telephone follow up at 2 week, 4 week, 2 month, 4 month and 6 month intervals.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean age of the participants was 79 years (65-93). The cognitive impairments of 15 were due to Alzheimer's disease. Family members were the primary care providers for 17 of the participants. 3 participants relied solely on paid care providers. Participants initially used a range of 0-18 devices, with an average of 5.35 devices per person. The majority of devices were used to facilitate performance of tasks that the participants had difficulty completing due to physical limitations (74%). Results indicated that devices for physical impairments were more readily accepted and used than devices that addressed cognitive impairments. However, participants were more satisfied with cognitive devices. User satisfaction with physical devices appeared to increase with training and support. Many of the stated reasons for dissatisfaction with physical devices were related to improper use. Participants did not know how to use the device correctly or the device was installed incorrectly. The overall dissatisfaction with cognitive devices appears to be related to the loss of cognitive capabilities of the participants rather than a function of training, support or the devices per se. The authors state that early intervention is key to acceptance and satisfaction with devices and home modifications by persons with cognitive impairments and their care providers.
Researcher's Comments		Supported through funding from the National Institute on Disability and Rehabilitation Research of the US Department of Education and the Administration on Aging of the Department of Health and Human Services.

RefWorks Number: 326	**["OUT OF THE MOULD"]**	Year/County: 1995 - UK
Reference		Burkitt J, Torrens GE, Kay GH, Sandbach D, Sutherland IA. The development of the Autosip: a hygienic, self-operated, drinking device for people with minimal sucking ability and/or minimal arm strength. J Rehabil Sci 1995; 8(4):115-8.
Objective/Questions		The purpose of this paper is to design a device that removes the need for a carer having to assist a person with Motor Neurone Disease [MND], and who has minimal sucking ability and/or arm strength, to have a drink.
Device/Product		Assistive Technology Device: The Autosip- a hands-free pumping device controlled by means of a single switch. It is a user-operated drinking and liquid feeding device.
Users		n = 15 people with MND and their carers received a home visit to identify products that could be designed as part of this study. n = 500 people with MND who returned the questionnaire (age or gender not defined).
Method/Tool/Approach		Firstly, 15 subjects were visited in their homes. Part of the project involved discovering what items of equipment would enable them to live more independent lives. This produced a list of over 30 items. To prioritize these items 2000 questionnaires were sent out with 500 being returned. The survey was designed specifically to establish priorities for equipment associated with arm mobility and communication. One item was chosen from 30 and the Autosip device was designed, which included evaluation of several existing eating devices. Consultations were held with potential users, and the appropriate care professionals, at every stage in the development of the Autosip, and the prototypes were frequently tested by volunteer users (not stated how many prototypes designed or how actual testing was carried out).
Product Development Stage at which users were involved	Concept	Discussions between the team and several end users to discover their actual needs.
	Design	A design specification was drawn up in consultation with users; following the research team's Interactive Design Process. Specification agreed with end users, and appropriate care professionals e.g. specialist therapists.
	Testing & Trials	1 Prototype trialled with the initial 15 [MND] end users and feedback taken on board 2 Small initial batch of units made for testing by other end-users, with MND, to get unbiased feedback and to test the market [unbiased because these users were not involved in the initial design process].
	Production	X
	Deployment	The first twenty five initial production Autosips had only a single 'on' position …..so a dial potentiometer was designed and fitted.
Conclusions		The device was assessed as being fully portable, easy to clean and easy to use. Since the initial prototype a variety of switches, which are used to control the device, have been designed to cater for the various MND end users with varying abilities. It has also been designed to alter the amount of liquid pumped at a time e.g. 3 teaspoonful to 1/4 teaspoonful. A selection of mouthpieces is available so that the user can choose which is most convenient for them. The final product was transferred to an outside manufacturer, so appropriate production techniques and distribution can make a low priced product widely available. Currently 60 devices have been placed mainly with people with MND, but are being evaluated in other groups with multiple sclerosis, cerebral palsy, muscular dystrophy and other diseases. The Autosip is now being distributed by Cane and Able, of Sheffield - UK.
Researcher's Comments		Grant from Action Research.

RefWorks Number: 379	**[TOOLS]**	Year/County: 1988 - USA
Reference		Huber PM, Medhat A, Carter MC. Prosthetic problem inventory scale. Rehabil Nurs 1988; 13(6):326-9.
Objective/Questions		The purpose of this project was to construct a reliable and valid instrument to identify problem areas in the broad range of activities within the capability of lower extremity amputees with prostheses.
Device/Product		Lower Limb Prostheses.
Users		n = 26 persons with amputations and registered with a rehabilitation clinic [pilot survey]. n = 131 lower extremity amputees who were registered in rehabilitation clinics in two large Midwestern Hospitals. Content Experts from the fields of: nursing, rehabilitation medicine, sex therapy, sports medicine, and sports and physical fitness.
Method/Tool/Approach		Tool Development: Maslow's Hierarchy of Needs and Roy's Adaptation Model were used as a conceptual framework in developing the Prosthesis Problem Inventory Scale. The instrument has four dimensions of activity performance: activities of daily living [4 items], social participation [3 items], sexual activity [3 items], and athletic participation [3 items]. Each item was scored using a 5-point Likert scale ranging from 'not applicable' to 'always'. Items were selected from a comprehensive literature review, existing instruments assessing other disabilities, and the clinical experience of the authors. Responses were obtained by a self-report mail survey. Interviewers administered the instrument [but this was not elaborated on]. To help assure content validity, the instrument was reviewed by content experts from the fields of nursing, rehabilitation medicine, sex therapy, sports medicine, and sports and physical fitness. Content experts were asked to review the instrument for adequacy of content, comprehension, clarity, representativeness of content, and ease of completion. Evaluative statements focused on language and additional content. Suggestions by experts were incorporated in the instrument. A pilot study was then conducted to develop the content validity of the instrument. In this pilot study, the amputees were asked to complete the instrument, to comment on its adequacy of content, ease of administration, clarity, use of terminology, and to make any other comments. As a result of this study, directions for completion of the instrument were modified and additional space was provided for the Likert scale. Two items were added to the activities of daily living dimension. The revised 46-item instrument was then given to 131 amputees. Alpha coefficients were computed on the responses of these subjects for the four conceptualized dimensions [activities of daily living, social participation, sexual activity, athletic participation] and the total instrument.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The Cronbach Alpha coefficients for the 26 subjects were: daily living- 0.97, social participation- 0.88, sexual activity- 0.95, and athletic participation- 0.90, and for the total instrument- 0.83. These results provided assurance of the instrument's validity and internal consistency. The revised 46 item instrument given to the 131 amputees coefficients were: daily living- 0.95, social participation- 0.96, sexual activity- 0.97, and athletic participation- 0.97, and for the total instrument- 0.97. Procedures carried out in the development of the Prosthesis Problem Inventory Scale have provided considerable support for its reliability and validity. Highly significant alpha coefficients support its internal consistency. Construct validity is supported by its linkage with theory, high internal consistency coefficients, and results of factor-analytic techniques supporting the internal association of items defining the dimensions. Reports from the interviewers administering the tool attest to its efficiency, simplicity and comprehensibility.
Researcher's Comments		Funding not addressed.

RefWorks Number: 401	**[ORTHOPAEDIC]**	Year/County: 2004 - USA
Reference		Ritter MA, Thong AE, Davis KE, Berend ME, Meding JB, Faris PM. Long-term deterioration of joint evaluation scores. Journal of Bone & Joint Surgery - British Volume 2004; 86(3):438-42.
Objective/Questions		To investigate the long term changes in the Harris Hip and Knee Society scores (HSS and KSS) to determine whether they result from overall functional decline rather than actual changes in the condition of the prosthesis.
Device/Product		Hip (Integral or Biometric Stems and Universal, Bioclad, or Ring Loc Cups - Biomet, Warsaw, Indiana) and knee (AGC - Biomet) Prostheses.
Users		n = 287 patients (122 with hip arthroplasty: 51 men & 71 women; 165 with knee arthroplasty: 64 men & 101 women)
Method/Tool/Approach		Retrospective series analysis of total hip and knee arthroplasties undertaken for osteoarthritis. Review of 665 primary hip arthroplasties undertaken between 1989 and 1992, and 1972 primary knee arthroplasties undertaken between 1983 and 1990 at one centre. Hip arthroplasties that had at least a 10 year follow up and knee arthroplasties with at least a 12 year follow up were selected. Patients with any medical complications or radiological problems with the prosthesis during the entire study period were excluded. 287 patients met the qualifications for the study. All the components of the HHS and the KSS were collected preoperatively and at standard follow up visits. All clinical data were collected at the clinic visit by the operating surgeon or his/her assistant.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The 122 patients in the hip sample had 136 total hip arthroplasties and the 165 patients in the knee sample had 264 knee arthroplasties. 14 patients underwent bilateral hip arthroplasty and 99 had bilateral knee arthroplasty. The mean age of surgery was 66 (36-87) for the hip sample and 66 (40-86) for the knee sample. There were statistically significant drops in the functional scoring components of the joint evaluation systems despite no loosening of the prostheses or other significant medical complications. The HHS declined at an average of 0.67 points per year from between 3 and 10 years after operation. Contributing to this were deterioration in gait and limp, the use of support aids, the distance walked, and the ability to climb stairs. The functional component of the KSS declined significantly at an average 0.88 points per year between the third and 12th years. There were significant declines in every component of the functional score including the distance walked, the ability to climb stairs and the use of support aids. The knee score component of the KSS did not decline significantly. The combination of functional and pain scores within the HHS system leads to an inaccurate decline in the entire score. The decline of the HHS and Knee Society functional scores in total joint arthroplasties, in the absence of implant related problems suggests that deterioration in the functional capacity of ageing patients is an important factor in longitudinal studies using these scoring systems. The authors conclude by questioning the effectiveness of these systems in the evaluation of long term mechanical outcomes of total hip and knee arthroplasties.
Researcher's Comments		No commercial funding.

RefWorks Number: 402 [TOOLS]		Year/County: 2003 - Canada
Reference		Miller WC, Miller F, Trenholm K, Grant D, Goodman K. Development and preliminary assessment of the measurement properties of the Seating Identification Tool (SIT). Clinical Rehabilitation 2004; 18(3):317-25.
Objective/Questions		To present and discuss the development and measurement properties of the Seating Identification Tool [SIT], a screening tool designed to identify the need for formal seating and wheelchair intervention among institutionalized elderly. Specifically, investigation of the inter-rater and test-retest reliability, sensitivity, specificity, the positive and negative predictive values of the SIT was conducted.
Device/Product		Mobility Devices: manual wheelchairs.
Users		INITIAL ASSESSMENT: n = 40 consecutive individuals from 2 long term care facilities who completed the SIT. Raters for this study included a nurse and an occupational therapist: neither knew the subjects before the study. n = 13 health professionals: nursing [2], occupational therapy [6], physical therapy [5], who worked in the London region and had experience [5-13 years] working with people who use wheelchairs. n = 42 randomly selected residents from a long term care facility. Subjects were>=60 years, using a wheelchair as their primary seating or mobility device >=4 hours a day. n = 2 health care assistants from the facility [rater] collected data using SIT. They had no wheelchair/seating experience.
Method/Tool/Approach		DEVELOPMENT OF THE SIT: A modified form of the Delphi Technique was used to develop the SIT. The Parkwood Hospital Seating Program team, consisting of an occupational therapist and physical therapist, generated a list of 25 items considered important indicators of the need for wheelchair/seating intervention. The list was derived from clinical experience and review of the published studies from CINAHL and Medline. These indicators were then circulated to 13 health professionals to ensure that all possible indicators were included. Only items identified by two or more members of the panel were included in the final list. The list was then collated and operationalised into questions. The reformatted items were circulated to the 13 health professionals, again to solicit feedback regarding the wording of the questions and identification of items each believed were critical to include. Initial assessment of test-retest and inter-rater reliability and the diagnostic properties of the SIT was completed using the sample of 40 individuals. Validity was assessed by comparing SIT scores obtained by the raters to the assessment by an occupational therapist who had eight years experience prescribing wheelchair systems. The original SIT was reasonably good at identifying individuals who required intervention, but had limited ability identifying individuals who did not. The present version was reduced to 11 items and consists of five areas: pressure, discomfort behaviours, mobility, positioning and stability with yes or no responses. To examine the measurement properties of SIT, a prospective 2 weeks study was conducted using a simple random sample [different sample] of 43 subjects selected (one died) from a list of all wheelchair users at a large long term care facility. The raters applied the SIT with each subject within 30 minutes of one another. Ratings occurred in separate rooms to limit contact between raters and ensure SIT scoring was independent. One rater returned 2 weeks later to test each participant again to estimate test-retest reliability. A blinded assessment by an OT with 10 years prescribing wheelchair systems was carried out 2-6 hours after the first application of SIT. This was used as the criterion standard to determine whether intervention was needed.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Forty three subjects began the study, but one died before final collection of the data. The primarily female [n=40] sample had a mean age of 83.2 years. The primary medical diagnosis was related to musculoskeletal [n=11], neurological [n=10], cognitive [n=8], or cardiorespiratory [n=8] impairments while five subjects had other diagnoses. All subjects used manual wheelchairs. The intra-class coefficient for both test-retest and inter-rater reliability was 0.83. The criterion identified 28/42 subjects requiring intervention. A cut-off score of 2 maximized the sensitivity [100%] and specificity [64% and 57% for raters 1 and 2 respectively]. The positive and negative predictive values ranged from 82% to 100%. SIT scores are stable between raters and over time. SIT scores appear to distinguish long-term care residents who need and those who do not need intervention to improve their wheelchair system. Other potential uses include population-based surveys to estimate the need for including seating intervention in strategic planning for the institutionalized elderly.
Researcher's Comments		Financial support provided by the Multiple Sclerosis Society of Canada.

RefWorks Number: 419	**[ORTHOPAEDIC]**	Year/County: 2004 - Japan
Reference		Miki H, Sugano N, Hagio K, Nishii T, Kawakami H, Kakimoto A, et al. Recovery of walking speed and symmetrical movement of the pelvis and lower extremity joints after unilateral THA. Journal of Biomechanics 2004; 37(4):443-55.
Objective/Questions		To assess recovery of walking speed and symmetrical movement of the pelvis and lower extremity joints after unilateral total hip arthroplasty.
Device/Product		Hip Prostheses: BHR system (MMT, Birmingham), ANCA fit system (Wright Cremascoli Ortho, Milan), Versys Hip system (Zimmer, Warsow, USA), SROM (DePuy, Warsow, USA) and Partnership system (Stryker Howmedica Osteonics, Mahwah, USA).
Users		n = 17 patients (6 men & 11 women)
Method/Tool/Approach		The gait of the patients was analysed preoperatively and 1, 3, 6 and 12 months after surgery using a Vicon system (a 3D optical analyser) to assess the recovery of walking speed and symmetrical movement of the hip, knee, ankle and pelvis. Movements of the bilateral lower extremity joints were measured using the Vicon system and 15 surface markers. 2 Kistler force plates were used to measure the ground reaction force with a sampling rate of 600Hz. The beginning of a gait cycle was defined as the moment of heel strike and the end of the cycle was defined as the next heel strike of the same leg. After several rehearsals each patient performed 3 freely moving gait trials per examination on a walkway.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean age of the patients was 52.6 years. 14 patients had a diagnosis of secondary osteoarthritis due to a dysplastic hip and the remaining 3 had aseptic necrosis of the femoral head. The walking speed of these patients reached that of normal Japanese persons by 12 months after surgery. Walking speed was correlated with the range of hip motion on the operated side at 1 month postoperatively and was correlated with the hip joint extension moment of force on both sides from 3 to 6 months after surgery. Before total hip arthroplasty asymmetry was observed in the range of hip motion, maximum hip extension, maximum knee flexion as well as in pelvic obliquity, pelvic tilt and pelvic rotation. There were no differences of the stride length or step length between both sides throughout the observation period. The preoperative range of hip flexion on the operated side during a gait cycle was significantly smaller than on the non-operated side and the difference between sides was still significant at 12 months after surgery. The majority (74%) of the difference in hip motion range during this period was due to the difference in maximum extension of the hip. The increase in the range of pelvic tilt and the range of motion of the opposite hip showed an inverse correlation with the range of motion of the operated hip, suggesting a compensatory preoperative role. However this correlation became insignificant after 6 months postoperatively. A symmetry of the range of hip motion persisted at 12 months after total hip arthroplasty in patients with unilateral coxoarthropathy during free level walking, while the operation normalised the spatial asymmetry of other joints and the walking speed prior to the recovery of hip motion.
Researcher's Comments		No commercial benefits received.

RefWorks Number: 439	**[TOOLS]**	Year/County: 2003 - Canada
Reference	Tam C, Rigby P, Ryan SE, Campbell KA, Steggles E, Cooper BA, et al. Development of the measure of control using electronic aids to daily living. Technology & Disability 2003; 15(3):181-90.	
Objective/Questions	This paper reports on the development of the Measure of Control using Electronic Aids to Daily Living [MCEADL], a tool that measures the functional changes specifically related to the use of Electronic Aids to Daily Living [EADL] devices.	
Device/Product	Mobility Devices: Electronic & Powered Wheelchairs.	
Users	n = 36 individuals with spinal cord injuries at or above C5/6 level, except three participants, one with Guillan Barre Syndrome, one with transverse myelitis and one with peripheral neuropathy, all presented with a functional level at or above C4/5 level spinal cord injuries. 15 were EADLs users [activated two or more appliances by means of devices that were chosen to facilitate the user's function] and 21 were non-users of EADLs [directly activated most of the appliances using commercial remote controls and were able to use a standard or adapted telephone]. All depended on powered-wheelchairs for mobility. Mean age 41 years. They were recruited through three major rehabilitation centres in Ontario, Canada. All participants completed at least Grade 9 Education at high school, with most having received or completed university or college education. n = 2 occupational therapists [conducted the interviews] had good interviewing skills, and familiarity with EADL and the study. They were not service providers to any participants.	
Method/Tool/Approach	The MCEADL [2001- Unpublished] was modified from the Lincoln Outcome Measures for Environmental Controls and Audit of Installation Quality [LOMEC, 1998 unpublished] which was originally developed to evaluate the functional outcomes of environmental control services provided in the northern UK. MCEADL is divided into three parts: Part A records the use and control of EADL. Respondents are asked to identify the appliances that they use in their home, indicate if the appliances are controlled by EADL or by commercial remote controls. Respondents also report on where, how and if there have been any changes in their use of their EADL. Part B concerns the functional impact of EADL and includes 26 tasks/functions. These 26 items are grouped under 4 functional domains: home security, comfort, communication, and occupation. MCEADL uses four 7-point scales for rating: 1) Importance 2) Ease of performing tasks from chair 3) Ease of performing tasks from bed 4) Satisfaction with performance for each task/function. Part C includes rating perception of EADL devices and services. These are grouped under three domains: acceptability, availability and device. Respondents rate how true the statement is to their situation and the importance of these items on a 7-point scales. The MCEADL can be used with both users and non-users of EADL, or as an outcome measure for users before and after provision of EADL to compare functional performance and satisfaction with performance. A comparative study between EADL users and non-users was conducted to evaluate the ability of MCEADL to detect the differences in functional status between the two groups. A comparative study was chosen instead of a prospective study because of the anticipated difficulties with recruiting a large enough population for statistical analysis in a time efficient manner. All participants were interviewed twice at a time interval of 4-8 weeks. Most of the study participants were interviewed in their place of residence, place or work/study. Two participants completed both interviews by telephone. Three participants completed the second interview by phone. Telephone interviews were chosen for convenience because these participants lived a long distance from the centre in which the study was conducted. The initial interview [by the 2 occupational therapists] with the participants started with the administration of the Functional Independence Measure [FIM] followed by the questions on personal demographics to ensure that all participants met the inclusion criteria for functional abilities and EADL usage. Following that, the MCEADL was administered. In the second interview, participants were asked to respond to all the items on Part B and Part C of the MCEADL. To ensure consistency of scoring, the two interviewers took part in the interviews with eight participants together but scored the questionnaires independently. They took turns asking the questions. Prior to analysing the MCEADL data, statistical analyses were performed to demonstrate that the two groups being compared were similar in terms of age, gender, level of injury, education, and FIM scores.	
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing/Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions	The two groups did not differ in their mean age. There was a significant relationship with gender i.e. women were less likely to be users than men. There was no significant relationship between level of injuries and group membership [user or non-user groups]. The two groups did not differ in the mean FIM scores. Non-users accessed a mean of 7 electrical appliances by direct access or with stand alone remove controls. EADL users accessed a mean of 12 electrical appliances through EADL devices and standard remote controls. All users were using their EADL devices. Cronbach's alpha was higher than 0.73 in all the analyses, Pearson correlation coefficients for all calculations were higher than 0.74 for test-retest reliability. Users scored significantly higher than non-users. Future work is necessary to examine the clinical utility of the measure with different diagnostic group. While the sample size was adequate for statistical analysis, it was somewhat small and should be noted as a limitation. The selection criteria of Grade 9 education was both a strength and limitation. It limited the representation of the participants of this study to the entire spinal cord injuries population. The authors previously used the original LOMEC in earlier studies [both 2003]. Some problems were identified then which led to the modification to the instrument.	
Researcher's Comments	Funded by the Ontario Neurotrauma Foundation.	

RefWorks Number: **470** **["OUT OF THE MOULD"]**		Year/County: 2003 - USA
Reference		Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T. Using usability heuristics to evaluate patient safety of medical devices. Journal of Biomedical Informatics 2003; 36(1-2):23-30.
Objective/Questions		Modification of a heuristic evaluation method [originally used in software usability assessment] so that it can be applied to medical devices and used to evaluate the patient safety issues of those devices through the identification and assessment of usability problems.
Device/Product		Medical Device: 1-channel volumetric infusion pumps.
Users		4 evaluators: 2 = graduate students in the School of Health Information Sciences; & 2 = graduate students from Department of psychology. They had taken at least a graduate level course in human factors or human-computer interaction.
Method/Tool/Approach		The Nielsen-Schneiderman Heuristics [1994] was used to evaluate and compare the patient safety of two 1-channel volumetric infusion pumps. Heuristic evaluation is a type of usability inspection method, which refers to a class of techniques in which evaluators examine an interface for usability issues. Modification: The original evaluation described 10 major heuristics and Schneiderman [1998] described 8 golden rules, and based on the authors own considerations 14 heuristics were described and applied by the four evaluators to the user interfaces of the two volumetric pumps. They identified usability problems in various areas/sections of the pumps, and identified one or more heuristic violations for each usability problem. Before the evaluation they were given a copy of a report of a heuristic evaluation carried out on a different product, and they were instructed by an expert in heuristic evaluation. A list of usability problems was generated, heuristic violations were ascertained for each problem, and each evaluator independently assessed each problem for severity. The 14 heuristics include: consistency and standards, visibility of system state, match between system and world, minimalist, minimize memory load, informative feedback, flexibility and efficiency, good error messages, prevent errors, clear closure, reversible actions, use user's language, users in control and help and documentation.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Pump 1 heuristics were violated a total of 192 times for 89 usability problems. Consistency & Standards and Visibility were the two most frequently violated heuristics, with Feedback and Match the next most common. These four heuristics account for 64% of the violations. Pump 2 heuristics were violated a total of 121 times for 52 usability problems. Visibility was the most frequently violated heuristic, with Memory and Consistency & Standards being the next most common. These three heuristics comprised 54% of the violations. In general, Pump 1 was found to have more usability issues that are likely to induce errors. Historically heuristics using 3-5 evaluators can capture 60-75% of usability problems, and is the best benefit ration. The authors stated that 2-3 hrs of training combined with clear examples and a practice evaluation with feedback is often sufficient using the technique. Some limitations to the method include: it does not reveal major missing functionality, does not indicate what is right with the system, evaluator needs some understanding of the heuristics as well as minimal training in human factors engineering [the level of domain knowledge will impact on the problems identified], may not incorporate the user's environment [will need a short clinical trial]. Could be used in combination with other techniques. The method was successfully applied to medical devices. It was found to be a useful, efficient, and low cost method.
Researcher's Comments		Sponsored by US Department of Army under a Co-operative Agreement. Supported in part by a grant from the Agency for Healthcare Research and Quality.

RefWorks Number: 509 [ASSISTIVE DEVICES: MOBILITY AIDS]		Year/County: 2003 - Japan
Reference		Liu M, Mineo K, Hanayama K, Fujiwara T, Chino N. Practical problems and management of seating through the clinical stages of Duchenne's muscular dystrophy. Archives of Physical Medicine & Rehabilitation. Vol 2003; 84(6): 818-824.
Objective/Questions		To describe seating problems in patients with Duchenne's muscular dystrophy for the purpose of identifying management solutions which are practicable for both patient and caregiver.
Device/Product		Mobility Devices: wheelchairs and seating systems.
Users		n = 95 patients (93 men & 2 women), n = 60 caregivers.
Method/Tool/Approach		Case series: of wheelchair dependent patients with Duchenne's muscular dystrophy living in 1 of the 27 national long term care facilities for patients with neuromuscular diseases in Japan. 2 physical therapists independently observed and palpated the spinal curvature, and classified the spinal deformities according to Wilkins & Gibson into 5 groups: early straight, kyphosis, combined kyphosis and lateral curve, severe lateral curve without kyphosis and extended spine. When the observers disagreed which occurred in 6 patients final classifications were reached through consensus. The patients were interviewed about whether they experienced pain, numbness and or discomfort while sitting and if they did where the problems Existed. Activities of daily living were also assessed focusing on eating, wheelchair mobility and toileting. These activities were observed to note what kind of problems existed as related to seating. Motion analysis of manual wheelchair propulsion on a level surface was videotaped, recording 25 patients conveniently selected from the overall sample. An experienced physiotherapist observed the videotaped recordings and proposed a classification of the patterns of wheelchair propulsion (later verified by the other Physiotherapist). In relation to the problems of care giving 60 formal caregivers involved in the daily care of the patients were interviewed with a questionnaire to learn whether they had experienced some kind of trauma or trouble related to the seating systems while caring for the individual.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean age of the patients was 15.9 years (8-33). 33% of the patients belonged to the early straight group, 21% to the scoliotic group, 20% to the kyphoscoliotic group, 2% to the kyphotic group and 24% to the extended spine group. The percentage needing support for sitting was higher in patients with spinal deformities. 41% had pressure problems, and the percentage increased with advancing stages, with pain sites related to spinal deformity types. Self-feeding was difficult in 10 patients having spinal deformities. 4 patterns of manual wheelchair propulsion were observed: upper extremity, anterio-posterior trunk flexion, lateral trunk flexion, and wrist hand patterns; and propulsion became increasingly less practical in this order. It was observed that 60 patients (63%) could not lift their heads up by themselves when they were tilted backward whilst sitting on their wheelchairs. This could lead to asphyxia if unnoticed which was reported in 2 patients. For toileting more patients were cared for on wheelchairs with backrests reclined with stage progression. Of 60 caregivers, 58% experienced trauma related to seating systems (such as snagging of clothes and difficulty in making bodily contact with the patients when lifting them from behind the wheelchair). The authors conclude that the seating problems that were identified enabled specific practical suggestions to be made for improved management such as appropriate use of well fitted knee-ankle foot orthoses, trunk support, pressure distributing cushions, powered wheelchairs and adjustable systems.
Researcher's Comments		No commercial benefits or interests.

RefWorks Number: 520	**[ORTHOPAEDIC]**	Year/County: 2003 - USA
Reference		Kwong LM, Miller AJ, Lubinus P. A modular distal fixation option for proximal bone loss in revision total hip arthroplasty: a 2- to 6-year follow-up study. Journal of Arthroplasty 2003; 18(3 SUPPL. 1):94-7.
Objective/Questions		To evaluate the clinical and radiographic performance of a modular cementless femoral prosthesis in revision reconstruction of the proximally deficient femur.
Device/Product		Hip Prostheses: the Link MP reconstruction hip stem. Constructed of titanium alloy with a 70-um grit blast finish. It has a tapered fluted geometry incorporating a 3 degree angular bow to accommodate the curvature of the femur. With the system the leg length, version, offset and neck shaft can be changed independently. The changes can be performed in vivo without removing the stem even after implantation.
Users		n = 143 patients (62 men & 81 women)
Method/Tool/Approach		Retrospective series analysis of patients who had undergone revision total hip arthroplasty using the Link MP reconstruction hip stem at 3 clinical sites. The preoperative femoral deficiencies were evaluated radiographically and classified according to the Mallory type. The clinical outcomes for the patients were assessed using the Harris Hip Score and all patients underwent analysis of several postoperative radiographs.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The average follow up was 40 months and the average age 67 years. The preoperative diagnoses included 108 cases of aseptic loosening and 14 peri-prosthetic fractures. There was a 97.2% survival rate. The 2.8% failure rate included 1 peri-operative infection 1 case where the implant was reconstructed too long. In 1 case femoral component fracture occurred in a non-standard custom device made for a patient with developmental dysplasia of the hip. An inadequately tightened locking screw resulted in failure due to a loose head neck segment in 1 patient. The average subsidence was 2.1mm. The average postoperative Harris Hip Score was 92. Complications included 7 wound infections (1 patient underwent resection arthroplasty and the other 6 underwent debridement procedures) and 4 deep venous thromboses. Traumatic fractures of the femur occurred in 4 patients secondary to a fall. These complications all occurred within the first 8 weeks after surgery and all were successfully treated with open reduction and internal fixation with retention of implants. Other complications included 3 subluxations or dislocations, 1 superficial wound infection and 1 sciatic nerve injury. 12% of patients did not report marked improvement in pain (88% did), 27% did not report improvement in function (73% did) and 24% were not satisfied with the procedure (76% satisfied). The authors conclude that the device allows successful revision total hip arthroplasty reconstruction of the proximally compromised femur, with good to excellent functional restoration and pain relief achievable.
Researcher's Comments		No benefits or funds were received in support of this study.

RefWorks Number: 535	**[ORTHOPAEDIC]**	Year/County: 2003 - Sweden
Reference		Tidermark J, Blomfeldt R, Ponzer S, Soderqvist A, Tornkvist H. Primary total hip arthroplasty with a Burch-Schneider antiprotrusion cage and autologous bone grafting for acetabular fractures in elderly patients. Journal of Orthopaedic Trauma 2003; 17(3):193-7.
Objective/Questions		To investigate the clinical and functional outcome in an elderly population with acetabular fractures after low energy trauma treated acutely with total hip arthroplasty supported by a reinforcement ring and autologous bone grafting of the acetabulum.
Device/Product		Hip Prostheses: A cup (Charnley LPW or OGEE) cemented into a reinforcement ring (Burch-Schneider APC) and a femoral stem (Exeter or Charnley) cemented in the femoral canal.
Users		n = 10 patients (7 men & 3 women).
Method/Tool/Approach		Based on a retrospective review of 14 consecutive patients with acetabular fractures were treated with total hip arthroplasty between 1993 and 1999 in a single centre. The patients were included if they were over 55 with clinically established osteoporosis and an acute displaced acetabular fracture after a low energy trauma. At the time of follow up 2 patients had died, 1 refused follow up and another was lost to follow up. At follow up patients received clinical and radiographic examination. The Harris Hip Score (HHS), activities of daily living, and the need for walking aids were recorded. Patients were also asked to rate their health related quality of life according to EuroQol (EQ-5D).
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The patients had a mean age at time of surgery of 73 years (57-87). The mean duration of follow up was 38 months (11-84). The mean operating time was 159 minutes (125-185). The mean intraoperative blood loss was 1100mL (700-1600). 1 patient had 2 dislocations at 2 and 12 months postoperatively treated with closed reduction. The authors surmise that alcohol abuse may have contributed to this. Another patient sustained a deep vein thrombosis. The reinforcement ring was stable and there were no signs of loosening of the acetabular component or stem in any of the patients. The bone graft was completely incorporated in all cases. 4 patients presented slight heterotopic bone formation. All patients were still independent walkers at follow up but with a slightly increased need for walking aids. The mean HHS was 85 (65-99) and the mean EQ-5D was 0.62. Nearly all of the patients regained their preoperative walking status and achieved good hip function and an acceptable health related quality of life. The authors conclude that total hip replacement with a reinforcement ring and bone grafting of the socket seems to be a promising treatment alternative in displaced acetabular fractures in elderly patients with osteoporotic bone, except in those with an increased risk of dislocation, providing immediate mobilisation for the patient and rapid pain relief.
Researcher's Comments		No financial support of this research project occurred.

RefWorks Number: 539 [AUDITORY, OPTHALMIC & ORBITAL]		Year/County: 2003 - Nepal
Reference		Hennig A, Kumar J, Yorston D, Foster A. Sutureless cataract surgery with nucleus extraction: Outcome of a prospective study in Nepal. British Journal of Ophthalmology. 2003; 87(3): 266-270.
Objective/Questions		To report the short and medium term outcome of a prospective series of sutureless manual extracapsular cataract extractions (ECCE) at a high volume surgical centre in Nepal.
Device/Product		Intraocular lens: single piece polymethyl methacrylate posterior chamber lens (PMMA, FH 106, Fred Hollows IOL Laboratories, Kathmandu).
Users		n = 500 patients (54.2% female).
Method/Tool/Approach		Surgery was carried out on eyes with no co-existing diseases, in consecutive patients who were likely to return for follow up. Patients were recruited between 11/2000 and 02/2001, within 5 local districts and with visual acuity of 6/36 or worse in the affected eye. 532 patients were eligible but 32 refused follow up. The technique involved sclerocorneal tunnel, capsulotomy, hydrodissection, nucleus extraction with a bent needle tip hook and posterior chamber intraocular lens implantation according to biometry findings. On the first postoperative day the uncorrected visual acuity and best spherical equivalent were recorded and the eye was examined by an opthalmologist. Patients were followed up at 6 weeks and 1 year with visual acuity recorded with no correction, best sphere correction and best correction.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		42.6% of the sample was between 51 and 60 years. The uncorrected visual acuity at discharge was 6/18 or better in 76.8% of eyes, and declined to 70.5% at 6 weeks follow up, and at 64.9% at 1 year. The best corrected visual acuity was 6/18 or better in 96.2% of eyes at 6 weeks and 95.9% at 1 year. Poor visual outcome (<6/60) occurred in less than 2%. Surgery was uneventful in 452 (90.4%). Intraoperative complications included 47 (9.4%) eyes with hyphaema, and one eye with posterior capsule rupture and vitreous in the anterior chamber. Surgery led to an increase in against the rule astigmatism, which was the major cause of uncorrected visual acuity less than 6/18. 6 weeks postoperatively 85.5% of eyes had against the rule astigmatism with a mean induced cylinder of 1.41 D. There was a further small increase in against the rule astigmatism of 0.66 D between 6 weeks and 1 year. The mean duration of surgery was 4 minutes and the average cost of consumables including the lens was less than $10. The authors conclude that rapid recovery of good vision can be achieved with sutureless manual ECCE at low cost in areas where there is a need for high volume cataract surgery, but that further work is required to reduce significant post-operative astigmatism, which was the major cause of uncorrected acuity less than 6/18.
Researcher's Comments		Funding not addressed.

RefWorks Number: 541 [TOOLS]		Year/County: 2003 - Netherlands
Reference		Wessels RD, De Witte LP. Reliability and validity of the Dutch version of QUEST 2.0 with users of various types of assistive devices. Disability & Rehabilitation 2003; 25(6): 267-272.
Objective/Questions		In this paper, the reliability and validity of Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology [D-QUEST] will be analysed when the instrument is used with users of a large variety of assistive devices. [See Ref # 572 & #1873].
Device/Product		Assistive Technology Devices: for personal care, orthoses and shoe adaptations, hearing aids, optical aids, aids for diabetics, adapted finishing for homes, elastic compression stockings, prostheses, aids for communication and information and aids for personal mobility.
Users		n = 2002 respondents of all kinds of assistive devices provided by medical insurers in the Netherlands in the last 2 years.
Method/Tool/Approach		The D-QUEST instrument uses a 'client-centred approach' which lets respondents choose which aspects they consider to be applicable to their situation. The D-QUEST was applied to the population of users. 2 modifications were made to the version used in the study: 1) The addition of 2 questions: What is your overall level of satisfaction with your assistive device? & What is your overall level of satisfaction with the process of service delivery as a whole? 2) Adding a not applicable option for some questions. The total study population was not randomly sampled. The modified questionnaires were sent to 5112 people, 3148 returned the completed questionnaires and only 2002 met the criterion. The respondents rated their satisfaction with respect to 12 aspects on a five-point scale. Analyses were performed on each type of assistive device. Reliability was tested by analysing internal consistency. Content validity was tested by analysing applicability of the 12 aspects. And construct validity was tested by analysing correlations with problem solving and general satisfaction.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		A total of 3148 persons returned a questionnaire. From this group those who were <18 years old was excluded, as well as those who had received the assistive device more than 24 months ago, and respondents who received a device other than the ones provided by the insurers. Questionnaires were there were more than 4 missing answers were also excluded. Types or devices that were represented by less than 60 respondents were excluded [dentures, aids for respiratory therapy, aids for administering food and aids for therapy]. Additionally, respondents who failed to indicate the most recently received assistive device and those who had given multiple answers to that particular question were excluded. Mean age 58 years old with 60.7% female respondents. 2002 respondents in total and 2002 assistive devices were used. Reliability co-efficients with Cronbach's alpha ranged from 0.73 to 0.85 for all types of assistive devices. The non-applicability rates for the repairs and servicing aspect reaches 85.1%, for adjustment reaches 73%, and for users of aids for personal care reaches 18.8%. In a test with the previous version of the D-QUEST which did not have the non-applicability option the highest rates for missing data were found for the aspects of weight [62.1%], repairs and servicing [48.6%], adjustments [42.4%] and follow-up services [42%]. It seems reasonable to assume that respondents answering 'not applicable' would not have answered at all in the original version. Reliability proves to be good for all types of assistive devices. Including the non-applicability option improves the feasibility of the instrument without affecting content validity. Correlations between D-QUEST scores on the one hand and problem solving and general satisfaction questions on the other are as hypothesised, supporting validity. D-QUEST and thus QUEST proves itself to be an Applicable, reliable and valid instrument to assess user-satisfaction of users of all kinds of assistive device provisions. The high rates of not applicable responses and the diversity between various groups suggests that: 1 Respondents should be given an option to 'customise' the questionnaire to specific types of devices 2 It is not recommended to omit any aspects from the questionnaire. The authors recommend that an upper limit for the number of aspects considered 'not applicable' should be for e.g. 3 out of 8 for the device scale, and 1 out of 4 for the service scale.
Researcher's Comments		Funding not addressed.

RefWorks Number: 561	**[DENTAL & ORAL]**	Year/County: 2002 - USA
Reference		Ta Le, Phero JC, Pillemer SR, Hale-Donze H, McCartney-Francis N, Kingman A, et al. Clinical evaluation of patients with temporomandibular joint implants. Journal of Oral & Maxillofacial Surgery 2002; 60(12): 1389-1399.
Objective/Questions		To examine the possible relationship between temporomandibular joint (TMJ) implants and persistent pain, responses to sensory stimuli, quality of life and systemic immune dysfunction.
Device/Product		Temporomandibular joint implants: intra-articular disc implants composed of Teflon ethylene/propylene or teflon polytetrafluoroethylene and aluminium oxide (Proplast-Teflon, Vitek, Houston).
Users		n = 32 patients (5 men & 27 women), n = 23 age and gender matched pain free volunteers selected from a pool of 240 participants in a concurrent study.
Method/Tool/Approach		A case series were referred from university based orofacial pain centres and private practices from across the USA. Laboratory and clinical assessments evaluated orofacial pain symptoms, neurological function, clinical signs and symptoms of rheumatological disease, physical function, systemic measures of immune function and behavioural measures. Patients were eligible if they had a history of TMJ implant placement and complete medical and dental records. 33 patients met screening criteria and were invited to participate. 1 patient presented with cardiovascular instability resulting in 32 patients being evaluated. Patients were examined by specialists in orofacial pain, neurology, rheumatology, physical medicine, rehabilitation and psychiatry. Systematic evaluation for the presence of specific tender points using accepted criteria for diagnosing fibromyalgia and to measure responsiveness to thermal pain stimuli were used. To evaluate the impact of chronic pain on quality of life self-report questionnaires for psychological and health outcome measures were used. Rheumatological assessment was performed for the presence of autoimmune disease and inflammatory rheumatological disorders including autoimmune serology. Blood samples were evaluated. The clinical examinations performed by a dentist trained in orofacial pain consisted of medical/dental history review, head and neck examination, assessment of joint function, palpation of the masticatory muscles and the TMJ and intraoral examination. Subjects were asked to rate their usual level of orofacial pain during the month preceding their visit as well as their present orofacial pain. Separate visual analog scales for pain intensity and pain unpleasantness were used (100mm line from no pain/not bad at all to worst pain possible/most unpleasant feeling possible). Environmental exposure was evaluated using the Quick Environmental Exposure and Sensitivity Inventory. Psychological and quality of life issues were evaluated using the Minnesota Multiphase Personality Inventory, Millon Multiaxial Inventory-II, the Symptoms Checklist-90, Medical Outcomes Study Short Form Health Survey (SF-36) and the Sleep Quality Index.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance
Conclusions		The patients had a mean age of 47 (36-55) and the median duration of the implant was 10 years (<1-16). The number of implants in place was 7 and 25 had been removed. When the patients presented for study evaluation the majority reported pain and mandibular dysfunction as their chief complaint. The patients had evidence of widespread pain and tender points. Almost all patients (90%) in the moderate and severe pain groups had mood disorders as measured by self-report. TMJ implant patients appeared to have altered sensitivity to sensory stimuli, a higher number of tender points with a diagnosis of fibromyalgia, increased self-report of chemical sensitivity, higher psychological distress and significantly lower functional ability. Systemic disease was not evident in this series of TMJ implant patients. The authors conclude that given the problems observed in this patient population TMJ implant surgery for temporomandibular joint disorders should not be performed until new compelling evidence for the efficacy of implant surgery is obtained.
Researcher's Comments		Supported by the Division of Intramural Research, MIDCR.

RefWorks Number: 564	**["OUT OF THE MOULD"]**	Year/County: 2002 - UK
Reference		McCreadie C, Seale J, Tinker A, Turner-Smith A. Older people and mobility in the home: In search of useful assistive technologies. British Journal of Occupational Therapy 2002; 65(2):54-60.
Objective/Questions		Three main objectives: 1 To explore if older people, in focus groups, can identify problems and solutions with respect to their indoor mobility difficulties which may in turn be addressed by innovative Assistive Technology [AT] Research and Development [R & D]. 2 To use and build on these views to make proposals for further R & D of AT products. 3 To obtain older peoples responses to the proposals.
Device/Product		Assistive Technology Device: A stair-climber & an Information System: A cataloguing system of mobility equipment.
Users		4 Focus Groups of older people: 2 local Age Concern groups, 1group attending a Day Hospital, and 1 group was the University of the Third Age in London Design Group. The first 3 groups were approached because a significant proportion had members with disabilities and have difficulty with undertaking daily activities. The other group were particularly concerned about design and the older user. n = 36 subjects took part in the Focus Groups- Phase One. n = 45 subjects took part in the Informal Trials- Phase Two.
Method/Tool/Approach		The research was part of a programme between gerontologists, engineers, and older users. Phase One conducted 10/1999: The 4 focus groups lasted 90 minutes, each member given an envelope with 8 cards depicting mobility activities in and around the home. They were told to 'have a dream' about a typical day in their life, by listening to a short story told by one of the engineers. The story was based on a sequence of activities depicted by the 8 cards: getting out of bed, going down stairs, reaching and bending, carrying things to the table, answering the door, moving chairs, getting in and out of a car and walking outside. They then choose three cards that represented the most difficulty for them individually and members were invited to discuss the choices. The discussions were recorded both manually by one of the researchers and by tape-recorder. The activities most frequently identified were climbing stairs, reaching and bending and finding information. Phase Two conducted 12/2000: The second stage was to present AT solutions [stair-climber and catalogue] to the mobility and information problems identified by the focus groups using informal trials. The focus groups participants were invited to another meeting, where some tested the stair climber and the others the cataloguing system. Informal Trials- Stair-climber: the device was demonstrated and subjects were invited to use it and climb up 3 steps and come back down again, under supervision. [Usability Tests]. Cataloguing: This 'approach' was introduced to the group and then members were asked to try to use the system to find a piece of equipment that would help them to meet their own or a given mobility need. Two researchers sat with the group and made notes on what equipment they found using the catalogue and made any comments that the subjects made about the design of the catalogue or the equipment detailed within the catalogue.
Product Development Stage at which users were involved	Concept	The Idea for the stair-climbing aid [also the idea of wanting some sort of information provision - Information gained from focus groups.
	Design	X
	Testing & Trials	Prototype testing- Informal Trials.
	Production	X
	Deployment	X
Conclusions		The group members responded favourably to the principle of the stair-climbing aid, particularly to the general principle of having a 'bar in front', and came up with a number of suggestions for improvements. The feedback from the new cataloguing system was problematic, group members had difficulty using the system. A large majority misunderstood the task and commented on the design or value of the equipment that they were finding rather than on the catalogue itself. Because the focus group members were not very specific or detailed about how they would like their problems of information provision to be solved, the researchers made the assumption that the catalogue system would be useful. The study did show that older people are able to identify and describe their mobility problems and information needs, put forward ideas for the design of AT, analyse, evaluate and problem solve. The analysis of the results from the informal trials produced useful feedback on the design of the two products and indicated some limitations to the focus group methodology that could be addressed in future research. It was assumed that the standard medium of providing information - the catalogue - simply needed to be re-designed to match the way that older people think about their mobility problems. It may have been useful to ask the focus group members to validate the assumption before attempting to design a new catalogue.
Researcher's Comments		Funded by the EPSRC as part of the Extending Quality of Active Life [EQUAL] programme.

RefWorks Number: 571 [TOOLS]		Year/County: 2002 - USA
Reference		Smith RO. OTFACT: Multi-level performance-oriented software with an assistive technology outcomes assessment protocol. Technology & Disability 2002; 14(3):133-9.
Objective/Questions		An update and an overview of OTFACT. OTFACT: Multi-level performance-oriented software with an assistive technology outcomes assessment protocol. It is a data collection software system that implements several unique strategies for measuring Assistive Technology [AT] outcomes.
Device/Product		Assistive Technology Devices & Software instrument (a data collection system).
Users		Occupational Therapist.
Method/Tool/Approach		OTFACT was developed over a 15 year timeline with numerous paper, pencil and software development iterations that addressed validity and reliability design factors. OTFACT facilitates methods for documenting alternate perceptions of performance including both observed and the subjective scoring of one's self-satisfaction of performance. The software uses Trichotomous Tailored Sub Branching [TTSS]. The questions use a trichotomous scale. This provides a way for advancing through questions. If a question is answered at either extreme [total deficit or no deficit] for a given behaviour, then the software advances to the next question on the same level. If the response is ambiguous [partial deficit] then OTFACT responds by breaking down the question into sub-categories to inquire deeper into the performance area. In this way, OTFACT only asks the questions to the detail required for a given client in a given situation. OTFACT scoring process quantifies sub-totals and totals for each category of items. The raw scores are converted to a 0-100% score to normalise function to full performance in all functional categories deemed necessary for the individual. OTFACT includes a comprehensive set of functions with demographic and performance data collection modules, several memo and note areas, a report module which helps automated writing reports, and summary and graph modules for displaying single or comparative data. Additionally, a software supplement facilitates the compilation of OTFACT files into ASCII formats for data analysis.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		OTFACT has been examined and used as the basis for data collection in several studies. It has been tested on individuals with Multiple Sclerosis [1992], developmental disabilities in the community [1999], and Stroke [1996]. It has also been used to examine falling outcomes [1999]. The approach used in OTFACT applies a number of unique measurement strategies. For example, the branching feature serves to increase the reliability of the assessment process by allowing the responder to clarify the question as needed. By breaking down the item into its sub-parts, this allows the responder to score the subset and clarifies the broader question. The trichotomous nature of the scale also creates quick item response. The time savings allows for more detail. Version 2 of the software is available online. OTFACT is being used in several occupational therapy professional training programs to teach the domains of assessment to new occupational therapists by using the comprehensive taxonomy of questions. Occupational therapists who work in mental health, paediatrics, physical disabilities, and other comprehensive intervention settings can use a common structure and taxonomy to address functional assessment. Being software based, its relative old age [i.e. it barely runs on high end computers of the early 90's] warns of potential future incompatibilities among operating systems. The measurement concepts need to be reworked and updated with a modern software interface. At the same time OTFACT needs to be renamed and better enabled to more easily incorporate question sets from other disciplines and perspectives.
Researcher's Comments		Funding not addressed.

RefWorks Number: 572 [TOOLS]		Year/County: 2002 - Canada
Reference		Demers L, Weiss-Lambrou R, Ska B. The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0): An overview and recent progress. Technology & Disability 2002; 14(3):101-105.
Objective/Questions		This paper gives an overview of the Quebec User Evaluation of Satisfaction with Assistive Technology [QUEST 2.0] and outlines the recent progress with improvement and use of the tool. [See Ref # 1873].
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		The first version of QUEST consisted of 24 items on 5-point satisfaction scale, although the user could also add any other items considered important. QUEST 2, the current version, has 12 items rated on a 5-point satisfaction scale. QUEST can be either self-administered or interviewer administered. In either case each device being evaluated should require 10-15 minutes for completion. The instrument was developed in Canadian French and English. It was subsequently translated into Dutch, Swedish, Norwegian, Danish and Japanese. Previous Studies: RELIABILITY: was demonstrated in studies done in 1999 & 2000. With community-based adults with Multiple Sclerosis using mobility devices [walkers, wheelchairs, and scooters] in one study and users of wheelchairs and lower limb prosthesis in another. VALIDITY was demonstrated in paper ref #1585, 2000. The expected relationship between the Psychosocial Impact of Devices Scale [PIADS] outcome measure, 2002, and QUEST 2 was empirically tested and positive correlations were found between the QUEST 2 and three PIADS dimensions.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Reliability was assessed through test-retest stability, alternate-form equivalence between self and interview administration forms, and internal consistency. QUEST has been used successfully in a number of outcome studies with various ATs. QUEST 2.0 has better measurement properties and is an important improvement on the previous version. IT allows both item and test levels results and should become a valuable tool to enhance most studies concerned with consumer satisfaction.
Researcher's Comments		Funding not addressed.

RefWorks Number: 580 [TOOLS]		Year/County: 2002 - Argentina
Reference		Della Valle AG, Ruzo PS, Pavone V, Tolo E, Mintz DN, Salvati EA. Heterotopic ossification after total hip arthroplasty: A critical analysis of the Brooker classification and proposal of a simplified rating system. Journal of Arthroplasty 2002; 17(7):870-5.
Objective/Questions		The purpose of this study is to assess the intra-observer and inter-observer reproducibility of the Brooker Classification [1973] among physicians with different training backgrounds, and based on the results and weaknesses detected, to propose a modified system.
Device/Product		Total Hip Prostheses.
Users		n = 159 patients who had 169 consecutive primary THAs [20- bilateral]. n = 3 orthopaedic research fellows to act as observers, were trained in Argentina and Italy. n = 3 observers trained in North America: 1 operating surgeon, 1 4th year orthopaedic resident, and 1 musculoskeletal radiologist. All 6 observers were familiar with the Brooker classification, before the first evaluation, they reviewed the original article proposing the classification.
Method/Tool/Approach		Heterotrophic Ossification [HO] is a potential complication after Total Hip Arthroplasty [THA]. The surgeries were done by the same surgeon. Comparison of the effectiveness of different prophylactic treatments has been based commonly on the radiographic grading of the HO using the Brooker Classification into four classes. The images were studied individually by each of the 6 practitioners (observers), without supervision or time limit. To calculate the intra-observer reproducibility, each observer analyzed the images again after an interval of at least 2 weeks resulting in 2028 observations. Based on the results and the weaknesses observed, the authors designed a simplified system with addition of objective, quantifiable criteria, with the aim of improving the reproducibility and the ability to classify severe HO consistently. The modified system was evaluated using the same methodology. Assessment of inter-observer and intra-observer consistency was accomplished by the proportion of agreement and the k coefficient as proposed by Fleiss.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance
Conclusions		Inter-observer k averaged 0.43 [poor], intra-observer k averaged 0.74 [fair] for the Brooker Classification. For the modified classification, inter-observer k averaged 0.59 [fair], and intra-observer averaged 0.78 [good]. This study showed that the Brooker classification lacks adequate inter-observer consistency. The modified classification was conceived based on the weaknesses noted by all the authors from the 2028 observations. Inter-observer consistency to detect severe HO [Brooker 3 and 4 or grade C] improved from 52% to 76% with the modified system. The new classification showed adequate inter-observer reproducibility, less variability, and improved consistency for classification of significant HO.
Researcher's Comments		Funds were received in partial support of the research material described in this article from Dr and Mrs Alberto Foglia.

RefWorks Number: 611	**[TOOLS]**	Year/County: 2002 - UK
Reference		Dutt SN, McDermott A-, Jelbert A, Reid AP, Proops DW. The Glasgow benefit inventory in the evaluation of patient satisfaction with the bone-anchored hearing aid: Quality of life issues. Journal of Laryngology & Otology 2002; 116(SUPPL. 28):7-14.
Objective/Questions		This study evaluates patient satisfaction and quality of life after bone-anchored hearing aid [BAHA] implantation using the Glasgow Benefit Inventory [GBI].
Device/Product		Bone Anchored Hearing Devices.
Users		n = 312 bone-anchored hearing aid patients who used their aids for a minimum of 6 months. This was to avoid and initial 'enthusiasm bias', allowing a gradual learning process with the BAHA and to obviate initial difficulties with fitting and maintenance. A small number of patients, 15, used bilateral BAHA implants. They were instructed to fill in the questionnaire with reference to the use of their first BAHA i.e. longest worn. Patients were paediatric and adults.
Method/Tool/Approach		The BAHA provides an alternative to conventional air and bone conduction hearing aids. This is a subjective patient orientated post-interventional questionnaire especially developed to evaluate any otorhinolaryngological surgery and therapy. It is maximally sensitive to any change in health status brought about by a specific event: in this case the provision of a BAHA. The GBI is designed to be completed either at an interview or by the patient in their own home. The GBI questionnaire along with a pre-paid envelope was sent to each patient irrespective of their age. It consists of 18 questions based on a 5 point Likert scale. Half the questions ranged from a large deterioration in health status to a large improvement in health status. The design of the other half of the questions was reversed. This was to control response bias. The original 18 question GBI was first scored into a total score. It was then scored into the three subscales: 1) 12 questions relating to general factors; 2) Three questions relating to social support issues; 3) Three questions concerning physical health. Two additions were made to the questionnaire: 4 questions relating to the success of the BAHA and a 10cm linear analogue scale reflecting state of health before and after BAHA. Thus, the modified GBI consisted of 22 questions. The Wilcoxon signed ranks test was used to evaluate the linear analogue scale. This study was a retrospective postal questionnaire with a four month waiting time for responses from 312 patients.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		This study group consisted of 242 adults and 109 paediatric patients. The adults age range was 17 to 67, median 45 years. The paediatric range was 2-16, median nine years. 187 male, and 164 female. 39 BAHA patients had worn their hearing aid for less than 6 months and were excluded from the study. Of the 312 GBI questionnaires issued, 227 were completed and returned. Of the non-responders, 72% were children. The patients returning the questionnaire had used their BAHA for 6 months to 11 years, mean 5.8 years. Patient benefit was shown to be significantly improved following implantation with a bone-anchored hearing aid. In no situation did provision of a bone-anchored hearing aid result in a deterioration of health. When asked about the success of their bone-anchored hearing aid, the overwhelming response was extremely positive. 74% would encourage others with a similar condition to wear a bone anchored hearing aid. The analysis of the analogue scale showed that the improved state of health of the patients following the use of a bone-anchored hearing aid to be highly significant. The GBI was found to be responsive to cochlear implantation. Its use for evaluating [patient satisfaction] hearing aid devices was recommended. An attempt to cleave data into adult and paediatric groups did not prove satisfactory as some of the children who were implanted when they were under 16 years of age had since moved on to the adult programme.
Researcher's Comments		Funding not addressed.

RefWorks Number: 617	**[ORTHOPAEDIC]**	Year/County: 2002 - UK
Reference		Joshi AB, Markovic L, Hardinge K, Murphy JCM. Total hip arthroplasty in ankylosing spondylitis: An analysis of 181 hips. Journal of Arthroplasty 2002; 17(4):427-33.
Objective/Questions		To determine the utility of cemented total hip arthroplasty for patients with ankylosing spondylitis.
Device/Product		Hip Prostheses: cemented Charnley low-friction total hip arthroplasties - a stainless steel femoral component with a 22.5mm femoral head diameter and an all polyethylene acetabular component (Thackray, Leeds).
Users		n = 103 patients (70 men & 33 women).
Method/Tool/Approach		Retrospective case analysis: all patients with ankylosing spondylitis who had undergone total hip arthroplasty at one centre under the supervision of 2 of the authors were selected for study. A total of 186 hip arthroplasties were carried out in 108 patients. 5 patients had follow up care of less than 2 years, so were excluded from the study. The data were collected from patients' clinical records and radiographs. Clinical grading was carried out using the modified Merle d'Aubigne and Postel grading system. The radiographic study involved the review of radiographs taken in the post-operative period and at final reviews or immediately before revision surgery.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		A total of 103 patients underwent 181 total hip arthroplasties, 72 patients had bilateral surgery. The mean follow up was 10.3 years. The mean age of patients at surgery was 47 years (17-77). Before surgery 42 hips were ankylosed. There were postoperative complications in 19 hips (10.5%). 2 patients died within 24 hours of surgery (aortic dissection and pulmonary embolism). The other complications were: superficial wound infection in 7 hips, dislocation in 4, nonunion of the greater trochanter in 5 and sciatic nerve palsy in 1 hip. Revision surgery was carried out in 25 hips for infection or mechanical loosening (13.8%). Heterotopic ossification was present in 21 hips (11.6%), however no patients had functional impairment or reankylosis. At follow up examination 173 hips (96%) had an excellent pain score and 53 hips had a normal or near normal function score (29.2%). The probability of survival of the implant was 71% at 27 years. The authors conclude that total hip arthroplasty provides long term improvement in hip function for patients with ankylosing spondylitis.
Researcher's Comments		No benefits or funds were received in support of this study.

RefWorks Number: 628 [TOOLS]		Year/County: 2002 - UK
Reference		Harwood RH, Ebrahim S. The validity, reliability and responsiveness of the Nottingham extended activities of daily living scale in patients undergoing total hip replacement. Disability & Rehabilitation. 2002; 24(7): 371-377.
Objective/Questions		The Nottingham Extended Activities of Daily Living [EADL] scale is a popular outcome measure in stroke research. Its psychometric properties have not been tested in other conditions. This study analyses data from the changes in health status before and after hip arthroplasty.
Device/Product		Hip Prostheses.
Users		n = 129 patients who were about to be admitted to hospital for hip replacement, were asked to complete a questionnaire. They were identified via the admissions office. Surgeon's clinical decision that hip arthroplasty was likely to be beneficial to patients helped identify patients to include in the study.
Method/Tool/Approach		A Questionnaire booklet comprising the London Handicap Scale, the Nottingham EADL scale and SF-36 was sent by post, along with a letter of explanation. All the scales were in self-completion format, and were returned on admission to hospital. A follow-up questionnaire was sent out 3 months after the operation, comprising the same 3 scales, and asking for an overall assessment of the effect of their operation on a 4-point ordinal scale from 'as good as I could have hoped' to 'no improvement or deterioration'. Patients failing to reply were telephoned to give encouragement or help, or sent a single reminder. A further questionnaire was sent 6-12 months after the operation. A sample of 13 patients was sent a second questionnaire 2 weeks after returning the first to assess test-retest reliability. Statistical analysis methods include Guttmann scaling parameters and Cronbach's alpha.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		83 [64%] patients returned the 1st questionnaire, 75 [93%] completed 2nd questionnaire at 3 months and of the 73 patients sent questionnaires at 6-12 months only 58 [79%] responded. One patient died between 0 and 3 months after the operation, and another died between three and six months. Mean age of respondents was 72 years, range 40-97. The EADL alpha coefficient (Cronbach's) was 0.9 overall, indicating good internal consistency. The instrument correlated strongly with the handicap scale, and SF-36 physical function and social function scales, accounting for about a third of variance in each of these scales. There were moderately strong correlations with the pain, and energy and vitality scales, and weaker correlations with the rest, including role limitation and health perception. Responsiveness was relatively disappointing. Measuring changes resulting from an intervention serves 2 purposes: to demonstrate that an intervention makes a difference compared to another, and to estimate how big the difference is. The latter is especially important in economic analyses. Hip arthroplasty has almost iconic status as a dramatic, life-transforming intervention. Large changes in measures of health status have been demonstrated in previous studies, including this one, using hip directed and generic instruments. The physical function and pain dimensions of the SF-36, in particular, demonstrated large gains after surgery compared with before. By contrast, effect sizes for the EADL were trivial or small. Likert-type scoring of the EADL gave results that were somewhat better than those using conventional scoring. It would be sensible to adopt this scoring scheme in the future. The EADL scale is not wholly insensitive to change. Four randomized controlled trials have demonstrated statistically significant gains in scores after interventions with stroke patients [Juby et a 1996, Logan et al 1997, Walker et al 1999, Gilbertson et al 2000]. The lack of responsiveness will in part be due to a ceiling effect. Someone scoring near the tip of the scale range cannot score much higher, regardless of how much their health improves. However, the SF-36 and London Handicap Scale showed much greater responsiveness. The EADL is a useful scale, and appears to measure something close to disability. However, it is unsuitable for evaluating interventions outside the setting for which it is designed. Osteoarthritis of the hip is a common disabling condition. Hip arthroplasty, in appropriately selected patients, can lead to dramatic improvements in both pain and mobility over a relatively short period of time. It therefore provides a useful 'model' condition for evaluating the responsiveness of scales. The quest for brief generic instruments for measuring outcomes must be viewed with considerable caution. Outcome scales must fit the interventions, and the relationship of the intervention to the outcome has to be understood.
Researcher's Comments		Funding not addressed.

RefWorks Number: 639	**[IMAGING DEVICES]**	Year/County: 2001 - Italy
Reference		Berrettini S, Ravecca F, Forli F, Franceschini SS, Neri E, Volterrani D. Evaluation of osteogenesis imperfecta with temporal bone imaging techniques: HRCT, 3D-MRI, SPECT. Journal of Audiological Medicine 2001; 10(3):200-9.
Objective/Questions		To study the utility of imaging evaluation in patients affected with osteogenesis imperfecta (OI).
Device/Product		Imaging techniques: high resolution computerised tomography (HRCT), magnetic resonance with three dimensional reconstruction (3D-MRI, Signa, GE/Medical System, Milwalkee, Wilconsin) and single photon emission computerised tomography (SPECT, ELGEMS Optima).
Users		n = 3 patients (women).
Method/Tool/Approach		Case series analysis: 3 cases affected by OI tarda (OI type I) with bilateral progressive hearing loss were observed in a single centre and underwent complete evaluation with temporal bone imaging techniques.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		HRCT disclosed partial or complete involvement of the oval and round windows in 2 subjects and partial obliteration of the oval window in the third case, thus it proved particularly useful for the evaluation of the pathological changes in the middle ear in order to define the extent of the disease and to plan surgical treatment. The 3D-MRI appeared to provide useful information regarding the status of the cochlear lumen and in the 3 patients it detected no anomaly in the inner ear. The authors conclude that this imaging examination should be used for those patients suffering from OI who undergo a cochlear implant. Biphosphonate bone SPECT found high uptake values of the petrous bone in all 3 cases suggesting an increase of the bone metabolism due to the underlying pathology. The authors argue that a complete imaging evaluation is important in the assessment of patients suffering from OI and SPECT appeared to be the only functional technique that could quantify the activity of the disease and evaluate the results of medical therapy with biphosphonates.
Researcher's Comments		Funding not addressed.

RefWorks Number: 640	**["OUT OF THE MOULD"]**	Year/County: 2002 - USA
Reference		Peckham PH, Kilgore KL, Keith MW, Bryden AM, Bhadra N, Montague FW. An advanced neuroprosthesis for restoration of hand and upper arm control using an implantable controller. Journal of Hand Surgery 2002; 27(2):265-76.
Objective/Questions		To survey neuroprosthesis users and treating therapists to identify aspects of the first generation neuroprosthesis technology in which performance and acceptance could be improved. To develop the second generation neuroprosthesis and evaluate its performance.
Device/Product		Neuroprostheses: Freehand, (NeuroControl Cleveland). Provides control of grasp release, forearm pronation and elbow extension to individuals with cervical level spinal cord injury.
Users		n = 29 neuroprosthesis users and treating therapists (to evaluate the first generation technology). n = 4 subjects with the second generation technology (gender not stated).
Method/Tool/Approach		A survey (methods not stated) of neuroprosthesis users and therapists to identify how the first generation technology could be improved. Development of a second generation device based on the results of the survey. Implantation of the second generation device and evaluation of its performance and outcomes using technical assessment.
Product Development Stage at which users were involved	Concept	X
	Design	The survey identified performance issues relative to the first generation device, most frequently inadequate hand opening (lack of finger extension) and difficulty placing the external controller on the chest. Users also frequently wanted added arm function, especially overhead reach, as well as forearm pronation and improved shoulder function. It was determined that 2 electrodes, 1 placed between the second and third metacarpals and the second between the third and fourth metacarpals provided full extension of the index, long and ring fingers and resulted in improved extension patterns. A new form of external control was developed using retained voluntary wrist extension to control grasp opening and closing. The functional specifications for the second generation device were therefore: 1) increased number of stimulus channels to allow stimulation of the finger intrinsic muscles, triceps and or forearm pronator 2) an implanted control source 3) bidirectional transcutaneous communication allowing sensor data to be transmitted outside of the body 4) reduced size of the implantable device 5) reduction of all external cabling. The objectives were: 1) restore hand opening and grasp with a sufficient number of grasp configurations for users to manipulate common objects 2) expand effective arm movement over the workspace contained within the movement of the arm 3) provide ease of control that is "natural" and integrated within the user's movement strategies 4) implement the above objectives in a way that is biologically safe, easy to operate, easy to don and doff, cosmetically acceptable, transportable, reliable and clinically effective.
	Testing & Trials	The 4 study participants who had the second generation device implanted were tetraplegic as a result of traumatic spinal cord injury at the C5 or C6 level. All were medically stable and healthy and at least 1 year had elapsed since injury. 3 of the 4 had both the 10 channel stimulator-telemeter (IST) and implanted joint angle sensor (IJAT) implanted and the other had the IST implanted and used an external wrist position sensor.
	Production	X
	Deployment	X
Conclusions		The neuroprosthesis was found to be operational in all 4 subjects with a minimum follow up time of at least 4 years since the initial implant. All subjects reported using the system regularly for eating, drinking and other activities of daily living. Wrist motion returned to preoperative levels in all cases. All electrodes (40) had functionally sufficient levels of strength. No cases of implant infection or device rejection occurred. Radiological evidence showed that the bones healed around the insertion holes for the IJAT with no bone resorption or breakage. One case of IST device malfunction occurred after 2 years (it was replaced successfully after 36 months). One case of a lead failure occurred after 2 years of operation and was replaced with a new one in the same muscle with no further incidents. Slight connector leakage occurred in the first subject to receive the IJAT. The IJAT was inserted in a second surgical procedure and connected to the existing IST device. Pinch force increased markedly in all grasp patterns. Active range of motion of the fingers and thumb, which was zero in all cases without stimulation, increased for every digit with stimulation. Stimulated range of motion was increased notably for the elbow and triceps stimulation and for the forearm with pronator quadratus stimulation. The device provided all subjects the ability to manipulate 6 objects in the grasp release test (a peg, block, tape, can, fork and weight). When the device was turned off none of the subjects could pick up the weight and 3 could not perform the fork task. Every subject had an increased level of independence in activities of daily living when using the device. 3 subjects showed an increased level of independence in at least 5 different activities when using the device and indicated a preference for using the device in at least 8 activities (the activities included eating with a fork, drinking from a glass, writing, typing and brushing hair). The authors conclude that the device is safe and can provide grasping and reaching ability in individuals with cervical level spinal cord injury enabling individuals to gain additional abilities that are important to their independence.
Researcher's Comments		Supported by the National Institutes of Health, the Spinal Cord Research Foundation and the Department of Veteran Affairs Rehabilitation Research and Development Service Project. No benefits had been received from a commercial party.

RefWorks Number: 642 [TOOLS]		Year/County: 2002 - Spain
Reference		Carod-Artal FJ, Gonzalez-Gutierrez JL, Herrero JAE, Horan T, De Seijas EV. Functional recovery and instrumental activities of daily living: Follow-up 1-year after treatment in a stroke unit. Brain Injury 2002; 16(3):207-16.
Objective/Questions		To assess the utility of the Frenchay Activities Index [FAI] to measure instrumental activities of daily living [IADL] and functional recovery in stroke patients compared to other measures such as Barthel Index [BI] and the Scandinavian Stroke Scale [SSS].
Device/Product		Mobility & Other Assistive Technology Devices
Users		n = 118 subjects. The study included all patients consecutively admitted to a Stroke Unit between Jul 1-Dec 31 1996. Stroke was defined as a sudden focal neurological deficit persisting more than 24 hours. Diagnosis of stroke had to be confirmed by clinical examination and neuroradiological findings on CT scan and/or MRI.
Method/Tool/Approach		The IADL addresses a distinctly higher level of ADL and social functions, compared to those measured by the BI and SSS. The FAI measures more complex physical and social functioning. The patients were followed up for one year. A cross-sectional descriptive analysis design was held. Demographic and co-morbidity information were recorded on admission. Follow-up outpatient interview, clinical evaluation and examination were obtained from the patient, together with relatives 1 year post-stroke. This included the completion of the BI, SSS and FAI. Two patients were evaluated at nursing homes because travel difficulties prevented an outpatient visit to the hospital. All patients were personally evaluated by the first author.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		118 patients met the inclusion criteria. At one year, 17 patients were lost to follow-up, 10 patients died, and one refused to participate. Thus, 90 survivors were available for the study, 41 women and 49 men, mean age 68 years, range 32-90 years. Ischemic stroke occurred in 79 and haemorrhagic in 11. Modifications of living conditions occurred in the year following stroke, 18.9% of patients had their locale changed, either temporarily or permanently, to a relative's house or nursing home. Structural modifications to the home, particularly in the bathroom and lounge, were necessary for 13.3% of patients. Personal assistance with walking or walking with a cane or use of a wheelchair was necessary for 31%. Difficulties in achieving and maintaining personal hygiene persists, 20% were incontinent or had accidents in their vesical control, 32% were dependent on assistance to accomplish bathing, and 7% were completely dependent for personal hygiene 1 year after stroke. Quantification of these difficulties was accomplished by BI and SSS. Frenchay Activities Index correlated with Barthel Index's capacity for walking, strength in upper limb, and the total Scandinavian Stroke Scale 1-year after stroke. The Barthel Index was the strongest predictor of independence in Frenchay Activities Index social activities category. IADL and ADL scales should be used as a routine complementary approach to measure long-term outcome in stroke survivors. This approach could permit comparison of management strategies of the acute stroke. Two deficiencies were observed. It does not include phone use or church visits, so a limitation in the extension of the activities occurs. Constructive validity is also diminished for indoor leisure activities because it does not include watching television. Similarly, the distinction between light and heavy domestic work is not always clear. Moreover, ambiguity between activities performed in the last 3 versus 6 months can potentially induce biased responses in aged people answering the FAI questionnaire. In consideration of some of the deficiencies of the FAI, it is felt that perhaps a new, more comprehensive tool covering higher specific activities for patients surviving a stroke, might have additional benefits for measuring long term outcomes in stroke patients.
Researcher's Comments		Funding not addressed.

RefWorks Number: 663	**[TOOLS]**	Year/County: 2002 - USA
Reference		Scherer MJ, Cushman LA. Determining the content for an interactive training programme and interpretive guidelines for the Assistive Technology Device Predisposition Assessment. Disability & Rehabilitation 2002; 24(1-3): 126-130.
Objective/Questions		Development of a interactive training programme and interpretive guidelines for professionals administering the Assistive Technology Device Predisposition Assessment [ATD PA] consumer form. This involved: 1 Obtaining professional and consumer feedback on the process of completing the ATD PA. 2 Developing and pre-pilot testing prototype content for the interpretive guidelines and interactive training programme to make fundamental knowledge of assistive technologies and the Matching Person with Technology [MPT] process widely available to professionals in an easy-to-use, affordable, and accessible format.
Device/Product		Assistive Technology Devices.
Users		n = 22 professionals who had completed surveys on the ATD PA, recommendations for interpretative guidelines and an interactive training programme. Criteria included use of the MPT process with a minimum of 12 consumers [persons with disabilities] within the last 24 months. Professionals were either: Occupational Therapists [1], Physical Therapists [1], Rehabilitation Engineer [4], and Vocational Rehabilitation Counsellor [16]. Random selection of 30 from a database of 325 professionals. 14 women and 8 men, from 8 American states and Italy. Each professional had 1-2 of their consumers each. Inclusion criteria for consumers included: articulate communication, willingness to participate in telephone survey, and willingness to articulate their perspectives of the MPT process and recommendations for a training programme in its use as well as user profiles and guidelines. n = 14 people on the advisory committee comprising consumers with disabilities as well as national assistive technology, assessment, and education experts.
Method/Tool/Approach		The ATD PA is a self- reporting tool for consumers to identify their functional capabilities and limitations, satisfaction with and priorities for Quality Of Life achievement, psychosocial characteristics and device preferences. The 63 item ATD PA consumer form primary format uses a 5-point Likert scale and checklists. The ATD PA consumer form addressed one of the MPT assessments. The solicitation of professionals and their consumers was targeted to represent diverse geographical regions, cultural backgrounds, a range of ages and both genders. The 22 professionals were exposed to the new, pre-pilot, interpretive guidelines and informed that they will be provided with complimentary copies of the commercial products emerging from subsequent research. The participating professionals and consumers who were exposed to and used the ATD PA were asked to complete a survey on their experiences with it. The advisory committee members read summaries of the responses to the survey and identified the essential content for the ATD PA interpretive guidelines and interactive training programme. This information was used by the advisory committee using a modified Nominal Group Technique and all feedback was conducted via e-mails and/or telephone interview. No face-to-face meetings were held due to geographic distance and time differences. All responses were summarized and distributed to the advisory committee members until the group was unable to provide additional responses. Finally, all acceptable topics were redistributed to participants who rank-ordered the ones they believed were most important in: a) the process of matching person and assistive technology; b) to include in computerized interpretive guidelines; and c) to include in the interactive training programme.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		In general, the professionals and consumers who participated in the study found the MPT process and ATD PA tool to be useful and rated their value highly. They especially liked the way it engages the consumer in the process of technology evaluation and structure the discussion to include key considerations that might be missed otherwise [such as topics in which the professional might have some discomfort in raising, personal and social/environmental influences. The forms helped to ensure all relevant areas were systematically reviewed and that a comprehensive assessment was done. In summary, there is both professional and consumer preference for a reliable assessment process that includes three essential elements: 1) It should incorporate the consumer's perspective and accommodate individual user preferences, 2) Go beyond functional capabilities to the consideration of personal and social/environmental influences on assistive technology use, and 3) Provide documentation to support the chosen assistive technology. The results strongly support the further development of scoring and interpretative guidelines, as well as an accessible means of getting comprehensive training in the use of the MPT process and assessment forms, and ways to maximise benefit from their use. These products are not currently available, yet consumers, providers of assistive technology, and professionals in related fields articulate a strong desire for these products and services. Their further development remains a goal of future research.
Researcher's Comments		Funded by the National Institutes of Health, the National Institute of Child Health and Human Development, National Center for Medical Rehabilitation Research, through a grant to The Institute for Matching Person and Technology Inc.

RefWorks Number: 664	**["OUT OF THE MOULD"]**	Year/County: 2002 - Canada
Reference		Stickel MS, Ryan S, Rigby PJ, Jutai JW. Toward a comprehensive evaluation of the impact of electronic aids to daily living: Evaluation of consumer satisfaction. Disability & Rehabilitation 2002; 24(1-3): 115-125.
Objective/Questions		1 To explore consumer satisfaction with Electronic Aids To Daily Living [EADL]. 2 To investigate the value that people with degenerative neuromuscular conditions place on these technologies.
Device/Product		Assistive Technology Devices: Electronic devices including some commercial systems: Chec 2, Quartet, Leviton, and Imperium amongst others.
Users		n = 20 EADL users and n = 20 non-users with Muscular Dystrophy who require the use of a power wheelchair. 30 males, 10 females between 17 and 55 years old. Users were included if they had the capability of activating two or more appliances by means of devices that had been chosen to facilitate the user's function. Non-users were the control group- they had the potential to benefit from using EADLs, but either did not have them or, at most, had access to and could independently control a telephone, a commercial remote control, and/or directly activate appliances, but could not do so when in a manual chair or bed. Interviewers: 3 occupational therapists, 1 physical therapist, and 1 research therapist; none were EADL service providers to any study participant.
Method/Tool/Approach		Interviews were conducted with the 40 subjects to compare their views about EADLs and their daily life experiences. EADL users were interviewed twice, six months apart, to establish the stability of their views and experiences with EADLs. Four measures were used during the structured component of the interviews, while semi-structured, open ended questions formed the latter part of the interviews, to explore and expand upon the participant's responses to the structured questions. 15 EADL users were interviewed again at six months [3 died, and 2 declined to participate]. Most interviews were conducted in the participant's home by a research therapist. Tools used to determine functional levels of subjects, gather personal data pertinent to the study of device utility and explore user satisfaction include: The Quebec User Evaluation of Satisfaction with Assistive Technology [QUEST], The Functional Independence Measure [FIM], The Psychosocial Impact of Assistive Devices Scale [PIADS] & the personal profile. Qualitative Methods used to explore: views and experiences concerning EADLs.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		70% of users of EADLs lived in apartments either alone or for example with attendant support, whereas only 25% of the non-users were living similarly. The access to EADLs seem to have an obvious impact on the ability for this group to live on their on. The results suggest that overall consumers were quite satisfied with their EADLs and that this was relatively stable over time. However, some consumers expressed concern regarding the cost of these technologies and their associated services. Both users and non-users rated EADLs similarly in relation to the degree of importance ascribed to them examples: 'very important' or 'quite important'. Combining the QUEST with outcome measurement tools that explore other important dimensions such as the effect on quality of life and psychosocial impact will help service providers to justify the costs associated with the prescription of sophisticated, costly assistive devices such as EADLs. Limitations: Caution must be taken when interpreting these results due to the small sample size and the variability in the systems used and service provided. Some caution has to be exercised when evaluating perceived importance reported by non-users who had to estimate what it would be like to have EADLs installed in their homes. The lack of guidelines in interpreting the QUEST data is a major limitation to using this version which will be addressed by using QUEST version 2.
Researcher's Comments		Grant from the Bloorview Children's' Hospital Foundation.

RefWorks Number: 686 [TOOLS]		Year/County: 2001 - Sweden
Reference		Nilsdotter A-, Roos EM, Westerlund JP, Roos HP, Lohmander LS. Comparative responsiveness of measures of pain and function after total hip replacement. Arthritis Care & Research 2001; 45(3):258-62.
Objective/Questions		To compare the responsiveness of the Functional Assessment System [FAS], the Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC, Version 3] and the Medical Outcomes Study 36-item Short Form [SF-36] in patients with osteoarthritis scheduled for total hip arthroplasty.
Device/Product		Total Hip Prostheses.
Users		n = 20 patients with primary osteoarthritis of the hip, mean age at surgery 72.6 years [13 women and 7 men]. All had primary unilateral total hip arthroplasty between Sep 1997 and Apr 1998 at the Department of Orthopedics, Sweden. 15 had replacements with both components cemented, and 5 were done with acetabular component uncemented. n = 7 physiotherapists to completed the questionnaires.
Method/Tool/Approach		This prospective study was designed to investigate whether it would be beneficial to add the FAS, an observer-administered measure of impairment and disability, to commonly used patient-administered questionnaires for the evaluation of patients assigned for total hip arthroplasty. The preoperative hip radiographs were classified by one radiologist according to the Osteoarthritis Research Society criteria with a radiographic atlas as a guide. The patients were evaluated preoperatively and at 3, 6 and 12 months post-operatively. In the post-operative evaluations the responsiveness of the FAS, WOMAC and SF-36 scales were compared. Using the FAS questionnaire, the quadriceps strength and hamstrings strength were not assessed because the required equipment was unavailable. The ratings were carried out by 7 different physiotherapists working in the same department who were well acquainted with the test. Each testing session lasted 45 minutes. The SF-36 subscales measuring physical function and bodily pain were used in comparison with the FAS. The WOMAC version 3 has been proven to be reliable and valid for Swedish populations. To make comparisons with the SF-36 easier, the WOMAC was transformed to a 0-100 worst-to-best scale. The WOMAC subscales measuring pain and function were used in comparison with the FAS. Responsiveness was calculated as standardized response mean, effect size, and relative efficiency.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The pain and function variables of WOMAC and SF-36 showed greater responsiveness than the FAS already at 3 months after hip arthroplasty. These differences remained at 6 and 12 months post-operatively. The differences between these 3 outcome measures were found to be similar using several methods for calculating responsiveness. Self-administered questionnaires like WOMAC and SF-36 are more responsive measures of pain and function than range of motion, performance tests, and observer-administered questions [FAS] following total hip arthroplasty. The authors found no advantages in terms of responsiveness, in using a costly and time-consuming observer-administered functional test compared with patient-administered questionnaires in this prospective follow-up after total hip replacement. A limitation of the study was the relatively small sample of patients who were assessed, albeit at many testing sessions. However, the greater the responsiveness of the outcome instrument used, the smaller the sample size that is required [Davies et al 1999, Rosner 1995].
Researcher's Comments		Funding not addressed.

RefWorks Number: 689 [PROSTHESES: LIMB, FACIAL & PELVIC]		Year/County: 2001 - France
Reference		Cottias P, Jeanrot C, Vinh TS, Tomena B, Anract P. Complications and functional evaluation of 17 saddle prostheses for resection of periacetabular tumors. Journal of Surgical Oncology 2001; 78(2):90-100.
Objective/Questions		To report the experience regarding a series of saddle prostheses inserted following resection of pelvic malignant tumours.
Device/Product		Saddle Prostheses: Endo-Modell Mark II (Waldemar Link GMBH & Co, Hamburg.
Users		n = 17 patients (11 men & 6 women).
Method/Tool/Approach		Retrospective case series analysis: 17 saddle prostheses were inserted between 1988 and 1997 following resection for periacetabular tumours. The modified Musculoskeletal Tumor Society Score (MSTS) and the Toronto Extremity Salvage Score (TESS) were used for functional analysis. The tumours involved zones II and III of Enneking classification in 13 patients, the zones I and II in 2 patients and zone II in 2 patients. The tumours included 11 chondrosarcomas, 3 Ewing sarcomas, 2 giant cell tumours and 1 metastatic renal carcinoma. The tumour resection was wide "en bloc" in 14 cases, marginal in 2 cases and intratumoural in 1 case.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean follow up period for the patients was 42 months (8-84). Local recurrences occurred in 5 cases and metastases in 4 cases. 5 patients died of tumoural disease and 1 of intercurrent disease. Complications were observed in 11 cases (65%) including nerve damage (3 cases), deep infections (3 cases), upward migration of the saddle (4 cases), saddle dislocations (3 cases), sacroiliac subluxations (2 cases) and mechanical failures (2 cases). Functional results were available for only 9 patients - as 6 had died, 1 was lost to follow up, and 1 was excluded as removal of the prosthesis secondary to deep infection (mean MSTS of 17 and mean TESS of 58). The authors concluded that the prosthesis provided in all cases an early painfree weightbearing reconstruction with minimal limb shortening, but the functional results remained fair in most patients due to a limited range of motion and a poor abductor strength, with a high complication rate of 65%. The validity of TESS was questioned because 1 patient aged 17 years had a TESS of 95 points which represented a patient aged 50 years. This patient was a student who walked without aids. The best functional outcome was obtained for a 56 year old patient who had a TESS of 73 points, however he walked using a crutch and was unable to return to work.
Researcher's Comments		Funding not addressed.

RefWorks Number: 697 [TOOLS]		Year/County: 2001 - Netherlands/Italy/Sweden/Norway
Reference		Wessels R, De Witte L, Andrich R, Ferrario M, Persson J, Oberg B, et al. IPPA, a user-centred approach to assess effectiveness of assistive technology provision. Technology & Disability 2001; 13(2):105-15.
Objective/Questions		A description of the Individually Prioritised Problem Assessment [IPPA], a new instrument, as well as the empirical data to support the contention that the IPPA is a valid measure of the change caused by Assistive Technology [AT] service delivery as perceived by the service delivery client/end-user.
Device/Product		Assistive Technology Devices.
Users		n = 248 subjects were clients of service delivery centres in the four participating countries. During a four month period, all clients aged >=16 years with a problem in mobility, hearing, speech related communication or self-care related to use of the bathroom, who requested a new AT device through one of the participating centres were asked to take part in the investigation. People with serious cognitive impairments were excluded from the study. Interviewers = therapists/counsellors working as professionals in the service delivery process, they were strictly independent from the service delivery process. The interviewers were instructed and trained beforehand.
Method/Tool/Approach		In the field of rehabilitation research several instruments exist for assessing disability status: Barthel, SIP68 or FIM. These instruments only measure general condition of respondents and pay no attention to specific individual goals pursued by those who apply for an AT provision. TOOL: IPPA is intended to measure the effectiveness of the provision of AT. It assesses the extent to which the problems in daily activities identified by the respondent have been diminished as a result of this provision. The client is asked to identify the problems that he or she experiences in daily life and that he or she hopes are eliminated or diminished as a result of an AT provision. This is done early in the delivery process as possible so that a client's account of his or her problems is not influenced by service providers. The client is allowed to identify up to seven major problems and to assign scores with respect to importance of the problem and level of difficulty on a 7-point scale. The difficulty scores are added up and divided by the number of problems to get the total IPPA score. During the follow-up interview the client again has to assign a difficulty score for each of the same activities. The difference between the total IPPA score before and after provision of AT represents the effectiveness, thus indicating the degree to which the perceived inconvenience with respect to problems diminished. An English version was translated into the languages of the four participating countries. The IPPA instrument was applied in the context of AT service delivery in Italy, Netherlands, Norway and Sweden. The baseline interview [n = 248] was carried out during the early stages of AT service delivery and the follow-up interview [n = 188] took place after the AT provided had been used for 3 months. The 60 subjects did not receive a second interview because they did not receive an AT provision. The duration of each interview was recorded. Reliability could not be performed because every respondent 'creates' their own questionnaire with a variable number of questions making analysis impossible. Feasibility was assessed by the interviewers rating aspects of each interview using an evaluation form containing: duration of the assessment; the level of difficulty experienced by the respondent, as perceived by the interviewer; the number of problems identified for each subject; and other observations relevant to improve the instrument. In addition, a meeting with all interviewers took place. During this one-day meeting experiences were exchanged and relevant aspects of feasibility discussed. After the last interview, each interviewer received a questionnaire with questions about their experiences and opinions on aspects of feasibility. Construct Validity of IPPA was assessed by comparing the scores with the results of SIP68 [a measure for assessing problems in daily functioning] and EuroQol [a general health measure], these instruments were not described here. Thus, all three instruments were assessed during the interview.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Study population- 60% female, 40% male with a mean age of 60-70 years, except for clients with speech related communication problems these participants had a mean age 32 years old. The median number of problems actually mentioned at baseline was 3. The direction of changes measured by IPPA is consistent with the direction of changes measured by SIP68 and EuroQol, supporting construct validity. Changes measured by IPPA are considerably larger, supporting our view that solving problems is a key outcome in provision of assistive devices. Results support the ideas behind the instrument and are promising enough to continue.
Researcher's Comments		Funding not addressed.

RefWorks Number: 719	**[DIGESTIVE & EXCRETORY]**	Year/County: 2000 - Italy
Reference		Mosca F, Stracqualursi A, Portale TR, Consoli A, Latteri S. Palliative treatment of malignant esophageal stenosis: The role of self-expanding stent endoscopic implantation. Diseases of the Esophagus 2000; 13(4):301-4.
Objective/Questions		To examine the role of self-expanding stents endoscopically implanted for the palliative treatment of malignant oesophageal stenosis.
Device/Product		Oesophageal stents: Ultraflex prosthesis (Boston Scientific Microinvasive, Natick MA, USA), Instent prosthesis (Medtronic Inc, USA) and the Wallstent (Schneider Medintag, Switzerland).
Users		n = 40 patients (29 men & 11 women).
Method/Tool/Approach		Endoscopic tube implantations were carried out in patients with malignant stenosis of the oesophagus and gastric cardia using self-expanding metallic stents between 05/1993 and 12/1999. The indications for endoscopic intubation were the advanced stage of the tumour in 27 cases and risk factors that made resection inadvisable in 13 cases. Ultraflex self- expandable metal mess used in 34 cases, Ultraflex coated used in 24 cases.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The patients had a mean age of 71.1 years (52-88). In 25 cases dysphagia was total, whereas 15 patients were able to swallow liquids only. In 3 patients it proved impossible to implant a stent endoscopically because the guide wire could not be passed through the stenosis, whereas correct stent placement was achieved in 37 cases. Functional results were good in 33 patients but 4 patients did not show any improvement of symptoms. After stent implantation dysphagia immediately improved in 28 patients and 5 patients were able to swallow semi-solids. Complications occurred in 9 patients (24.3%): 2 bleedings, 3 neoplastic obstructions, 1 food obstruction and 3 distal dislodgements of the prosthesis were observed but could be readily corrected. No deaths occurred. The median survival time was 151 days (25-545). The authors conclude that endoscopic placement of metallic self-expanding stents is safe and is to be preferred to plastic stents for easier implantation and lower morbidity.
Researcher's Comments		Funding not addressed.

RefWorks Number: 725	**[ORTHOPAEDIC]**	Year/County: 2001 - UK
Reference		Salmon P, Hall GM, Peerbhoy D, Shenkin A, Parker C. Recovery from hip and knee arthroplasty: Patients' perspective on pain, function, quality of life, and well-being up to 6 months postoperatively. Archives of Physical Medicine & Rehabilitation 2001; 82(3):360-6.
Objective/Questions		To provide a more detailed description from patients' perspectives than is yet available of recovery from hip and knee arthroplasty and to use this information to test 2 assumptions about recovery from these procedures: that recovery from knee arthroplasty, as assessed by patients, routinely reaches the level achieved by hip arthroplasty; and that fatigue is prolonged after major orthopaedic surgery.
Device/Product		Hip (usually Charnley) and knee (usually Install-Burstein or Miller-Galante) Prostheses.
Users		n = 160 patients (107 undergoing hip arthroplasty: 37 men & 70 women; and 53 undergoing knee arthroplasty: 23 men & 30 women).
Method/Tool/Approach		Cohort study of consecutive patients undergoing hip or knee arthroplasty within 2 teaching hospitals. Patients were excluded if they had systemic illness or were using steroid medication. Of 226 eligible patients, 39 declined to participate and 27 were subsequently excluded because of procedural problems, cancellation, change of surgery, noncompliance or withdrawal from the study. Questionnaires were administered on the preoperative day, and days 1, 3, 7 postoperatively in hospital and then at 1 and 6 months when 8 patients (5%) could not be contacted and 15 (9%) declined to participate. Multiple assessment procedures were used: functional impairment by the Western Ontario and McMaster Osteoarthritis Index (WOMAC); overall pain using a 100mm visual analog scale; fatigue by the Chalder et al scale; subjective health by the Recovery Inventory; four moods (tension-anxiety, depression, fatigue, vigour) by the Profile of Mood States (POMS); quality of life by the Medical Outcomes Study Short Form Health Survey (SF-36) and an overall rating of life evaluation by a visual analog scale, Cantril's Life Satisfaction Ladder.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Pain and function improved significantly less after knee arthroplasty than after hip arthroplasty, but the 2 procedures led to similar improvements in life evaluation, mood and subjective health. Fatigue was only transiently increased (up to 3 days postoperatively and by 7 days it had returned to baseline values). The authors concluded that the findings were inconsistent with both assumptions but despite poorer recovery in pain and function, patients receiving knee arthroplasty felt that life had improved as much as did those patients who had undergone hip arthroplasty.
Researcher's Comments		Funding not addressed.

RefWorks Number: 738 [PROSTHESES: LIMB, FACIAL & PELVIC		Year/County: 2001 - Germany
Reference		Wuisman P, Lieshout O, Van Dijk M, Van Diest P. Reconstruction after total En Bloc sacrectomy for osteosarcoma using a custom-made prosthesis. Spine. 2001; 26(4): 431-439.
Objective/Questions		The objective of this study is to describe the planning and design of a device, a surgical technique, and clinical and functional outcome of a patient with a large sacral osteosarcoma.
Device/Product		A custom-made Sacral Prosthesis.
Users		n = 1 patient with a highly malignant primary osteosarcoma. 42 year old female, with progressive bowel and urinary incontinence and radiating pain to her lower left leg.
Method/Tool/Approach		Case Study. Pre-Study Clinical Analysis included a physical examination, plain radiographs, CT and MRI imaging and histologic assessment of a specimen. After 3 cycles of chemotherapy, repeated scans were taken. Repeated biopsies showed excellent response with the chemotherapy with 90% devitalisation of the tumour. To allow time for manufacturing an individual prosthesis, another two cycles of chemotherapy were administered. A 3D real-sized model was produced using computer assisted reconstruction of computer tomographic [CT] images from T12 downward including the whole pelvis. Resection margins were drawn on the model, and drawings of a custom made implant were worked out. Wax models of the different parts of implant were made. Thereafter, implants were produced and mounted on another real-sized model for definite approval; this was also used as a guideline during surgery. This enabled design and testing of a custom made prosthesis, to provide stable libosacral reconstruction.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Although there have been case reports about reconstruction methods after total sacrectomy, to date, there has not been a reported clinical case of successful reconstruction using an individual designed prosthesis based on a three dimensional real-sized model. Within 3 weeks after surgery, mobilization began, and the adjuvant chemotherapy continued. The patient needed local revision due to wound dehiscence, which was successful. At the 36 month follow-up, the patient was disease free, had a stable, painless spinopelvic junction, and could walk short distances using ankle orthoses and crutches. Radiographs show complete incorporation of the pelvic grafts and unchanged position of the implant. In planning and performing a total sacrectomy, including substantial parts of iliac wings a three dimensional real-sized model offers surgeons distinct advantages. Wide bony resection margins can be drawn on the model, and in individual custom-made prosthesis to re-establish spinopelvic continuity can be designed and tested before the intervention. Regarding tumour extension seen on MRI, the sites of osteotomy can be marked on the model, providing healthy wide margins. In addition, an individual prosthesis can be designed and mounted on a model before surgery. However, the system is then unable to make adjustments during surgery. Exact pre-operative planning is required. In another patient treated in this way, repeated local interventions were needed because of deep wound infection. In the author's opinion this patient was high risk for local infection irrespective of the reconstruction method.
Researcher's Comments		Engineers from Stryker Howmedica Osteonics, Inc, Kiel, Germany co-operated in the design and testing of the prosthesis.

RefWorks Number: 754	**[TOOLS]**	Year/County: 2000 - UK
Reference		Gallagher P, MacLachlan M. Development and psychometric evaluation of the trinity amputation and prosthesis experience scales (TAPES). Rehabilitation Psychology 2000; 45(2):130-54.
Objective/Questions		To develop a multi-dimensional self-report instrument to better understand the experience of amputation and adjustment to a lower limb prosthesis.
Device/Product		Artificial Lower Limb Prostheses.
Users		Study 1: hospital charts of potential participants attending a limb fitting clinic in Ireland were reviewed. Participants had to be at least 18 years old and had to have a lower limb amputation. 170 potential respondents of which n = 104 completed the mailed questionnaire; mainly below knee amputations; 78 men and 26 women, mean age of 45.3, 18-84 years. Study 2: TAPES sent to 166 people who had lower limb amputations and attended the limb fitting clinic, and were over 18 years old. n = 60 completed the mailed questionnaire; 41 men and 19 women, mean age 47.1 years, 19-84.
Method/Tool/Approach		STUDY ONE: Questionnaire content and subsequent item selection were developed through three processes: a review of the literature and existing measures, expert opinion [clinical and research psychologists, prosthetists, and rehabilitation and orthopaedic consultants], and focus groups involving people who have had a lower limb amputation to identify what they considered to be the important factors in adjusting to lower limb amputation and wearing a prosthetic limb. The questionnaire was pre-tested with 5 members of a target group. Three main sections were developed in the Trinity Amputation and Prosthesis Experience Scales [TAPES] included: 1) Psycho-social adjustment, consisted of 89 items evaluating adjustment and the impact of having an artificial limb, rating individual statements on a 5 point scale from 'strongly agree' to 'strongly disagree'; 2) Activity restriction, as a result of having an artificial limb, consisting of 19 activities using a 3-point scale ranging from 'limited a lot' to 'not limited at all' [some items modelled after items from SF-36]; 3) Prosthesis satisfaction, respondents were asked to rate 10 items on different aspects of their prosthesis on a 5-point scale, ranging from very dissatisfied to very satisfied. STUDY TWO: was performed to establish construct validity. Validity measures were established by comparing the findings with that of the World Health Organisation Quality of Life Questionnaire [short version or WHOQOL: BREF, 1998].
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		In its final format, the TAPES comprises 3 psycho-social adjustment subscales consisting of 5 items each [general adjustment, social adjustment, and adjustment to limitation], 3 activity restriction subscales consisting of 4 items each [functional restriction, social restriction, and athletic activity restriction], and 3 satisfaction subscales consisting of 10 items [functional satisfaction, aesthetic satisfaction and weight satisfaction]. A fourth section of the TAPES have not been discussed because it was not factor analysed. The experience of phantom limb pain and stump pain etc are in this section. It is an important section because a significant factor in the amputation experience is pain and how the individual experiences pain. Overall the TAPES consist of 54 items and the administration time is approximately 5-10 minutes. There is empirical justification for the final content of TAPES. The factor analysis resulted in a smaller number of variables from the original list complied from suggestions from people who had amputations, previous instruments, and a review of the literature. The subscales displayed high internal reliability, and preliminary evidence indicated various forms of validity. These findings suggest that the Trinity Amputation and Prosthesis Experience Scales may be applied as a clinical and research tool.
Researcher's Comments		Funded by the National Rehabilitation Board of Ireland and Trinity College.

RefWorks Number: 763	**[CARDIAC]**	Year/County: 2000 - Japan
Reference		Kawahira Y, Yagihara T, Uemura H, Yoshizumi K, Yoshikawa Y, Kitamura S. Replacement of the tricuspid valve in children with congenital cardiac malformations. Journal of Heart Valve Disease 2000; 9(5):636-40.
Objective/Questions		To evaluate the use of replacement tricuspid valves in children with congenital cardiac malformations.
Device/Product		Cardiac valve prostheses: Carpentier-Edwards porcine bioprosthesis and bileaflet mechanical prosthesis.
Users		n = 11 patients (gender not stated).
Method/Tool/Approach		The atrioventricular valve was replaced in the subjects. A bioprosthesis was implanted on 7 occasions and a bileaflet mechanical valve on 8 occasions. Between 04/1982 and 09/1997 275 patients under 15 years of age underwent surgical intervention to the regurgitant right sided atrioventricular valve associated with congenital cardiac malformations at one institution. In a subgroup of 11 children the valve was replaced a total of 15 times. Postoperative anticoagulation therapy consisted of life long administration of warfarin and anti-platelet agents in those with a mechanical prosthesis. In those with a bioprosthesis warfarin and anti-platelet agents were given for 1 year only post valve replacement.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Mean age for surgery 7.9 years (8 months - 13 years). 1 patient died 2 years after implantation due to respiratory problems. Tricuspid stenosis due to valve calcification occurred in 4 bioprostheses at between 4 and 9 years after initial replacement (57%). In 3 cases the native valve leaflets had not been removed. Following replacement of the tricuspid valve with a bioprosthesis the proportion of valves that were free of dysfunction and did not require reoperation was 80% at 5 years and 0% at 10 years. Thrombosis occurred in 1 patient with a mechanical valve; replacement was successful. Anticoagulant related haemorrhage occurred in another patient. Among patients receiving a mechanical valve 83% of valves were dysfunction free after 5 and 10 years. The authors state that structural deterioration occurred less frequently among patients who received a mechanical valve but that the possibility of thrombus formation in the mechanical valve should be noted as low pressure haemodynamics of the right heart predispose the artificial material to clot formation. In contrast the bioprosthesis leaflets are prone to calcification and peel formation. The preference of the authors is to use a mechanical valve in children when extensive repair of intra-cardiac malformation has been carried out, but ventricular function is good. In children with poor cardiac performance a bioprosthesis is preferred with total resection of the native valve leaflets.
Researcher's Comments		Funding not addressed.

RefWorks Number: 772 [ASSISTIVE DEVICES: MOBILITY AIDS]		Year/County: 2000 - India
Reference		Mukherjee G, Samanta A. Evaluation of ambulatory performance of the arm propelled three-wheeled chair using heart rate as a control index. Disability & Rehabilitation 2000; 22(10): 464-470.
Objective/Questions		To assess the ambulatory performance of the users of an arm propelled 3 wheeled chair using heart rate as a control index at graded speeds.
Device/Product		Mobility Device: An arm propelled 3 wheeled chair (APTWC). It is a modified version of the hand propelled tricycle to a wheelchair - consisting of a single wheel at the front and 2 at the back. The fly wheel of the front wheel is coupled with the arm crank unit that consists of bicycle pedals by means of a chain and sprocket mechanisms. The arm crank unit is mounted at the shoulder height of the rider which is steerable. Ordinary friction type brakes are used at the front or rear wheels or both. Properly inflated pneumatic tyres are used to provide necessary comfort.
Users		n = 15 regular users of APTWC (men with paraplegia or poliomyelitis).
Method/Tool/Approach		The users were ambulated at 7 (60, 100, 136, 165, 187, 225 and 250m/min) different graded speeds in outdoor settings and the resting and ambulatory heart rate was measured during steady state with the physiological cost index and comfortable speed of propulsion ascertained. Physiological strain was characterised according to the scale of heaviness proposed by Christensen. The average heart rate of each of the seven speeds that fall within the range 75-100 bts/min may be characterised as light, 100-125 bts/min as moderately heavy, 125-150bts/min as heavy and 150-175 bts/min as very heavy. The physiological cost index was calculated at ambulatory heart rate (bts/min) minus resting heart rate (bts/min) divided by propulsion speed (m/min).
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The users were all proficient users of the APTWC for at least the last 6 years (6-17). They aged between 20 and 46. All participants performed the test except 2 who were omitted due to their reactions on the highest speed (250m/min). Their average daily use ranged from 68-136 minutes covering between 6.3 and 12.7km. The average heart rate range was 91.26bts/min at 60m/min and 160.3 bts/min at 250m/min indicating that heart rate and speed of propulsion has a linear relationship throughout the range of speeds. Propulsion to a speed of 165m/min and beyond was found to be moderately heavy in terms of physiological strain. However the authors note that Christensen's physiological strain index was based on the able-bodied individual and that 9 out of 15 participants (60%) had a heart rate above 110 bts/min at 165m/min and at that speed and above the participants experienced tiredness and fatigue. They found that the physiological cost index increases significantly above and below the speed of 120m/min, therefore this is the physiologically comfortable speed. The authors conclude that heart rate is an important parameter to evaluate ambulatory performance and that the physiological cost index can be used to determine the comfortable speed of the ambulatory aid, physical status of an individual and evaluation of performance in relation to effectiveness of the APTWC.
Researcher's Comments		Funding not addressed.

RefWorks Number: 782	**[TOOLS]**	Year/County: 2000 - Sweden
Reference		**Andren E, Grimby G. Dependence and perceived difficulty in activities of daily living in adults with cerebral palsy and spina bifida. Disability & Rehabilitation 2000; 22(7):299-307.**
Objective/Questions		The aims of the study are: 1 To demonstrate the reported use of assistance in community-living young adults with Cerebral Palsy or Spina Bifida. 2 To identify differences between the two groups of subjects in dependence and perceived difficulty in performing the various items in the Functional Independence Measure [FIM] and Instrumental Activity Measure [IAM] and to compare the rated dependence and the perceived difficulty. 3 To compare the reported use of assistance with rated dependence according to FIM and IAM.
Device/Product		Assistive Technology Devices.
Users		n = 73 persons living in the community, and who attended the special unit for rehabilitation of young adults at the Department of Rehabilitation Medicine in Goteborg. 20 with spinal bifida and 53 with cerebral palsy, aged between 20-39 years.
Method/Tool/Approach		FIM used here was in the Swedish translation, version 3.0. It has 18 items and a 7 level scale, which assesses severity of disability in six areas: self care, sphincter control, mobility, locomotion indoors, communication and social cognition. In a previous study, by the authors, seven instrumental items called the IAM were developed with a design form similar to those of the FIM using seven levels according to dependence and the need of assistance. Subjects were interviewed [semi-structured interview] by an occupational therapist in their homes about their abilities in daily life and living conditions. The interview included the subject's impairments, use of assistance and limitations in various daily activities related to living conditions, work and leisure. Ratings were performed using items from FIM and the IAM. The subjects gave an account of how they performed each item and activity during the past month and the interviewer scored the answers concerning dependence or need of assistance at the seven levels. At the same time, the subjects had to rate their own perception of difficulty for each item. Four levels were used for the subject's perceived difficulty: 'none, little, great or impossible'.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Subjects in both groups needed help in basic and instrumental Activities of Daily Living [ADL]. The ability of spina bifida subjects was more influenced in toileting, bladder, and bowel than the cerebral palsy subjects and tended also to be so in mobility instrumental tasks. More than 75% of the subjects reported use of assistance in ADL, and they needed assistance both in personal ADL and other daily activities. There was a difference between the reported use of assistance and the rated dependence according to FIM and AIM. This might be explained by FIM not including tasks as hair washing, nail cutting, for and skin care etc. FIM and IAM do not cover all aspects of significance in community-living adults. Further items have to be developed, covering personal care and occupational as well as leisure domains.
Researcher's Comments		Funding by grants from Greta and Einar Asker Foundation and the Wilhelm and Martina Lundgren Foundation.

RefWorks Number: 838	**[ORTHOPAEDIC]**	Year/County: 1999 - Sweden
Reference		Hedlundh U, Karlsson M, Ringsberg K, Besjakov J, Fredin H. Muscular and neurologic function in patients with recurrent dislocation after total hip arthroplasty: A matched controlled study of 65 patients using dual-energy x-ray absorptiometry and postural stability tests. Journal of Arthroplasty 1999; 14(3):319-25.
Objective/Questions		To assess muscular and neurological function in patients with recurrent dislocation after primary total hip replacement.
Device/Product		Hip Prostheses (no specific devices named).
Users		n = 65 patients (13 men and 52 women): 22 with recurrent dislocation post total hip arthroplasty and 43 without dislocation.
Method/Tool/Approach		A matched controlled study: comparing patients with recurrent dislocation after total hip replacement with randomly selected, stratified patients without dislocation with regard to radiographic cup position; body composition of bone, fat and muscle as determined by dual energy x-ray absorptiometry; strength in abduction and adduction; range of motion; balance; and vibration sense. All patients available between 10/1992 and 12/1994 with dislocations after primary total hip arthroplasty operated at a university hospital from 1979 were selected for study. For each patient with a recurrent dislocated total hip arthroplasty 2 control patients were randomly selected from a chronological computer register. The closest matching patients were selected with the same prosthesis and approach, the same gender, similar age (with 8 years) and the same hip disease operated on within 1 year - 1 before and 1 after the patient with the dislocation. Patients were excluded with: a single dislocation, no dislocations in the last 3 years; radiographic loose or worn cup and previous prosthetic operation, arthrodesis, hip osteotomy or Girdlestone procedure. The functional score according to d'Aubigne and Postel as modified by Charnley had been registered preoperatively in 60 of 65 patient files, and the Harris Hip Score was registered in nonrheumatoid patients operated after 09/1988. All postoperative radiographs were blindly evaluated by a radiologist except for 3 patients for whom no radiographs could be found. Dual energy x-ray absorptiometry measurements were made by the Luna DPX equipment (Lunar Corporation, Madison) and included the bone mineral density (g/cm2) of the femoral neck, the spine, arms, trunk and legs together with the total body. The physical examinations were performed by one of the authors and included active range of movement determined with a goniometer. Stability was assessed by counting the number of seconds that patients were able to stand upright with their feet together and their eyes closed (max. 60 seconds), followed by standing on 1 leg (left and right) with eyes open and closed (max. 30 seconds for each). Walking capacity was measured by the time taken to walk 30m with 1 turnaround and by counting the no. of steps required. A threshold of vibration sense was achieved by a Bio-Thesiometer (Bio Medical Instrument Company, Newbury) positioned on the left and right malleoli.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The median time between the first dislocation and the operation was 207 days (3-4610). No differences were seen between the 2 groups in preoperative assessments according to Charnley or the Harris Hip score. Radiological measurements of the socket version and inclination as well as the estimated femur position in relation to the pelvis did not differ. There were no differences in total bone mass density between the groups. The dislocated hips presented a decreased range of motion. Balance and sensitivity to vibration were impaired in the patients with dislocation, partially caused by a limited number of neurologically compromised patients in the dislocation group. No differences were found in any other variables except a subset of tall men in the dislocation group. The authors conclude that the existence of neuropathy should call into question whether revision surgery for recurrent dislocations should be performed.
Researcher's Comments		Funding not addressed.

RefWorks Number: 846	**[CARDIAC]**	Year/County: 1999 - USA
Reference		Joglar JA, Hamdan MH, Welch PJ, Page RL. Interaction of a commercial heart rate monitor with implanted pacemakers. American Journal of Cardiology 1999; 83(5): 790-792.
Objective/Questions		To investigate whether interactions occur between a commercial heart rate monitor and implanted pacemakers that might affect the function of the pacemaker or the accuracy of the monitor.
Device/Product		Cardiac pacemakers (dual chamber and ventricular devices: 8 from Medtronic, 3 from CPI and 1 from Pacesetter) and a heart rate monitor (Polar Accurex Plus, Polar Electro, Oy, Finland).
Users		n = 12 patients with permanent pacemakers.
Method/Tool/Approach		The heart rate monitor was placed around the chest of each patient. The surface electrocardiogram was recorded at all times. Evaluation for electromagnetic interference by the monitor on the pacemaker was performed using the annotated electrocardiogram obtained through the pacemaker programmer to note inappropriate inhibition of pacemaker output, abnormal tracking or safety pacing, mode switching, asynchronous pacing, switching to the noise-reversion mode and inappropriate reprogramming. Both atrial and ventricular sensing were tested in dual chamber pacemakers. Evaluations were repeated while the monitor was worn by a separate individual who stood within 2 feet of the pacemaker patient. The monitor was worn by each individual for at least 15 minutes. To evaluate the accuracy of the monitor during pacing the displayed heart rate was obtained for a minute at the programmed heart rate and beat to beat accuracy was determined by the palpable pulse. In addition the monitored heart rate was compared with the actual heart rate determined from the surface cardiogram.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		No case of pacemaker inhibition or inappropriate sensing was seen in any of the patients at any sensitivity, with either bipolar or unipolar sensing. In 1 patient with chronic atrial fibrillation when programmed to unipolar ventricular mode at a rate that was higher than the patient's predominant intrinsic rate the monitor failed to sense each of the patient's occasional intrinsic beats. This occurred only in unipolar mode at the maximum pacemaker output. In 2 patients immediately after the dual chamber device generator was programmed to the unipolar from the bipolar mode the monitor double counted for 4 or less seconds before synchronising with the electrocardiogram and regaining accuracy. This only occurred at maximum pacemaker output in unipolar mode. The authors acknowledge the study limitations as the small sample size, the fact that the heart rate comparisons were compared at rest, and that most of the pacemakers were from one manufacturer. They conclude that despite warnings to the contrary the heart rate monitor does not adversely affect pacemaker function and operates satisfactorily in patients with permanent pacemakers.
Researcher's Comments		Funded in part by Medtronic Incorporated, Minneapolis, Minnesota.

RefWorks Number: 858 [TOOLS]		Year/County: 1998 - UK
Reference		Poulson D, Richardson S. USERfit - A framework for user centred design in assistive technology. Technology & Disability 1998; 9(3):163-71.
Objective/Questions		This paper provides an overview of the concepts of user centred design and usability engineering, and shows how these concepts have been applied to develop a methodology called 'USERfit', published in 1986. This is a tool which was designed to ensure that human issues are adequately considered through the development process of an AT device.
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		It is a user-centred design methodology which provides a design framework and supporting tools tailored to the needs of the AT design community. Techniques used to gather information are described in a design manual and include- Brainstorming, Task Analysis, Interviewing Techniques and User Trials. [The USERfit methodology is described in another published document and not provided here]. A key aspect of the methodology is that it forces design issued to be made explicit, and is intended to ensure that developers justify any design assumptions they have made, either about technology or users. It is intended to be applied in a flexible manner, and different elements of this framework are likely to be applied at different times in the product development cycle. Some of the elements of USERfit include: environmental context, product environment, user analysis, user activities, product analysis, product attribute matrix, requirements summary, design summary, and usability evaluation. Once a fully working product is available, it is possible to carry out more comprehensive evaluation. USERfit assists in the planning of these activities. This includes the selection of methods for evaluation as well as establishing suitable evaluation criteria. The documentation of the results of such evaluation activities is supported, along with action points for the necessary improvement of the product before full commercial release.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Approximately 2400 copies of USERfit have been distributed. A handbook has been compiled and includes a collation of general design guidelines and more specific prescriptions taken from a number of sources, along with guidance on sources of further information and reading. A survey was done in 1998 with a sample of 114 UK developers and academics who requested the USERfit manual. 16 out of 25 who responded to a postal questionnaire and had read some part of it. 5 had made use of the methodology and 8 had used the tools and techniques, with 2 rating the methodology as being of little use. More comprehensive analysis of the data found that user analysis and task analysis was found to be most useful. A modified version was applied in the ARIADNE (1997), ACTION, TASC, HOMEBRAIN, DAILY and FORTUNE projects. The University of Loughborough is currently using the manual for the training of design and ergonomics undergraduates. Feedback from users [type of users not stated] indicated that some improvement to the tool is required if its effectiveness as a design resource in the AT sector is to be increased, although they have had relatively limited feedback. The framework has been developed to assist in the process of design communication and for this reason is likely to be of most value when used in team design work. These can include multi-disciplinary design teams involving different design experts, and those containing end user representatives. The authors acknowledge the criticism that there are too many paper based forms to complete and that a simplified methodology with an online tool for completing design forms could improve the usability of the product considerably. A more realistic scenario for use might be for developers to apply only those aspects which they found to be useful in a given design scenario.
Researcher's Comments		Funding not addressed.

RefWorks Number: 875 [TOOLS]		Year/County: 1998 - Sweden
Reference		Garellick G, Malchau H, Herberts P. Specific or general health outcome measures in the evaluation of total hip replacement. A comparison between the Harris hip score and the Nottingham Health Profile. J Bone Joint Surg Br 1998; Jul; 80(4):600-6.
Objective/Questions		To assess patients with a primary total hip replacement using the Harris Hip Score and the Nottingham Health Profile at 1, 3 and 5 years post surgery and compare the specific and general outcomes measures in evaluating total hip replacement.
Device/Product		Hip Prostheses: 2 cemented prostheses (Charnley and Spectron) and 2 uncemented prostheses (Harris Galante I and PCA).
Users		n = 100 patients (gender not stated).
Method/Tool/Approach		Prospective study: 54 patients had a cemented total hip replacement and 46 an uncemented prosthesis. Both groups were cohorts of larger prospective and randomised studies comparing 2 cemented and 2 uncemented systems. The groups were classified into clinical categories according to Charnley (A describes unilateral disease, B bilateral disease and C multiple joint disease or other disabilities impairing walking). Patients were examined before operation and at 1, 3, and 5 years after. An independent physiotherapist performed the clinical follow up. At each review the Harris Hip Score (HHS) and Nottingham Health Profile (NHP) were administered and patients were asked if they were satisfied, uncertain or dissatisfied with the operation and an anteroposterior radiograph of the pelvis and lateral views of the hip were taken.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Eight patients died and 2 hips were revised within the 5 year period. The mean HHS before surgery was 38 (8-76) and the mean pain score 12 (0-30). The lowest HHS was for category C patients. The most pronounced problems were with pain, energy and mobility. 1 year after surgery the mean HHS was 88 (61-100) and the mean pain score 42 (20-44). The patients had progressed within all aspects of the NHP part 1. There was significant improvement in all items of the activities of daily living. At 3 years the results for both methods of assessment were similar to those at 1 year. At 5 years the mean HHS was 89 (44-100). According to the Harris definition of success 78% of the patients were classified as good or excellent. The gain in quality of life continued over the 5 years and was not affected by the length of follow up. The global score varied significantly between categories A and C. The HHS had a strong correlation with the NHP global score at the follow up at 5 years. Within the 2 groups there were no differences in either HHS or NHP global score between the different implants. When the cemented and uncemented groups were compared the HHS and the NHP global score differed significantly but there were no differences in the pain score or in overall satisfaction. 5 implants were loose at 5 years. None of these patients had clinical symptoms. The authors conclude that the HHS and the NHP correlated well with each other and were both heavily influenced by the Charnley system of classification. Both scores reflected general health and function but were not able to detect subtle differences in the performance of 2 different types of hip replacement at 5 years. They call for a short, simple and internationally standardised hip score.
Researcher's Comments		No benefits were received from a commercial party related directly or indirectly to the subject of the article.

RefWorks Number: 878	**["OUT OF THE MOULD"]**	Year/County: 1998 - USA
Reference		Bauer SM, Lane JP, Stone VI, Unnikrishnan N. The voice of the customer - Part 2: Benchmarking battery chargers against the consumer's ideal product. Assistive Technology 1998; 10(1):51-60.
Objective/Questions		Description of a method for systematically transforming end-user requirements into a form that is useful and accessible to product designers, manufacturers, and vendors. In particular, product requirements, importance weightings, and metrics are developed from the Consumer Ideal Product [CIP] battery charger outcomes.
Device/Product		Assistive Technology Devices: Battery Chargers (Six Types) for Wheelchairs (from Invacare, Lester, Schauer, Exide, Soniel, and Pride-MRC).
Users		Process of analysing the battery charger outcome and transforming these outcomes into QFD form involved a cross functional team of : 2 electrical engineers, a marketing specialist, a CIP focus group moderator and a qualitative methods specialist. n = 100 consumers with at least 3 year's experience using battery chargers completed a survey generated from the focus group containing more that 150 battery charger characteristics, grouped under the 11 evaluation criteria. Respondents rated them on a 7-point scale of ideal device importance.
Method/Tool/Approach		In part 1 of this series of two articles the method for capturing the expectations 'voiced' by end users regarding assistive devices was described- the CIP program. The CIP program draws heavily on concepts from the Quality Function Deployment [QFD] and Kano's Focus Group Model. QFD is a customer-centred, product-planning tool that provides a systematic framework for the concurrent integration of consumer, market, technical, production and other factors. The methodology helps companies focus their design efforts on product requirements having great importance to the customers. Thus companies save on their design efforts and production costs by eliminating or reducing their attention to product requirements having little importance to the customers. A critical assumption of the QFD is that all the important product requirements and requirement weights have been obtained. The Kano Focus Group Model provides a framework for examining this issue. Under the Kano model, a focus group is considered to be 'complete' only if three types of product requirements are elicited from and discussed by focus group participants. Expected product requirements are normally unspoken or 'too obvious'. Revealed product requirements are normally spoken and refers to 'day to day concerns' that seem important. Exciting product requirements are normally unspoken because they involve unknown concepts or ideas that appear to be 'too far fetched'. The CIP consumer team uses 11 'device evaluation criteria' (e.g. repair, manuals, warranties, performance..) that are framed in non-technical terms, as a framework for obtaining and organizing consumer input. Consumer input is obtained in 3 steps: 1) Experienced end users of the device operationalise the 11 criteria in focus group sessions. According to their own perception of what each criterion implies, they identify device characteristics or features grouped under the 11 criteria. 2) These input statements are examined and organised into a survey format, with appropriate modifications. 3) A larger, national sample of experienced device users then responds to the survey and judges the statements as to their fitness into 'ideal' device characteristics on an agreement/disagreement scale. They also rank the criteria themselves in order of their perceived importance for that particular device.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		13 device dependent categories were produced for the battery charger. The categories broadly focused on issues most important to vendors, manufacturers or product designers. Two were vendor focused: purchase, replacement and repair. Three were manufacturer-focused: testing, warranties, and manuals. Eight were product designer-focused: gauges, connectors, safety, physical description, switches, durability, cords and performance. The cross-functional team screened all statements and distilled them down to 49 statements useful for benchmarking purposes. Then the benchmark metrics were obtained for the statements by finding the product of the statement weight and the scaling factor [a fraction of the full product weight requirement assigned, given that a specific condition is satisfied]. 68% of CIP survey statements were not used for benchmarking which addressed many issues important to product design, vendor support, and manufacturers. This is because the CIP study was not guided by the necessities or rigor of the QFD or Kano methodology. The results from the six battery chargers suggest improvements for each product's design, service and support. Overall, the six chargers meet roughly 45-75% of the ideal product's requirements. Many of the suggested improvements are low-cost changes that, if adopted, could provide companies a competitive advantage in the market place. The majority of deficiencies relate to product design rather than manufacturer or vendor policies. Out of the eight product design categories, the six chargers fully satisfied only the user benchmarks for durability. The users concerns across the other six product design categories are not fully addressed by any of the chargers evaluated. Battery chargers are very reliable devices, yet end users still placed high importance on having service arrangements with vendors. Vendors may see an opportunity to increase their value to manufacturers and customers alike by feeding back unmet consumer expectations to the manufacturers and hence product designers. With the exception of the Schauer charger, warranty policies were of insufficient length. Given that battery chargers are very durable, warranty length might be increased with little cost to manufacturers. The product literature and manuals provided to end users do not provide appropriate and sufficient information. Manufacturers could improve their products by including test, safety, operation, hazard, and other information. This work relies upon the consensus and expertise of a cross-functional team to define device dependent categories and distribute product requirements into these categories. More sophisticated approaches to qualitative data analysis may be explored in future work.
Researcher's Comments		Funded by the National Institute on Disability and Rehabilitation Research of the Department of Education under a grant.

RefWorks Number: 913	**["OUT OF THE MOULD"]**	Year/County: 1997 - Germany
Reference		Schneider A, Leyrer M, Albegger K, Doring WH. Assessment of auditory skills in hearing-impaired children: Theoretical foundations and a practical approach. American Journal of Otology 1997; 18(6 SUPPL.): S81-2.
Objective/Questions		To describe theoretical foundations and methods for the assessment of auditory skills in hearing impaired children with cochlear implants or hearing aids.
Device/Product		Hearing Devices: cochlear implants and hearing aids (no specific devices named).
Users		Not stated with how many children these tests were developed.
Method/Tool/Approach		Two exemplary tests are described whereby acoustic stimuli and answering tasks are been chosen according to the needs of hearing impaired children in the age range of 3-6 years of developmental age. The Salzburger Seven Sound Test: is a phoneme identification test with 3 different degrees of difficulty. 7 phonemes are presented to the child via live voice with prosodic support. For example a box is opened and its contents shown to the child with a surprised "aaaa". When the child is familiar with the phonemes the therapist presents acoustically without visual support. They state that this test proved possible for children from 2.5 years of cognitive age. The Monosyllable Identification Test: is a computer based test. It is a modified version of one subtest of the Early Speech Perception Test adapted to German language. All words begin with b and have consonant-vowel-consonant structure. A cartoon mouse moves its arm showing the child what to do: 1) touching another cartoon figure who is then opening its mouth to speak the word 2) listening to the acoustic stimulus or 3) touching one of the picture cards to identify the spoken word. Each word is presented 3 times. The child's answers are stored automatically and tests show that this is appropriate for children from 3.5 years of cognitive age.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The authors argue that with such defined assessment tests of auditory skills the performance profiles of hearing children, children with hearing aids and cochlear implants can be mapped.
Researcher's Comments		Supported by the German Federal Ministry of Education, Science, Research and Technology.

RefWorks Number: 930 [TOOLS]		Year/County: 1997 - Sweden
Reference		Barck AL. Agreement among clinical assessment scales for knee replacement surgery. Knee 1997; 4(3):155-8.
Objective/Questions		The analysis of the 'performance variability' of 15 different knee assessment scales after knee replacement was analyzed.
Device/Product		Knee Prostheses.
Users		n = 52 patients admitted from a 10 year follow-up of 104 patients operated consecutively with compartmental knee arthroplasty carried out in 1985. 36 women and 16 men. Median age 75 years, interquartile range of 65-79. A complete follow-up was made of 103 knees. Among the excluded 52 patients, 44 were dead, 6 refused to be examined, some felt it was meaningless because the knee was very poor=3, very good=1 or 2 felt to ill to participate. And, 2 could not talk. Osteoarthritis afflicted 37 and rheumatoid arthritis 15 patients. n = 1 orthopaedic surgeon with 10 years clinical experience.
Method/Tool/Approach		15 knee evaluation systems [revealed in a literature search and that could be utilized in this study] were applied to the same sample of a cohort of patients, most of them with a compartmental knee replacement in one or both knees. Where applicable, both knees were included to broaden the spectrum of clinical manifestations and increase the challenge to the assessment systems. The same orthopaedic surgeon carried out all the examinations in a standardised way. To be able to compare the different rating systems a common scale was developed. The aggregated arithmetical overall score for each rating system was standardized and normalized to a T-score with a mean of 50 and a Standard Deviation of 15. Non-parametric descriptive statistics and stochastic tests interpreted with two-tailed probabilities were used. A factor analysis was carried out to explore if the indexes reflected a small set of common underlying factors.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		To explain the underlying structure at least six factors had to be considered. This meant an unwanted heterogeneity. The six underlying factors showed a pattern suggesting that the 15 indices (tools) could be reduced to 6 or 10 indices by clustering. The results varied from 16% to 81% depending on the choice of index. These results suggest there is a great need for studies of the conformity and consistency of the knee replacement evaluation systems. The results contradicted the opinion that the outcome differences between knee evaluation systems are small. The notion that different knee evaluation systems measure different underlying factors was supported. More detailed operative specifications for the different systems were suggested as a first step to decrease the variability among assessment systems. Reasons given for the wide spread of the results was: different demarcation of categories, the indices measure different factors, poor operating instructions.
Researcher's Comments		Funding not addressed.

RefWorks Number: 934	**["OUT OF THE MOULD"]**	Year/County: 1997 - USA
Reference		Sheredos SJ, Cupo ME. The Department of Veterans Affairs Rehabilitation Research and Development Service's Technology Transfer Process. Technology & Disability 1997; 7(1-2):25-9.
Objective/Questions		To describe the Department of Veterans Affairs Rehabilitation Research and Development Service's technology transfer process.
Device/Product		Assistive Technology Devices.
Users		Not stated with how many users this process has been developed and utilised.
Method/Tool/Approach		The Department's technology transfer section implements a proactive process that incorporates aspects of manufacture, evaluation and if deemed appropriate commercialisation. This proactive mechanism can: 1) provide resources to accomplish manufacture of pre-commercial models 2) conduct national clinical evaluation studies to validate the product's success in meeting an identified need and 3) define readiness for commercial production. The ultimate goal is timely transition of prototype developments into commercially viable products and techniques that can be readily available and accessible to benefit veterans and non-veterans with disabilities. This is accomplished through the funding of R&D proposals that will improve treatment, management and rehabilitation of veterans within the following defined priority areas: prosthetics, amputations, orthotics; spinal cord injury; sensory, cognitive and communication aids; and ageing. The process attempts to bridge the gap with the manufacturing sector by use of the procurement contract to purchase pre-commercial models as an enticement to attract companies. A national clinical evaluation on these models is then performed to validate the product or technique's success in meeting the specified clinical need, and defining readiness for commercial production and marketing. The manufacturer is identified in the early stages and is committed to the future production and marketing of the product/technique.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Products that have evolved through the process include: Synergetic Prehensor (a myoelectric powered upper extremity prosthesis), AdVAntage Arm (a body powered above elbow prosthesis that allows independent terminal device and elbow function), a modular electromechanical lock actuator (to assist individuals with high level above elbow amputations who experience difficulty in operating existing manual elbows) and the Franklin Applied Physics cover for lower and upper limb prostheses. A large part of successful technology application relies primarily on effective mechanisms that help bring emerging research and development prototypes from the lab into the commercial marketplace. The Department's technology transfer process offers a unique approach to breaking through the barriers facilitating new rehabilitation technology being available to veterans, and the entire population, with disabilities. The process begins and ends with a clinically defined need and in turn can significantly improve the availability of products and techniques with the potential outcome to impact the lives of individuals with disabilities. The authors conclude that "locking-in" a manufacturer early in the process and utilising clinical evaluation from an objective environment, apart from the developer's lab, are major elements that assist in ensuring the process can affirm market opportunity for the final product.
Researcher's Comments		Funding not addressed.

RefWorks Number: 994	**["OUT OF THE MOULD"]**	Year/County: 1996 - USA
Reference		Hefzy MS, Nemunaitis G, Hess M. Design and development of a pressure relief seating apparatus for individuals with quadriplegia. Assistive Technology 1996; 8(1):14-22.
Objective/Questions		Design and build an affordable pressure relieving device that is adaptable for wheelchairs, and which allows individuals with quadriplegia [C5 or C6 spinal cord injury] to relieve the pressure from the ischial tuberosities.
Device/Product		Mobility/Seating Device: Pressure relieving seating. The system uses inflatable air cushions.
Users		n = 1 - a person with C6 quadriplegia, who had frequent breakdowns [pressure ulcer development] on his buttocks beneath his ischial tuberosities. 35 year old male, who used a manual wheelchair. He relied on others to tilt back his chair to help him relieve the weight on his buttocks. When others were not around, he threw his body forward to try to shift his weight forward off his ischial tuberosities.
Method/Tool/Approach		Case study & Usability Test. Four methods were considered to allow the person with quadriplegia to relieve the pressure on the ischial tuberosities. These include (1) elevating one side of the buttocks at a time (2) reclining the entire body by either reclining the back of the wheelchair or reclining the whole chair (3) lifting the entire body completely out of the seat just enough to raise the buttocks of the seat, and (4) finally returning the individual to the seated position after he has thrown himself forward out of the seat. Different mechanical systems were considered in order to adapt each of these methods. Each method was judged on 10 specific criteria using the Pugh method. This method was used primarily to select the most practical design concept without building and testing the other concepts. It involves an iterative process that is repeated again and again. During each repetition, the better concepts are carried forward with the best one at each step selected as the datum for the next iteration. The evaluation process ends when it is no longer possible to improve the best concept. The 10 criteria used to judge each idea: 1) Does it relieve the pressure? 2) Does it provide the person with quadriplegia with exercise? 3) Is it safe? 4) Is it affordable 5) Does it interfere with other wheelchair functions? 6) Can it be used independently by the person with quadriplegia [user]? 7) Can it be instrumented on a standard manual wheelchair? 8) Is it too heavy/bulky/large? 9) Is it simple to install and remove from the wheelchair? 10) Does the system need to be maintained frequently or is it reliable? This means the best solution was found and the inflatable air cushion using a pneumatic system was selected. After completing the first generation prototype several improvements became evident and a second generation prototype was designed. Then the prototype was tested by the user.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	Prototype testing.
	Production	X
	Deployment	X
Conclusions		A Pneumatic system utilising two inflatable air bladders was employed. One cushion was placed under each buttock and inflated separately to tilt the user from one side to another. The inflated cushion elevates on side of the buttock, which relieved the pressure from the other side. The user did 20 repetitions [5 more than was calculated] of flexion of each elbow to pump each cylinder until 10psi was reached in the storage cylinder, which took 5 minutes. He was then able to flex his elbow to fill the cushion under his right ischial tuberosity to 2 inches and after one minute to depress the switch and then elevate the right side. This procedure was repeated four times in a 1-hour trial. Following each 1-hour, the skin of his buttocks was examined and no breakdown was noted. A pressure monitor and a 2.5cm sensor was placed under each ischial tuberosity, one at a time, to monitor the interface pressure during the trials. The subject demonstrated independent pressure relief without the assistance of another person. He was also able to transfer on and off his chair without any problems. The arm rest with an air pump attached to it was simply swung away for easy side-to-side transfer, but the latch to release the arm rest had to be released by another person. The authors report that the system is functional, simple, easy to use, affordable [~$1600, less than an electric wheelchair], and provides independence.
Researcher's Comments		Supported in part by a grant from Aiding the Disabled Program of the Bioengineering Division of the National Science Foundation.

RefWorks Number: 1045 [TOOLS]		Year/County: 1995 - USA
Reference		Curtis KA, Roach KE, Brooks Applegate E, Amar T, Benbow CS, Genecco TD, et al. Development of the Wheelchair User's Shoulder Pain Index (WUSPI). Paraplegia 1995; 33(5):290-3.
Objective/Questions		This article describes the development of the Wheelchair User's Shoulder Pain Index [WUSPI], a shoulder pain index designed to measure the severity of shoulder pain associated with functional activity in individuals who use wheelchairs.
Device/Product		Mobility Device: Wheelchairs.
Users		n = 64 subjects drawn from a group of more than 400 athletes attending a large wheelchair athletic event for paralyzed veterans. They used a wheelchair as their primary means of mobility and used their wheelchair for at least one year. Subjects ages ranged from 23 to 68 years, 62 men and 2 women.
Method/Tool/Approach		Instrument Development: A 38 item index was modelled after the Shoulder Pain and Disability Index [SPADI, 1991] which created and measured 2 dimensions: (1) Difficulty associated with shoulder problems during functional activities and (2) Shoulder pain with functional activities in individuals who use wheelchairs. The SPADI was modified by including common functions and activities of daily living performed by the wheelchair user, drawn from a comprehensive literature review. To establish content validity, a group of long term wheelchair users were asked to review the authors list of selected wheelchair activities and to suggest additional functional activities associated with chronic shoulder pain. A 10cm visual analog scale [VAS] anchored at 'no difficulty' and 'so difficult require help' was used to measure the 19 items addressing the difficulty dimension during functional activities. An identical VAS anchored at 'no pain' and 'worst pain ever experienced' was used to address the 19 items addressing the pain dimension during functional activities. Thus, the lowest possible score for each item was zero and the highest was 10. A demographic questionnaire was developed to identify factors relevant to the subject's lifestyle and shoulder dysfunction, including items to assess age, gender, marital status, occupational and recreational activities, nature of their primary disability, and years since the onset of their disability. Medical history data collected included the presence or absence of past or current shoulder pain, the shoulder(s) involved, treatment received, and presence of other hand and elbow dysfunction. Subjects: All subjects were given instructions for completion of the instrument. Experimenters were available to answer any questions the subjects had regarding the wording on the index. Subjects took approximately 10 minutes to complete the index.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Internal consistency of the 38-item pilot questionnaire was calculated using Cronbach's Alpha. The index demonstrated high internal consistency, as did each of the difficulty and pain dimensions. Re-analysis of internal consistency of the 15-item final WUSPI showed that Cronbach's alpha was unchanged following the revisions. Individual item analysis revealed that the subjects in this study experienced the most shoulder pain when wheeling up an incline or on outdoor surfaces, when lifting an object from an overhead shelf, when trying to sleep, when transferring from tub to wheelchair and when washing their backs. The WUSPI is easily administered as a paper and pencil measure, which can be completed in person or by mail. Completion takes only 5 minutes. Because of the instrument's simplicity, the authors suggest that it would be easily translated into other languages and the visual analog scale eliminates the need to label an ordinal scale with multiple descriptors. The WUSPI is a valuable tool that can be used to detect and monitor upper extremity musculoskeletal complications in wheelchair users. It provides unique information, in that it measures pain across a variety of functional activities which are specific to wheelchair users. It differs from functional scales in that it measures subject change in individuals with chronic disabilities who are functioning independently, but with difficulty, due to problems such as pain or limitation of range of motion. This instrument is able to detect even small levels of shoulder pain, in a way that is practical and relevant to this population and their health care consultants.
Researcher's Comments		Funded in part by the Florida Paralyzed Veterans of America.

RefWorks Number: 1086	**[TOOLS]**	Year/County: 1994 - Sweden
Reference		Oberg U, Oberg B, Oberg T. Validity and reliability of a new assessment of lower-extremity dysfunction. Physical Therapy 1994; 74(9):861-71.
Objective/Questions		In this study, a 20-variable assessment system of the lower extremity was constructed, which incorporates special consideration of the needs of the therapist and covers impairment, disability and handicap according to the WHO classification.
Device/Product		Hip & Knee Prostheses.
Users		n = 105 patients referred to the orthopaedic clinic [Sweden] and accepted for total joint arthroplasty due to osteoarthritis of the hip and knee were evaluated pre-operatively with the assessment system. 37 men, 68 women, mean age 69 years. Most of the patients selected for surgery had a radiographically confirmed osteoarthritis of degree III [on a four grade scale] or disabling pain at rest.
Method/Tool/Approach		The assessment system consists of the evaluation of 20 variables, subdivided into five groups by the authors according to clinical knowledge: hip impairment, knee impairment, physical disability, social disability [handicap], and pain with a 5-point scale. Each variable is given a disability score on a 5-point scale according to a key for each variable. Zero means no reduced function, a score of 4 means severe dysfunction or total lack of function. The scores are plotted on a diagram, thus giving a profile that shows the functional reduction in every variable. The rating is done by a physical therapist in a standardised manner. Procedure: All the patients were tested by a physical therapist. The first 42 patients were measured by 2 independent physical therapists, this formed the basis for testing inter-tester reliability. Active range of motion in the hip and knee was measured with a standard manual goniometer. The tests were performed according to routines recommended by the American Academy of Orthopaedic Surgeons. Muscle strength, tested as isometric extension and flexion forces in the knee, was measured with a dynamometer at 45 degrees of knee flexion and with the patient in a sitting position. A cuff was applied to the leg 16cm distal to the knee joint space. The cuff was connected to the dynamometer via a cord running perpendicular to the leg. Maximum force was read from a display on the recording equipment. The subject was tested in a sitting position, with the knee at 45 degrees of flexion. Rising/sitting down was recorded as the lowest possible sitting height from a chair with adjustable height and without armrests. Step height was measured using a platform with different step heights, corresponding to ordinary stairs, bus and train stairs etc. Gait speed was tested on a 65m indoor walkway. The social variables were evaluated by a personal interview of the patient. Pain was evaluated in a manner related to standard clinical evaluation [quantitative and qualitative] of the reason for operation. The test results were converted to scores according to a special key explaining how to grade the measurements. The scores were plotted in a diagram, thus constituting a personal profile of lower extremity dysfunction. The total time needed to complete the profile was about 30 minutes.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The factor analysis indicated a factor solution consistent with the primary grouping except for 2 variables. The correlation between two independent physical therapists was 0.99 to 1.00 for different variables, indicating excellent intertester reliability. In the author's opinion, the new assessment system provides a reasonably valid, reliable, inexpensive, and easy-to-use measurement and fulfils the needs of the physical therapist for functional evaluation of the lower extremity. [Traditionally, physical status measures include goniometry, muscle force measurement, radiographic examination and so forth. The authors believe however, that the results obtained with such measures, to reflect relevant aspects of quality of life, should also be related to the physical and social ability of the patient.] Neither the choice of variables nor the monitoring of data is unique, but to our knowledge this type of profile is new in physical therapy.
Researcher's Comments		Supported by a grant from the Research Committee, County Council of Jonkoping. Definitions: Content Validity- if an assessment system has enough relevant items and adequately covers the domain under investigation. Construct Validity- if the assessment system properly reflects the theory behind the measurement.

RefWorks Number: 1126 [AUDITORY, OPTHALMIC & ORBITAL]		Year/County: 1992 - Canada
Reference		Davis PL. Comparison of function and fixation of small incision circular and oval poly (methyl methacrylate) intraocular lenses. Journal of Cataract & Refractive Surgery 1992; 18(2):136-9.
Objective/Questions		To compare the function and fixation of small incision circular and oval polymethyl methacrylate intraocular lenses.
Device/Product		Intraocular lenses: a 5mm circular optic (Pharmacia 740P), 14mm length lens; and an oval 5 x 6mm optic (IntraOptics SP18UB), 12.75mm lens.
Users		n = 40 patients (gender not stated.)
Method/Tool/Approach		A prospective study: 20 consecutive patients were implanted with each design and were surveyed 3 months post surgery for function: 1) best corrected Snellen distance acuity; 2) Miller-Nadler glare testing; 3) subjective awareness of glare at night and fixation; 1) did any implant show any clinical decentration? 2) was there a space between implant and posterior capsule? 3) did Soemmering's rings form? Inclusion criteria: 1) they had successful small incision phacoemulsification via an intact continuous curvilinear capsulorhexis 2) they were at least 55 years of age 3) their pupils did not dilate excessively prior to surgery.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Satisfactory visual acuity (all patients achieved 20/25 to 20/40 best corrected visual acuity) and absence of motor vehicle glare was found in all patients. 1 glare disability of 35% occurred in a patient with an off centre capsulorhexis that formed a Soemmering's ring partially posterior to a circular optic lens. Fixation was clinically central in all patients. A space between optic and posterior capsule persisted in 7 eyes with an oval optic lens and in 8 eyes with a circular optic lens. Therefore both designs were associated with a "no space no cells" situation that should decrease pearl formation. Total Soemmering's rings formed posterior to 9 of 20 circular optic lenses if the capsulorhexis was 5mm or larger in diameter (only 1 oval optic lens formed a Soemmering's ring). Compression of the posterior capsule occurred in 7 of the 9 patients with circular optic lenses and total Soemmering's rings. The author concludes that the circular optic design is best implanted via a 5mm or slightly larger central capsulorhexis to promote both Soemmering's ring formation and posterior capsule compression, and that both designs provide satisfactory clinical results.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1157	**[CARDIAC]**	Year/County: 1992 - Canada
Reference		Newman D, Dorian P, Downar E, Harris L, Cameron D, Waxman M, et al. Use of telemetry functions in the assessment of implanted antitachycardia device efficacy. American Journal of Cardiology 1992; 70(6):616-21.
Objective/Questions		To evaluate the use of telemetry functions to assess the efficacy of an implanted antitachycardia device.
Device/Product		Guardian model 4210 implanted defibrillator (Telectronics Pacing Systems, Sydney, Australia). The device delivers a monophasic, truncated, exponentially decaying, defibrillatory shock and uses 2 screws in epicardial leads or a transvenous endocardial lead for sensing and anti-tachycardia pacing. The device's telemetry capabilities include both stored and real time display of endocardial and device circuit signals.
Users		n = 20 patients with recurrent ventricular arrhythmias (gender not stated).
Method/Tool/Approach		Patients were treated between 12/1989 and 09/1991 with an investigational, implantable combined antitachycardia pacing cardioverter defibrillator and followed up at 2 month intervals. All patients had epicardial patches implanted. Electrophysiological studies were performed 5 to 7 days post surgery.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	Testing of a device.
	Production	X
	Deployment	X
Conclusions		The patients had a mean age of 50 (10-70). 13 had coronary artery disease, 2 idiopathic dilated cardiomyopathy, 1 primary electrical disease, and 4 nonobstructive hypertrophic cardiomyopathy. There were no intraoperative complications. 1 patient undergoing device replacement developed wound infection at the generator site within 30 days of surgery. The cultures grew S epidermidis and the device and all leads were explanted. At testing before 5-7 days postoperatively 26 episodes of induced ventricular tachycardia were treated with pacing in 10 patients. Antitachycardia pacing was successful in 24 of 26 episodes, 2 induced tachycardia episodes were successfully treated with a cardioverting shock. Patients were followed up post discharge for a mean of 10.1 months (1-17). During follow-up the device was used in 11 of 20 patients. In the entire group antitachycardia pacing was activated on a mean of 44 occasions per patient with shock delivery occurring on 8 occasions (mean) per patient. 26% of shocks were not appropriate and were due to atrial arrhythmias in 2 patients and dysfunction of the sensing lead in 3. Antitachycardia pace acceleration occurred in 5.3% of cases, 7% of attempts at pacing were unsuccessful and needed shock therapy. The authors conclude that enhanced telemetry in newer devices enables more accurate assessment of device use and enhanced diagnosis of inappropriate therapy delivery.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1163	**[TOOLS]**	Year/County: 1992 - USA
Reference		Johanson NA, Charlson ME, Szatrowski TP, Ranawat CS. A self-administered hip-rating questionnaire for the assessment of outcome after total hip replacement. Journal of Bone & Joint Surgery (Am) 1992; 74(4): 587-97.
Objective/Questions		Testing of a self-administered hip-rating questionnaire, developed specifically for the assessment of patients who have arthritis of the hip. The purpose of this paper is to present the questionnaire and report on the validation of its use in a prospective study of patients who had a total hip arthroplasty.
Device/Product		Hip Prostheses.
Users		n = 98 patients who were to be managed with total hip replacement because of arthritis, and who had not had a previous operation on the hip, and in whom the arthritis was not secondary to known trauma. Patients were recruited from private offices and from hospital clinics. The resulting cohort was composed mainly of patients from private practices. The study was performed within the larger context of a prospective study, with recruitment beginning in 1987. Mean age 65, with a range from 21 to 91 years, 61 women and 37 men. n = 4 surgeons carried out the operation/procedures.
Method/Tool/Approach		The hip-rating questionnaire is divided into four equally weighted domains: global or overall impact of the arthritis, pain, ability to walk, and ability to perform daily functions. A maximum of 25 points is possible in each domain. A score can range from 16 points- worse to 100 points-best. The response is continuous [recorded on a visual analog scale] in the global domain and ordinal in the other three domains [pain, walking, and function]. The 98 patients completed the hip-rating questionnaire and the Arthritis Impact-Measurement Scales before the operation and three months after the procedure. All patients in the cohort were followed up for at least three months, and sixty-two patients were followed for at least six months, and forty-two patients were tested at one year. The fact that fewer patients were evaluated at six and 12 months due to some patients being enrolled in the study too recent to have been due for either 6 or 12 months follow up. The reproducibility of the results of the hip questionnaire was tested by repetition of the test after two weeks by fifty patients whose condition was clinically stable. The paired tests were given before the operation. The arthritis impact-measurement scales were also given at the same time that each hip rating questionnaire was administered, the order of the two tests was randomized for the initial administration of the tests, and the tests were given in the same order to that patient two weeks later. Reproducibility was calculated using the kappa statistic. Validity was tested for each domain independently. The results of the visual analog scale [overall impact of arthritis] were correlated with the results of the visual analog scale for the global impact of arthritis in the arthritis impact-measurement scales. The result of the pain domain was also compared with the score for pain according to the arthritis impact-measurement scale. Assessments of the distance that the patient could walk and the results of a six minute walking distance test were compared at three months before the operation, and six months and twelve months after the operation. To test for responsiveness preoperative scores were compared with the follow-up scores, and the within-patient change. The questions in the hip-rating questionnaire were formulated after a review of other hip scales and after discussions with experienced hip surgeons regarding the relative importance of each issue that was addressed by the scales. Questionnaires were also sent to 50 orthopaedic surgeons, asking them to address the later issue.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Reproducibility: was tested with the use of kappa statistic in fifty patients whose condition was stable clinically, and it was found to be good or excellent both for individual questions and for the total score. Validity: the result of the six-minute walking-distance test correlated with the patient's response concerning walking distance on the hip-rating questionnaire. The score for pain from the hip-rating questionnaire correlated well with the score for pain from the arthritis impact-measurement scales, and the total score from the hip-rating questionnaire correlated well with the total score from the arthritis impact-measurement scales. Responsiveness: The total score averages 56.8 +/- 12.9 points preoperatively and 80.2 +/- 14.2 points at three months. The mean total score continued to increase until six months, when it was 87.2 +/- 11.4 points, and it was about the same at 12 months [88.1 +/- 12.6 points]. The authors determined that a difference of 12 points in the total score was clinically important. At three months, 80% of the patient in this study had an increase in the total score of 12 points or more, compared with the preoperative score. The score on the hip-rating questionnaire was responsive to the change in the clinical condition of the patient, as indicated by a favourable index of responsiveness. The results of the questionnaire were sensitive enough to demonstrate differences among treatment groups with relatively small sample sizes. This questionnaire has the characteristics of a useful instrument for assessment of outcome, such as that after an operation. The hip-rating questionnaire is not intended to replace professional clinical evaluation, and it must be studied further by means of a comparison of the recorded responses and clinical data. Radiographic evaluation must be included in the assessment of outcome.
Researcher's Comments		Funded by a grant from the National Institutes of Health Arthritis and Musculoskeletal Diseases Center. "…No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. Funds were received in total or partial support of the research or clinical study presented in this article…"

RefWorks Number: 1185 [AUDITORY, OPTHALMIC & ORBITAL]		Year/County: 1991 - USA
Reference		Egbert PR, Buchanan M. Results of extracapsular cataract surgery and intraocular lens implantation in Ghana. Archives of Ophthalmology 1991; 109(12):1764-8.
Objective/Questions		To evaluate the results of extracapsular cataract extraction with posterior chamber intraocular lens implantation in an outpatient clinic in Ghana.
Device/Product		Intraocular lenses (no specific devices named).
Users		n = 49 patients (22 men & 27 women), n = 5 surgeons (all American and had trained in the USA).
Method/Tool/Approach		Patients after surgery underwent an eye examination and an interview related to activities of daily life. Preoperative visual acuity was counting fingers or worse in all but 1 patient. Patients were followed up for 12 to 29 months to observe the occurrence of complications after the initial postoperative period. Patients who had undergone cataract surgery at least 12 months previously in one centre and lived within 32km of the clinic were eligible. Of 288 patients who had undergone cataract surgery between 07/1988 and 12/1989 77 were from the study area. 64% (49) of the 77 eligible patients were able to be contacted and all agreed to participate. Preoperative refractions could not be performed because of the dense cataracts, and biometry was not available therefore intraocular lenses were randomly selected. At times low and high power lenses had to be used because no standard power lenses were available. A psychologist and a trained Ghanian clinic administrator conducted the interviews, which covered demographics, the patient's subjective opinion of visual improvement, and questions about activities of daily living adapted from previous studies. The eye examination included determination of visual acuity, refraction, slit-lamp examination, Schiotz tonmetry, and dilated retinal examination by indirect opthalmoscopy. The refraction was performed by a Ghanian optometrist who used trial lenses to obtain a best spherical equivalent correction. The rest of the examination was performed by the first author.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The patients ranged in age from 25 to 88 years. The mean length of time from surgery to follow-up examination was 16.4 months (12-29). Visual acuity improved in 44 patients (90%) after surgery. 26 patients (53%) had a corrected visual acuity of 20/40 or better, 11 (22%) had a corrected visual acuity of 20/50 to 20/100 and 12 (25%) had a corrected visual acuity of 20/200 or worse. Compared with the preoperative status, visual acuity without correction improved in 41 patients (84%), remained the same in 5 (10%), worsened in 3 (6%); with correction, the visual acuity improved in 44 patients (90%), remained the same in 3 (6%) and worsened in 2 (4%). Subjectively 94% of patients believed their vision improved after surgery. Intra-operative complications included vitreous loss (in 5 patients), posterior capsule rupture, and iris prolapse. Several postoperative complications were noted. The most serious was diffuse corneal oedema in 4 eyes. Glaucoma developed in 2 of these eyes. Other postoperative complications were minor and included 2 cases of updrawn pupil, 1 case of vitrous in the anterior chamber, wound problems, iris prolapse, endophthalmitis and retinal detachment. The intraocular lenses were well tolerated except for: 1 anterior chamber device decentred, folding the iris and was removed; 1 posterior chamber device decentred by 2mm; and 1 posterior chamber device was partially anterior to the iris. No major late complications occurred following the immediate postoperative period. None experienced complications attributable to the outpatient format of the surgery. The authors conclude that outpatient surgery may be a safe and practical alternative to in-patient surgery in developing countries.
Researcher's Comments		Supported by the Elizabeth Butterway Fund and the Elsie B. Ballantyne Fund (private funds, Stanford University) and an unrestricted grant from Research to Prevent Blindness Inc, New York.

RefWorks Number: 1202 [ASSISTIVE DEVICES: OTHERS]		Year/County: 1991 - USA
Reference		Brooks NA. Users' responses to assistive devices for physical disability. Social Science & Medicine 1991; 32(12):1417-24.
Objective/Questions		To investigate how assistive devices for disability utilised in various social settings are perceived by persons with disabilities who also maintain valuable occupational positions. 1) How adults with disabilities view their assistive devices, 2) how users' attitudes toward their devices vary by social setting and user's disability type, 3) what issues about assistive devices concern users.
Device/Product		Assistive Technology Devices.
Users		n = 595 (475 men, 120 women).
Method/Tool/Approach		A postal survey of scientists and engineers with disabilities. Questionnaire design not discussed.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		1254 questionnaires were mailed, using the resource group of disabled scientists and engineers identified by the American Association for the Advancement of Science. 595 were returned (47.4%). 66% were employed full-time. Mean age of 47.2 years (19-88). Disability types: vision impairment (13%), hearing impairment (17%), speech impairment (1%), limb loss (27%), neuromuscular impairment (35%) and multiple or other disabilities (4%). The respondents reported that they were most likely to use assistive devices for mobility, transportation (car hand controls, vehicle wheelchair lifts and electric wheelchairs) and employment (such as tactile measuring devices and optical scanners), and least likely to use them for housekeeping and child care (such as baby monitors and child lifts). The findings display general user satisfaction with devices. Utilisation varies according to social setting and disability type, particularly between those individuals with sensory and non-sensory impairment. Respondents perceived the general public reaction to assistive devices as "about average", with more observing positive rather than negative reactions from the public. When asked about how they felt about devices, they indicated that they saw them as mostly beneficial, necessary and supportive of "normality". However 32% said devices were often restricting and 32% said they were often inconvenient. The authors found that negative attitudes toward devices tended to have associations with the use of the devices themselves and not the social environment, with attitudes toward devices being more favourable when considering device use in social settings than when reporting actual device use. Users' suggestions for future work mainly propose examination of the systems that develop and distribute the devices.
Researcher's Comments		Partially supported by joint consultantship from the American Association for the Advancement of Science.

RefWorks Number: 1305	**["OUT OF THE MOULD"]**	Year/County: 1982 - India
Reference		Sethi PK. Appropriate technology for rehabilitation aids in developing countries. Annals of the National Academy of Medical Sciences (India) 1982; 18(2):34-42.
Objective/Questions		Glaxo Oration regarding 24 years of experience providing rehabilitation aids such as artificial limbs and callipers for individuals in Northern India.
Device/Product		Assistive Technology Devices.
Users		n = over 5000 amputees.
Method/Tool/Approach		Lecture addressing issues of western design, population needs and appropriate device design for the local population.
Product Development Stage at which users were involved	Concept	"…I started spotting some amputees whom we had provided with artificial limbs and who were seen moving around on crutches. This obviously disturbed me and I started closely questioning these amputees about the reasons which made them discard the limbs…"
	Design	"…It quickly became evident that the design of the limb we were providing to our patients did not suit their lifestyle. These designs were originally conceived in the West and were appropriate for the people for whom they were meant… Our people often walk barefoot or use open, well ventilated footwear suitable for a warm climate. Our working level is the floor where we squat or sit cross-legged to perform our activities of daily living. We take off our shoes inside our homes; our women would not agree to wear closed shoes... Our farmers can not afford to wear shoes when tilling their fields, walking in water and mud." Design criteria: permit barefoot walking, natural looking foot-piece from a durable and waterproof material, permit squatting and cross-legged sitting, adapt to walking on rugged terrain…"
	Testing & Trials	Broke with conventional designs to provide a large sponge rubber universal joint located in the hind-foot region. A proximal wooden block was used for the carriage bolt with which the foot-piece is secured and a distal wooden block was used to provide rigidity for the take-off stage of the gait cycle. During testing rubberised tyre-cord was added to reinforce the foot because walking and field trials caused a number of broken foot-pieces. The breaking load rose to 6 tons and the durability of the foot-piece is up to 5 years in a rural environment (Jaipur design).
	Production	Vulcanised rubber was used because "every town in our country has re-treading shops where worn out tyres are reconditioned; rubber is easily available and the technology of vulcanisation is known to our people".
	Deployment	X
Conclusions		"…Our rural amputees now no longer are required to migrate to urban areas, seeking and learning sedentary occupations…" While attempting to work out alternative designs the author argues that his perceptions and value systems were challenged with regard to technological choices, demystification of professional knowledge and peoples' participation in a health delivery system, so as to reach the unreached. The author questions whether with 80% of the population living in remote villages and a third of whom live below the poverty line can a capital intensive technology imported from abroad be justified? As a result appropriate technologies are defined as meeting the needs of the neediest, generating endogenous self-reliance, being environmentally sound and rooted in the culture of the people.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1317 [ASSISTIVE DEVICES: MOBILITY AIDS]		Year/County: 1980 - USA
Reference		White RN. Szeto AYJ. Hogan HA. A practical curb-climbing aid for wheelchair-bound paraplegic persons (a progress report). Bulletin of Prosthetics Research 1980; 10(34):13-9.
Objective/Questions		To design and test a prototype curb-climbing aid for wheelchair bound paraplegic individuals.
Device/Product		Mobility Device: Trough shaped wheel ramps and telescoping articulating control rods that allow a wheelchair bound individual to ascend and to descend curbs as high as 8 inches.
Users		n = 13 able bodied volunteers (9 men & 4 women).
Method/Tool/Approach		An examination of various curb like barriers plus a review of past designs led to the development of a set of criteria for a practical curb climbing aid. The prototype was designed with 2 channel shaped ramps one on each side of the wheelchair held in alignment with the wheels by telescopic control rods. The rods are used by the individual to manipulate the ramps into position prior to curb ascent or descent. The volunteers were given demonstrations and verbal instructions for use of the aid which they use to mount 4 and 8 inch curbs. Each subject was allowed 1 practice effort before ascending and descending the same curb before being timed. After completing the tests the subjects were asked to estimate the percentage of their maximum effort that they used to ascend and descend the 4 inch curb and the 8 inch curb (the response options were 10, 25, 50, 75 or 100%).
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	Prototype development and testing: testing with trained and untrained able bodied subjects reported ("very limited testing with paraplegics" referred to).
	Production	X
	Deployment	X
Conclusions		The majority of the untrained subjects accomplished the curb ascents and descents within 1 minute. The field tests indicate that operation fatigue was not a significant problem associated with the operation of the aid. The authors state that preliminary data from 3 paraplegic individuals showed that they learnt to use the device quickly and that their task completion times were similar to the able bodied volunteers. Advantages claimed include simplicity, light weight (8lb) and low cost. Required modification of a standard wheelchair is limited to welding a bracket to the outer end of each extended main wheel axle. With ramps and control rods mounted chair width is increased by 6 inches. When the ramps and rods are stored in a canvas bag hanging from the seat back the wheelchair is 1inch wider than its unmodified width. The authors conclude that further testing is required with disabled individuals but that the users of the device require good arm, hand and lower back strength and movement.
Researcher's Comments		Funded by a grant from the Division of Vocational Rehabilitation of the State of Louisiana.

RefWorks Number: 1321	**["OUT OF THE MOULD"]**	Year/County: 2003 - USA
Reference		Ezzet KA. The prevalence of corporate funding in adult lower extremity research and its correlation with reported results. J Arthroplasty 2003; 18(7 Suppl 1):138-45.
Objective/Questions		Literature Review article looking at the prevalence of corporate funding in Hip & Knee Replacement Research.
Device/Product		Hip & Knee Prostheses.
Users		n = 0.
Method/Tool/Approach		The author reviewed all scientific papers, posters, scientific exhibits, and symposia relating to adult hip and knee reconstruction. 603 consecutive articles reviewed from a variety of sources including the Journal of Arthroplasty-2001, Journal of Bone and Joint Surgery-2001, AAHKS meeting-2001, AAOS meeting -2002. Each paper was screened for: 1) Presence of a disclosed commercial sponsor 2) Type of funding arrangement 3) Total number of authors participating in the research 4) County of origin 5) Type of institution performing the research 6) Subject matter of the report 7) Specific institution performing the research 8) Company sponsoring research 9) Conclusion of the study: Good, Bad, Mediocre or Cautious, or Neutral/Non judgemental [Subjective Analysis].
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The presence of commercial funding in these studies was 50%. The presence of a commercial sponsor for implant-specific hip and knee research strongly correlated with reported outcome, especially with American hip investigators. Hip- US 75% of research sponsored, compared to 50% CAD and 62% UK. Similar results were seen in knee surgery. Funding bias can be suggested but never definitely proven. Adult lower extremity orthopaedic research reports upward of 90% of studies reporting positive outcomes when carried out by commercial industry, and 30-60% of studies reported bad results or cause for caution when carried out by independent researchers. The author acknowledges that this study has several limitations: 1 No universally accepted method to perform the analysis- with some being subjective by the author. 2 Bias by editors as to which articles are published. 3 Does not address whether funded studies are better designed than non-funded. 4 Unable to analyse how often there are failures to disclose commercial relationships. In the US 17% of Medicare beneficiaries received revision total hip replacement, compared with 8% from the National Swedish Hip Registry. It is possible that the Swedish Registry has allowed the dissemination of objective implant information to all surgeons in Sweden, and has led to improved implant selection in these surgeons. In the US there is no such registry, and information on the performance of implants is via scientific literature and at meetings. Surgeons who are funded by corporations may provide the available literature. Because the criteria for disclosure vary from one format to the next, the same investigator presenting the same research may honestly and ethically fail to disclose a relationship in another format.
Researcher's Comments		No benefits or funds were received in support of this study.

RefWorks Number: 1329	**["OUT OF THE MOULD"]**	Year/County: 2003 - USA
Reference		Fuhrer MJ, Jutai JW, Scherer MJ, DeRuyter F. A framework for the conceptual modelling of assistive technology device outcomes. Disabil Rehabil 2003; 25(22):1243-51.
Objective/Questions		The development of a framework that has the potential for producing device-specific outcome models, and which will be applicable to multifarious types of devices and their outcomes.
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		Tool Development: A literature review identified the critical, unmet needs for the conceptual framework. 9 assumptions underlying the framework were specified/described. The conceptual framework has the following aspects: Procurement of a device-type; Introductory use; Shorter term outcomes; Longer term use; Moderating co-factors; Longer term outcomes; Continued use; and Discontinued use. Three considerations are entailed in 'device procurement': 1) Needs a device 2) The type of device, considering both intrinsic and extrinsic properties and 3) The services that may be involved. 'Introductory use' can be understood differently depending on whose vantage point it is being viewed. Regardless of the perspective, the period of introductory use applied to all Assistive Device Technologies [ADTs] and all users and its duration will have a likewise variation. 'Shorter term outcomes' is another way of considering efficiency. It consists of outcomes such as effectiveness, costs, and device satisfaction, and also includes psychological functioning and subjective well-being. 'Shorter term outcomes' results from an interaction between 'Introductory use' and 'moderating co-factors'. The latter representing body functions, body structure, activities and participation, environmental factors, personal factors and concurrent interventions. 'Shorter term outcomes' results in 'Longer term use or Discontinued use'. 'Longer term use' interacts with the specified 'Moderating co-factors' to produce a variety of 'Longer term outcomes'. However, the two may take different forms in causal models of specific devices. Two other features are considered to be essential, although they have not been represented in the framework figure. The first is allowing both a subjective [users] and an objective perspective on operationalising most of the variables that constitute the framework's outcomes and moderating co-factors. Second is the differentiation of multiple stakeholder perspectives including those of users family members, friends, and co-workers, ATD service providers, manufacturers, vendors, payers, researchers, and policy analysts. Particular ATD-specific models need not make provision for all of those perspectives, but their developers need to be explicit about which perspectives were adopted in selecting variables and in operationalising them.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The framework can assist causal/outcomes model developers in choosing the assumptions on which to base device-specific outcomes models, selecting the variables to include in them, and designating the user population to which they apply. It may also contribute to developing a research agenda for assistive technology outcomes research by highlighting measures that need to be developed and by identifying testable hypotheses concerned, example, the manner and duration of device usage. The development of device-specific models is likely to be motivated by utilitarian, clinical concerns such as comparing the outcomes of competing devices of different but related types.
Researcher's Comments		Funding was provided in part by a grant from the National Institute on Disability and Rehabilitation Research. Definitions: Assistive Devices: applied to or directly manipulated by a person e.g. wheelchairs. Special Equipment: attachments to the original structure of the physical environment e.g. handrails.

RefWorks Number: 1337	**[DENTAL & ORAL]**	Year/County: 2003 - The Netherlands
Reference		Raghoebar GM. Meijer HJ. van 't Hof M. Stegenga B. Vissink A. A randomized prospective clinical trial on the effectiveness of three treatment modalities for patients with lower denture problems. A 10 year follow-up study on patient satisfaction. Int J Oral Maxillofac Surg 2003; 32(5):498-503.
Objective/Questions		To evaluate the satisfaction of 3 treatment modalities in resolving lower denture related complaints.
Device/Product		Dentures and mandibular implants: in the implant retained overdenture group 2 endosseous implants were used Branemark (Nobelbiocare, AB, Gotenborg, Sweden) and IMZ (Friedrichsfeld, Mannheim, Germany) all using a metal clip retention system on a round Ackerman bar connecting the implants.
Users		n = 90 edentulous patients (39 men, 51 women).
Method/Tool/Approach		Randomised prospective trial. The inclusion criteria involved an edentulous period of at least 1 year and mandibular height in symphysis region between 15 and 25mm. Patients previously treated with preprosthetic surgery or dental implants were excluded. Patients were randomised into one of 3 groups: overdenture retained by dental implants in the lower jaw (implant retained overdenture group, IRO); patients treated with a vestibuloplasty and lowering the floor of the mouth before insertion of a new conventional complete denture (pre-prosthetic surgery group, PPS); and patients treated with a new conventional complete denture alone (complete denture group, CD). The main outcome parameters were denture satisfaction and chewing ability, which were assessed using validated self-administered questionnaires focusing on denture related complaints and problems with chewing different types of food. These parameters were tested before treatment, and 1, 5 and 10 years after treatment. Denture satisfaction was assessed with a self-administered questionnaire. 12 questions addressed problems with functioning of the lower denture and 7 questions concerned the upper denture. The extent of each specific complaint was rated on a 4 point intensity scale. 5 questions addressed chewing ability of tough and hard food, each with a 3 point intensity rating scale. The patient's overall denture satisfaction was expressed on a 10 point intensity scale. Sensory changes of lip and chin were evaluated by touching the lip and chin of the patient with a cotton pellet in different areas. After 1 year patients in the CD and PPS groups who were not satisfied had the opportunity to switch to an implant retained overdenture.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		At 1 year 4 patients were lost to follow up with 8 from the CD group and 4 from the PPS group choosing to switch to an implant retained overdenture. At 5 years another 8 were lost with another 6 patients from the CD group and 2 from the PPS group switching to an implant retained overdenture. At 10 years 3 were lost. During the 3 months osseointegration period, 3 patients lost in total 4 implants. During the first year of follow up 2 patients lost 3 implants. After a period of 3 months new implants were inserted successfully. No implants were lost between 5 and 10 years. The implant survival during the 10 years of follow-up was 93%. At the 1 year evaluation, significantly better scores were observed in the 2 surgical groups (IRO, PPS) than in the CD group. At the 5 year evaluation the complaints of the lower denture showed a significantly better score in the IRO group when compared to the PPS and CD groups. At 10 years the intention to treat analysis revealed no significant differences between the 3 groups, while a per protocol analysis showed that the IRO group was the most satisfied. The authors conclude that both on the short and long term denture satisfaction appears most favourable in the IRO group when compared with the PPS and CD groups.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1339	**["OUT OF THE MOULD"]**	Year/County: 2003 - USA
Reference		Lenker JA, Paquet VL. A review of conceptual models for assistive technology outcomes research and practice. Assist Technol 2003; 15(1):1-15.
Objective/Questions		Use of a systematic assessment to review six conceptual models from the Assistive Technology [AT], human factors, disability, and social psychology literature. This is done to assess whether there is a dominant conceptual model that describes and predicts outcomes research.
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		The models reviewed are: (1) Cook and Hussey's Human-Activity-Assistive Technology model [HAAT, 2002]. The HAAT includes social and cultural contexts, as well as environments and physical conditions. AT devices are an explicit component of HAAT. HAAT described an AT system in terms of a person [human] using an AT device to accomplish a desired task [activity] in a given context [environment]. It seeks to characterise AT system performance, rather than restrict focus to human or device performance. It reflects the perspectives of human factors engineering, which analyses how characteristics of tasks and environments impact human performance, and occupational therapy, which improves human performance in purposeful activities. (2) The World Health Organizations International Classification of Functioning, Disability and Health [2001]. The model describes individuals in terms of level of function, rather than describing levels of deficit or dysfunction. Its purpose is to provide a framework for assessment, diagnosis, intervention, and outcomes measurement, regardless of health or ability level. (3) Scherer's Matching Person and Technology model [MPT, 1998]. The MPT model presumes that the interaction of milieu, person, and technology influences long term use or non use of AT devices. It includes a structured assessment process to facilitate selection of an AT device that is the best 'match' for the end user, AT device, and the context of use. The premise is that AT devices are a means to an end that may or may not address an individual's unique needs and circumstances. Scherer states clearly that the model is not designed to predict use or non use of a technology. (4) Gitlin's model of AT users "career" [Biopsychosocial Framework and concept of 'Career', 1998]. The 'career path' model for AT use being in the hospital. It is grounded in a biopsychosocial framework that considers effects of physical, intrapsychic, and social aspects of a person's existence. Gitlin's rendering of an AT device career path is similar to Cook and Hussey's [2002] suggest that AT users exhibit time-varying levels of capacity and skill that affect performance of the AT system. The purpose of the career path model is to describe the changing nature of factors that influence AT use and impact over time. 5) Social cognition decision-making theories: The field of psychology offers several social cognition models whose goals are to predict behaviour. An implicit assumption with social cognition theories is that people naturally seek behaviours that maximise expected benefit. Individuals weight their attitudes, perceptions of benefits, and perceived control of behaviours against the expectations of others, ultimately choosing behavioural alternatives that offer the most Favourable set of consequences. (6) Roger's Perceived Attributes Theory [1995] identifies seven factors influencing innovation adoption: relative advantage, compatibility, complexity, trialability, observability, re-invention, and change agent contact. These attributes characterise interaction between person and environment. The theory lends itself to individuals of all ages, functional abilities, and contexts of device or product use. Each model is discussed in this paper according to 6 domains: Background/Goals; Descriptive Traits; Implicit Outcome Measures; Predictive Traits; Validation in the literature; and Utility to AT Practitioners, Users and Developers. The strengths and limitations are highlighted for each.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The continued lack of funding resources for AT portends the need for predictive algorithms that can facilitate decision-making by practitioners, reimbursement agencies, and consumers. Roger's Theory introduces fresh insights about elements of person-environment interactions that affect human behaviour. HAAT, ICF & MPT offer superior descriptive frameworks for classifying and describing the traits associated with individuals and their contextual environments. Gitlin's career model, the social cognition model, and Roger's Perceived Attributes Theory offer temporal and predictive elements that might ultimately shape decision-making. From the social cognition models, the concepts of perceived value show greatest promise for predicting AT use. These together with Roger's theory could form the basis for the type of predictive theory called for by Fuhrer et al [in press]. Other models worthy of mention are Sabala's [1995] SETT framework which is a structured set of questions that guide AT assessment in school settings based on relevant person and environmental factors; Bowser and Reeds [1995] Educational Tech Points and Langton and Hughes' [1994] Tech Points consider AT service delivery practices as part of the everyday educational and vocational rehabilitation processes, respectively. Each of the models would be bolstered by prospective research demonstrating that their usage in everyday practice improves clinical decision-making.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1349	**["OUT OF THE MOULD"]**	Year/County: 2004 - USA
Reference		Samore MH, Evans RS, Lassen A, Gould P, Lloyd J, Gardner RM, et al. Surveillance of medical device-related hazards and adverse events in hospitalized patients. JAMA 2004; 291(3):325-34.
Objective/Questions		To determine whether computer-based surveillance can reliably identify medical device-related hazards (no known harm to patient) and adverse medical device events (AMDEs, patient experienced harm) and to compare alternative methods of detection of device-related problems.
Device/Product		Medical Devices.
Users		n = 20,441 patients.
Method/Tool/Approach		Descriptive study conducted between 01/2000 - 09/2000 at a 520 bed tertiary institution including all regular and short-stay patients. Medical device events as detected by computer-based flags, telemetry problem checklists, International Classification of Diseases Ninth Revision (ICD-9) discharge codes, clinical engineering work logs, and patient survey results were compared with each other and with routine voluntary incident reports to determine frequencies, positive predictive values and incidence rates by each technique.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Of the 7059 flags triggered, 552 (7.8%) indicate a device-related hazard or AMDE. The estimated 9 month incidence rates (no. per 1000 admissions) for AMDEs were 1.6 for incident reports, 27.7 for computer flags, and 64.6 for ICD-9 discharge codes. Few of these events were detected by more than 1 surveillance method, giving an overall incidence of AMDE detected by at least 1 of these methods of 83.7 per 1000 admissions. The positive predictive value of computer flags for detecting device-related hazards and AMDEs ranged from 0-38%. More intensive surveillance methods yielded higher rates of medical device problems than found with traditional voluntary reporting, with little overlap between methods. Several detection methods had low efficiency for detecting AMDEs. The high rate of AMDEs suggests that AMDEs are an important patient safety issue, but additional research is required to identify optimal detection strategies.
Researcher's Comments		FDA funded.

RefWorks Number: 1355		**[CARDIAC]**	Year/County: 2002 - Sweden
Reference		Bolse K, Flemme I, Ivarsson A, Jinhage BM, Carroll D, Edvardsson N, et al. Life situation related to the ICD implantation; self-reported uncertainty and satisfaction in Swedish and US samples. Eur J Cardiovasc Nurs 2002; 1(4):243-51.	
Objective/Questions		To describe changes in the life situation related to the implantable cardioverter defibrillator (ICD) in Swedish and US samples with regard to uncertainty and satisfaction.	
Device/Product		Implantable cardioverter defibrillators (ICDs): no specific devices named.	
Users		n = 93 (56 Swedish patients & 37 US patients).	
Method/Tool/Approach		A descriptive study carried out over 3 and 6 months respectively at university hospitals in Sweden and in the USA. Exclusion criteria were psychological and/or medical complications, planned heart transplant or coronary artery bypass graft and language difficulties. The US sample was a convenience one obtained from an initial 40 patients identified. The Swedish sample was obtained from an initial 83 consecutive patients. Uncertainty in illness was measured by the Mishel Uncertainty in Illness Scale - community version (MUIS-C) used to determine levels of uncertainty before and after implantation. The Ferrans and Powers' Quality of Life Index (QLI), Cardiac III, parts I and II was used to measure patient satisfaction. The MUIS-C and QLI questionnaires were completed on 2 separate occasions: before implantation and after implantation (at 3 months for the Swedish sample and at 6 months for the US sample).	
Product Development Stage at which users were involved	Concept	X	
	Design	X	
	Testing & Trials	X	
	Production	X	
	Deployment	Post-market surveillance.	
Conclusions		A higher level of uncertainty was indicated in the US sample prior to ICD implantation and for the Swedish sample following the implantation. In the Swedish sample satisfaction with life showed a statistically significant difference within the socio-economic domain, indicating a higher degree of satisfaction 3 months after implantation. Satisfaction within the domains of health and functioning, socio-economics and psychological-spiritual showed a statistically significant difference between the Swedish and US sample both before and after ICD implantation, indicating a higher degree of satisfaction in the US sample. However the researchers acknowledge that the fact that the US sample was investigated at a later stage post-implantation than the Swedish sample may have influenced the results.	
Researcher's Comments		Funding not addressed.	

RefWorks Number: 1388 [HORMONAL & CONTRACEPTIVE]		Year/County: 2003 - UK
Reference		Reuter S, Smith A. Implanon: user views in the first year across three family planning services in the Trent Region, UK. Eur J Contracept Reprod Health Care 2003; 8(1):27-36.
Objective/Questions		To elicit the experiences of women who had the Implanon implant inserted in 3 family planning services in North Trent during the first year after its introduction.
Device/Product		Implanon (NV Organon, Oss, the Netherlands): single rod contraceptive implant releasing the progestogen etonogestrel.
Users		n = 75 women.
Method/Tool/Approach		Postal survey: a previously piloted questionnaire (including open questions and closed ones involving a choice of answers) was sent to all Implanon users who had the device implanted in the 3 services between 12/1999 and 12/2000. 190 users were identified, 171 of whom had not objected to contact and had questionnaires sent.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The overall response rate was 43.8%. Of the 75 responders 14 (18.6%) had their implant removed during the study period. Healthcare providers and family and friends were the main sources of information about the implant. Women considered themselves informed about the method prior to insertion irrespective of whether they continued to use the method or requested early removal. Ease of use was the most common (41%) reason for choosing Implanon and one of the best liked features. Bleeding irregularities were the most commonly (41%) reported side-effect followed by weight gain, moods and headaches. 17% experienced no side-effects. Bleeding problems led to the majority of removal requests; the wish for pregnancy was not stated at all. The implant compared favourably with most respondents' experiences of other methods of contraception.
Researcher's Comments		No funding was received. "…Both authors are trainers for subdermal techniques and have received payment from NV Organon when instructing…"

RefWorks Number: 1389	**["OUT OF THE MOULD"]**	Year/County: 2003 - USA
Reference		Barrett SF, Laurin KM, Bloom JK. University of Wyoming, College of Engineering, undergraduate design projects to aid Wyoming persons with disabilities. Biomed Sci Instrum 2003; 39:597-602.
Objective/Questions		This paper describes the creation and development of an engineering undergraduate program involving the University of Wyoming's College of Engineering partnered with three organisations that provide education and service related to disability.
Device/Product		Assistive Technology Devices.
Users		Persons with disabilities or persons receiving medical care requiring device intervention.
Method/Tool/Approach		To accomplish program objectives the College of Engineering joined with Wyoming Institute for Disabilities [WIND], Assistive Technology Program- Wyoming New Options in Technology [WYNOT] and its Sports an Outdoor Assistive Recreation [SOAR] program, as well as with the university's Special Education Department. The WYNOT project director serves as the co-ordinator with the community to identify specific assistive technology needs. WYNOT also provides training to the engineering students regarding assistive devices and services. In addition, the project assists students with research activities through their AT Information and Referral program. Project proposals may be initiated by the individual with a disability, his/her family members, caregivers, teachers, or any of the service agencies in the state of Wyoming. A short project application is used to identify the desired assistive device and the special needs of the individual. A project director from one of the organisations and the PI meet on a regular basis to evaluate the suitability of the submitted projects and if necessary interviews are conducted. One student or a small group of students selects a project from a specified list which needs to be completed within a year. Each project is aligned to a discipline-specific faculty mentor. Since these projects involve the use of human subjects, students are required to complete an Institutional Review Board study prior to initiating a specific project. "…Furthermore, projects are delivered to the recipients only after extensive testing…" [This aspect was not elaborated on].
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Autumn 2002, five projects successfully completed. These include: Star Writer learning disability demonstrator; "Life is a Switch"- adapting off the shelf toys for children with learning disabilities; Non-invasive Infant Respirator and Temperature Monitor; Automatic Casting Device for Fishing; Specialized Tricycle for Osteogenesis Imperfecta Type 111. The program provides the following benefits: 1 Prototypes, one of a kind assistive devices for persons with disabilities; 2 Meaningful, challenging, multi-disciplinary senior design projects; 3 Awareness and sensitivity training for the next generation of Wyoming engineers towards the needs of others; 4 Projects which serve as a springboard to graduate work in biomedical engineering; 5 Opportunities for participation in biomedical related symposia. Based on the first year's successes additional funding was received from NSF to continue the program for the upcoming academic year. Five additional projects are already underway. Since these projects involve the use of human subjects, students are required to complete an Institutional Review Board [IRB] study prior to initiating a specific project. These studies are completed and submitted to the IRB per federal and university guidelines. Furthermore, projects are delivered to the recipients only after extensive testing. At that time the recipient or their legal guardian will sign a "Hold Harmless" agreement.
Researcher's Comments		Funded in part by NSF grant.

RefWorks Number: 1391 [TOOLS]		Year/County: 2003 - USA
Reference		Ragab AA. Validity of self-assessment outcome questionnaires: patient-physician discrepancy in outcome interpretation. Biomed Sci Instrum 2003; 39:579-84.
Objective/Questions		The outcome of Total Hip Arthroplasty [THA] was evaluated using both a standard scoring system and a self-administered outcome questionnaire that was modified to allow comparison with the standard scoring system. Discrepancies were analyzed in detail in an attempt to reach the source, whether it was on behalf of the surgeon, the patient, or due to other factors.
Device/Product		Cementless Total Hip Prostheses with anatomically designed femoral stems.
Users		n = 103 patients who underwent 124 cementless THA, had an office visit/clinical evaluation within the past 2 years, and could be located by address. Average age 60.1 years, 67 females and 36 males. 84% had a preoperative diagnosis of degenerative joint disease, 3% rheumatoid arthritis, 5% avascular necrosis and 8% other causes. All procedures were performed through a standard posterolateral approach.
Method/Tool/Approach		Evaluation of Patient Satisfaction: A modification of two previously described questionnaires were distributed and completed by 103 respondents. The modifications allowed for calculation of a modified Harris Hip Score [HHS] based on the patients responses. On calculation of the scores, the maximum score was 91 not 100, since the presence of deformity and measurement of range of motion could not be assessed through the questionnaire. The questionnaire also provided additional information, including quality of life, various recreational activities that patients may have resumed, their ability to resume their housework/job, ability to drive a car and their need for analgesics. They were also asked about their overall satisfaction with their hip surgery, whether their expectations were fulfilled and whether they would have the same procedure again if necessary. Clinical Evaluation: Each patient who responded to the questionnaire was clinically evaluated at their latest office visit using the HHS. Telephone Interviews: Patients with a pain score of less than 30 points (highest = 44 points) on the self-administered questionnaire were subsequently interviewed in detail about their pain by telephone [n = 26]. Questions during the interview included the site of the pain, and whether the pain radiated to or from sites other than that from the operated hip. Inquiries also included aggravating and relieving factors, the nature of the pain, and the need for pain medication. The patients were also asked about newly diagnosed conditions since their last follow-up visit, which may be a potential source of this pain. Finally, an overall review of the questionnaire with the patient was done to resolve any misunderstandings of the questions on behalf of the patient.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Evaluation of patient satisfaction showed that 96% of the patients were either very satisfied or satisfied with their surgery. 4% were dissatisfied due to their inability to resume certain activities as noted on their questionnaire even though pain relief was obtained. On reviewing charts of the dissatisfied patients, preoperative evaluation showed that the patients' main goal from undergoing surgery was pain relief. It was obvious that their expectations from the surgery had changed. The correlation between the scores from the self-administered questionnaire and the patient's last office visit revealed a fairly low correlation coefficient. Relative lack of correlation between the HHS's obtained from these two sources was especially noted for patients with a pain score of 30 points or less. Of the 26 patients with a pain score of 30 or less points detailed interviews revealed the pain referred to in answering the question originated from a site other than the involved hip. Only in 5% of the 26 patients was the pain felt to be 'true pain'. Of these patients with 'true pain' i.e. involving the hip site: 3 had anterior thigh pain, 1 had groin pain and 1 had anterior thigh and groin pain. Further interviewing revealed that the discrepancy between the questionnaire and the charts originated mainly from the limp score. Patients had scored less on the questionnaire which was found to be due to the fact that a limp could be experienced only after walking long distances or may be experienced in relation to weather changes. Therefore this limp may not have been obvious to the examining surgeon during the office visit. Although outcome measures developed and administered by clinicians are subject to bias from several sources, results of this study suggest that self-administered patient outcome measures also have their limitations. The validity of self-administered patient outcome questionnaires can be severely impacted by the patients understanding of the questions asked, as even the most seemingly simple questions are subject to misinterpretation. The authors agreed with Kats et al in that a credible system for documentation of the results of arthroplasty should include both the traditional physician driven measures [physical examination, radiographic findings and complications], as well as patient derived measures of outcome. They also recommended a detailed analysis of discrepancies between these sources.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1406	**["OUT OF THE MOULD"]**	Year/County: 2003 - USA
Reference		Blanck P, Ritchie H, Schmeling J, Klein D. Technology for independence: a community-based resource center. Behav Sci Law 2003; 21(1):51-62.
Objective/Questions		Description of a new project "Technology for Independence: A Community-Based Resource Centre" [CBRC]. Designed to help bridge the gap between researchers and consumers with disabilities interested in assistive technology [AT]. This project is a partnership between the Law, Health Policy and Disability Centre at the University of Iowa, and the Independent Living Research Utilization at Baylor College of Medicine.
Device/Product		Assistive Technology Devices.
Users		Persons with disabilities.
Method/Tool/Approach		The purpose of CBRC is to expand research on AT for independence and environmental access by enhancing the capacity of community organizations to conduct and evaluate research on AT and related areas. The cornerstone of CBRC model is participatory action research [PAR]. PLAN: The project will solicit the participation of researchers, many with disabilities, who are interested in extending knowledge of research methods to the disability community. Researchers will team with disability community organizations to create knowledge rooted in scientific methods and relevant to the daily experiences of individuals with disabilities. The CBRC will provide technical assistance to the research teams and contribute to the empowerment of the disability community to conduct research as a means to help eliminate environmental and attitudinal barriers to independent living. Multiple methods will be used to obtain data on AT: focus groups, surveys- mailed written surveys and internet based surveys- and questionnaires from the network of independent living centres and consumer organisations. One emphasis will be on developing a database of categories of current or potential technology users who have disabilities. The source of the respondents will be from the network of independent living centres and consumer organizations. These organisations will recruit participants so that the target group participates.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Over a 5 year period, the CBRC hopes to increase the capacity of community and consumer-directed disability organizations to design, implement, and disseminate research that promotes access to and use of AT for independence. Some of the research projects include: "Community Research for AT" at the California Foundation for Independent Living Centres in partnership with California State University. "AT in the Community" at the Washington University School of Medicine Program in Occupational Therapy in collaboration with Paraquad, the ST Louis based centre for Independent Living. "Information Technology for Independence: Community Based Research" at the University of Pittsburgh in collaboration with Three Rivers Center for Independent Living, the Community College of Alleghany County Institute of Advanced Technology, the American Foundation for the Blind, and the National Federation of the Blind. The CBRC will use a combination of strategies to enhance the ability of community organizations to conduct research that is scientifically rigorous and relevant to social policy.
Researcher's Comments		Supported in part by grants from The National Institute on Disability and Rehabilitation Research, US Department of Education grants, The University of Iowa College of Law Foundation, and The Great Plains ADA and IT Centre.

RefWorks Number: 1418	**[CARDIAC]**	Year/County: 2003 - USA
Reference		O'Malley AJ. Normand SL. Kuntz RE. Application of models for multivariate mixed outcomes to medical device trials: coronary artery stenting. Stat Med 2003; 22(2):313-36.
Objective/Questions		This paper illustrates the techniques for determining the Objective Performance Criterion [OPC] for a new coronary artery stent to find out whether it is safe and effective compared to approved stents.
Device/Product		Coronary Artery Stent- Balloon Expandable Stainless Steel 316 L Stents.
Users		n = 5806 patients from 7 trials conducted between 1993 and 1998. Patients were recruited in one of two ways. Either patients were randomized into a two-arm trial based on broad eligibility criteria, or patients were assigned to a single-arm registry based on a restricted criterion for focused studies. Registries generally comprised patients with vessel diameters and lesions lengths outside the mainstream stent reference population.
Method/Tool/Approach		The outcome of FDA approved single-armed clinical trials is evaluated using the OPC pathway to determine a fair comparison between treatments. Two primary endpoints are typically measured after coronary stenting. The first which is obtained in all patients is the incidence of clinically driven repeat revascularization, denoted the Target Lesion Revascularisation [TLR] rate. The second, obtained on a small randomly selected subset of patients, is defined as the degree of re-narrowing and is quantified by a computer-based system that measures absolute and relative dimensions of the artery, including Proportion Diameter Stenosis [PDS]. Both measures are taken 9 months after stenting. Seven patient covariates were considered important predictors of restenosis: the length of the lesion, vessel diameter, thickness of plaque as a fraction of diameter immediately after stent inflation, enrolled as part of a single arm registry rather than as part of a randomised two-arm trial, history of diabetes mellitus, presence of disease in the left anterior descending coronary artery and the number of diseased vessels. Data collected from 7 randomized trials of patients with Coronary Artery Disease treated with stents that have been approved for use in the USA. Trials 1 and 6 do not contain registries, and in trial 1 no patients were angiographically followed up. Among patients with angiographic follow-up, the recruitment mode was fixed within a trial. In trials 3 and 7, all patients followed-up were in a registry, while in the other trials, no patient having angiographic follow-up was in a registry. Registry and the trial-level main effects are confounded with respect to PDS. This paper focuses on using statistical models to estimate the OPC, which incorporates mixed outcomes for stenting. A Hierarchical multivariate model was used with a hierarchical regression structure to pool information from the 7 trials for approved devices. Finally, the OPC for each model is defined.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance
Conclusions		The OPC is the expected outcome associated with approved devices, and may be used as a 'control group' in clinical assessment of a new device. An assumption of exchangeability allows the data to determine to what extent information is shared between the trials. Even though the outcomes from the trials appear very similar, they found substantial variation exists between trials. The posterior standard deviation of the OPC would be significantly underestimated if homogeneity was assumed. Bivariate modelling permitted information to be shared between the outcomes. The substantive conclusions indicate that for the average patient, the overall rate of TLR among historical trials is approximately 10.4% while PDS is 0.38. Analyses accounted for the health status of a patient prior to stenting [diabetes, diameter], characteristics of the disease [length, location, number of diseased vessels], procedural variables [thickness], and the mode of patient recruitment [registry]. However, the results should be interpreted in light of some limitations. In 5 of the 7 trials, multiple stents were used. For reasons of convenience, it was assumed that there was no effect of stent within trial, apparently a reasonable assumption given that equivalence was previously assessed in each of these trials. Secondly, several of the predictor variables contain a small proportion of missing values. They used a complete case analysis and discarded 586 observations [9.2%] observations of TLR and 38 [3.3%] of observations of PDS. Although the proportions of missing data were relatively small, the analysis could benefit from multiple imputation. Conclusions: the OPC methodology is able to incorporate uncertainty and adjust for confounding variables. It offers a flexible solution to estimation of restenosis outcomes under conditions of varying reference populations and samples. This can allow manufacturers and clinicians to assess utility and cost-effectiveness. Even when every attempt is made to adjust for potential confounding variables, historically controlled clinical trials remain vulnerable to the influence of unmeasured confounders. The size of the coronary stent database, the long history of research in cardiology, and understanding of the engineering properties of stents, provide a level assurance in this application. To formally investigate the possible bias on estimates of the OPC, sensitivity analysis could be employed.
Researcher's Comments		Supported by the Advanced Medical Manufacturers Association, a non profit consortium of health care product manufacturers.

RefWorks Number: 1474	**[BREAST]**	Year/County: 2002 - USA
Reference		Cash TF, Duel LA, Perkins, LL. Women's psychosocial outcomes of breast augmentation with silicone gel-filled implants: a 2-year prospective study. Plast Reconstr Surg 2002; 109(6):2112-21.
Objective/Questions		To examine the experiences of women receiving bilateral breast augmentation.
Device/Product		Silicone gel filled breast implants: Dow Corning's Silastic MSI (textured) and Silastic II (smooth).
Users		n = 360 patients.
Method/Tool/Approach		Evaluative study performed between 05/1990 and 01/2002 at 24 clinical sites. Before surgery the women completed a 2 page questionnaire designed to assess their reasons or expectations for the surgery and their concerns about perceived risks of both surgery and the implants. At 6, 12 and 24 months postoperatively before clinical evaluation by the surgeon the women completed another 2 page questionnaire, rating on a 5 point Likert scale their satisfaction with surgery and its specific psychosocial outcomes, their concerns and their benefits-to-risk appraisals of the augmentation. The authors state that the questionnaires were adapted based on an existing survey instrument and from information obtained from focus group research with women who had sought breast implants. Eligible participants were those over 19 years of age, were healthy, had not had previous mammary implants, primary diagnoses of bilateral amastia, hypomastia or hypoplasia and agreed to at least 2 years follow up.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The women had an average age of 32. The availability of postoperative questionnaire data varied across assessment points: 76.6% at 6 months, 81.3% at 12 months and 61.5% at 24 months. A substantial majority of the women sought surgery primarily to enhance their body image satisfaction - to feel better about the size and shape of their breasts, their body proportions and overall appearance. In turn such changes could facilitate attainment of a secondary goal - an improved self-image. Having decided to have the procedure the women still reported moderate concerns about it. Their greatest concerns pertained to the rupture or gel bleed from the implants (58%), changes in nipple sensation (52%), mammographic cancer detection (47%), surgical scarring (44%) and surgical pain (43%). They reported very high levels of satisfaction with the procedure and its psychosocial outcomes, which did not change over time. Throughout the 2 year period, over 90% of the women were satisfied with surgery and their resultant body image changes. Their concerns about risks, reported by 19% before surgery declined after surgery and remained subsequently stable. Most participants (75-85%) reported that the benefits of surgery exceeded its risks. Postoperative events such as significant capsular contracture that compromised aesthetic results diminished aspects of satisfaction whereas less obvious events did not. However where significant capsular contracture occurred 71% of affected women were still satisfied with the surgery, 72% with their body image changes, and 77% with their self-image improvements. The nature and incidence of postoperative events are not detailed in this paper but elsewhere.
Researcher's Comments		Funded in part by an unrestricted grant from the Dow Corning Corporation.

RefWorks Number: 1482	**["OUT OF THE MOULD"]**	Year/County: 2002 - USA
Reference		Malassigne P, Nelson AL, Cors MW, Jensen RP, Amato M, Schnurr ES, et al. Iterative design and evaluation of new prone carts for individuals with SCDs: a technical note. Journal of Rehabilitation Research and Development 2002; 39 (1):127-139.
Objective/Questions		The paper summarizes a series of projects funded since 1992 to improve the Quality Of Life of persons with Spinal Cord Dysfunction [SCD] who use prone carts.
Device/Product		Mobility Device: Prone Cart- a flat horizontal stretcher, propelled by a patient while lying in a prone position. Prototypes were designed at the Milwaukee Institute of Art and Design with the assistance of Ortho-Kinetics, Inc. and Everest & Jennings.
Users		All subjects have SCD. n = 3 patients evaluated 3 Sammy LSs design, includes the one Mr Schnurr has lived on since 1993. First prototype: n = several (not specified) paraplegic and tetraplegic patients tested SCI-PC 22, a prototype built [1994] on evaluation results from the Sammy LS. Second prototypes: n = 12 patients tested the Tabular Manual Prone Cart. This prototype incorporates findings from SCI-PC 22. Designs include both long and short frames. n =13 patients & n = 26 carers tested the Motorised Prone Cart, with both long and short framed designs available.
Method/Tool/Approach		The studies are focused on developing new consumer-driven designs for prone carts. Approach - A team of clinicians and designers: 1) Evaluated existing prone carts; 2) Designed a new manual prone cart; 3) Designed a new motorized prone cart; 4) Collaborated with the manufacturers to market and commercialise the new prone carts. Evaluation of the existing prone carts yielded functional and performance criteria for establishing the development of new prone carts for clinical evaluation. Whenever possible, design suggestions, observations, and responses received in the clinical evaluation from patients and caregivers were incorporated into the next prototype design until the new design was completed and met the established performance goals and design criteria. In addition to the first Sammy LS which Mr Schnurr has been used extensively since 1993, two other Sammy LSs, were used for several months at the Milwaukee and Tampa Veterans Association Medical Centers [VAMCs]. Based on user feedback evaluation results of the Sammy LS, another prototype named the SCI-PC 22 was designed and fabricated in 1994. Redesign then took place which incorporated the evaluation findings in the design of the Tubular Manual Prone Cart, producing short and long versions to accommodate different body sizes, and the Motorized Prone Cart -both short and long versions, designed for patients who cannot use a manual cart because of limited arm-hand function, fatigue, or other medical conditions. Methods [not elaborated on further than what is mentioned here]: 1 Patients and carers were provided with questionnaires that addressed issues of their interactions with motorized prone cart. The questions related to the user's body positioning on the cart, the physical characteristics of the cart, the cart's manoeuvrability and performance, and the user's access from the cart. 2 Informal discussions also took place. 3 Interviews with patients and caregivers. 4 Photography, which provided valuable information to the designers.
Product Development Stage at which users were involved	Concept	"The original impetus for designing a new prone cart was given by Mr Emil (Sammy) Schnurr, a Milwaukee patient with SCD and a double above- knee amputee who had 'lived' on a prone cart for many years. Mr Schnurr formulated the idea for a cart for which the body support would be angled up as opposed to being horizontal. The angled up prone cart would help him look up without developing neck and shoulder pain, thus improving his quality of life and other's who use prone cart. The first conceptual design for a new prone cart, a 1992 student project at the Milwaukee Institute of Art and Design, received the prestigious 'Industrial Design Excellence Award' from the Industrial Designers Society of America. Based on this initial work, the team designed new manual and motorized prone carts".
	Design	Evaluation of existing prone carts.
	Testing & Trials	Design of new prone carts- manual and motorised.
	Production	Prototype testing.
	Deployment	Collaboration with manufacturers to market and commercialise.
Conclusions		From the initial clinical evaluation of the existing prone carts critical problems which were identified include: interfered with socialization, caused discomfort, pain and fatigue, presented safety risks and limited independence in Activities of Daily Living. 4 manual prone carts were continuously used for 2 years and evaluated at the Milwaukee and Tampa VAMCs. Of the 12 patients who evaluated the manual prone cart over time, 67% were paraplegic and 33% were tetraplegic. 78% reported complete injuries. Respondents had been injured for an average of 13 years, aged between 24 and 60 years, median age 42. For one year, 13 patients and 26 caregivers used and evaluated one motorized prone cart at the SCI Center of the Tampa VAMC. All were between the ages of 26 and 65 years, with a mean age of 51.5 years, 20% were amputees or had another impairment, 60% were paraplegics, 20% were tetraplegics, the average injury occurring 17 years ago. The iterative process of prototype fabrication and clinical evaluation enabled: 1 The design of a new manual prone cart 2 The design of a new motorized prone cart 3 Collaboration with manufacturers to market and commercialize the new prone carts. The design team first collaborated with Ortho-Kinetics, Inc, a durable medical equipment manufacturer, for the frame fabrication of all new prone cart prototypes, which resulted in the manufacture of 6 prone carts. Four were purchased by the Milwaukee VAMC, the Wisconsin Paralysed Veterans of America, and the Medical College of Wisconsin, and two were used for the motorized prone carts [whose body support is identical to the manual version]. E & J Graham-Field Health Products Inc. and Gendron Inc. were interested in replacing their existing models with the new designs. A final decision has not yet been reached by a manufacturer to market the prone carts. The vast majority of users of both manual and motorized versions were satisfied with their design but both groups reported that both versions were not big enough for eating or writing. Only the motorized prone cart was tested at the Pittsburgh VA Human Engineering Research Laboratory for compliance with applicable ISO electric wheelchair standards, since there are no specific standards for prone carts. Of the tests performed, only the static, impact, and fatigue strength tests could not be completed, because of a rear-caster-stem weld failure. This led to the incorporation of gussets to strengthen the caster stem of new models. Future Work: caregivers outlined that another design of the motorised version should be designed to allow body support for a vertically elevated patient that will help to improve many physiological variables, example, bladder and bowel function.
Researcher's Comments		Sponsorship from National Institute on Disability and Rehabilitation Research, Veterans Service Organisation, and the VA Rehabilitation Research and Development.

RefWorks Number: 1488	**[NEUROLOGICAL]**	Year/County: 2002 - Canada
Reference		Berk C, Honey CR. Bilateral thalamic deep brain stimulation for the treatment of head tremor. Report of two cases. J Neurosurg 2002; 96(3):615-8.
Objective/Questions		To report the authors' experience of treating isolated disabling head tremor due to essential tremor with bilateral thalamic deep brain stimulation.
Device/Product		Neurological implants: electrodes (lead model 3475, Medtronic Incorporated, Minneapolis) and impulse generator (Kinetra model 3746, Medtronic Incorporated, Minneapolis) for deep brain stimulation.
Users		n = 2 patients (both women).
Method/Tool/Approach		Case report of 2 patients: both underwent placement of units that apply simultaneous bilateral thalamic deep brain stimulation. Surgical targets were verified by using intra-operative macro-stimulation and the stimulators were implanted during the same surgery. Patients were videotaped preoperatively and at 2, 4, 6 and 9 months postoperatively during periods in which the stimulators were turned on and off. Videotapes were randomised and rated for resting, postural and action tremors according to the Fahn clinical rating scale for tremor (on a scale of increasing severity ranging from a score of 0 to 4). Because the scale is not designed for head tremor the patients were also evaluated on the basis of a functional scale that reflected their quality of life and the amount of disability caused by head tremor. This scale is proposed by the authors as a functional scale for head tremor (rated from 0 no tremor to 4 severe tremor, tremor always interferes with social or professional activities and activities of daily living such as feeding and grooming).
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The women were 43 and 41 years of age and had experienced head tremors since the ages of 34 and 4 respectively. Magnetic resonance imaging revealed no structural abnormalities. Both patients experienced no tremor after their stimulators were turned on and adjusted at the 6th postoperative week. The results remained stable throughout the 9 month follow up period. No complications or adverse effects such as paresthesia, dysarthria, dysphagia, infection or cognitive changes were encountered. The authors conclude that bilateral thalamic deep brain stimulation appears to be an effective and safe treatment for isolated head tremor in patients with essential tremor.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1489 [PROTHESES: LIMB, FACIAL & PELVIC]		Year/County: 2002 - Australia
Reference		Davidson J. A survey of the satisfaction of upper limb amputees with their prostheses, their lifestyles, and their abilities. J Hand Ther 2002; 15(1):62-70.
Objective/Questions		To describe the demographics of the Australian upper limb amputees from a human factors point of view. Additional purposes included investigating prosthesis wearing times, the level of satisfaction with individual functional activities, the overall level of satisfaction with the prostheses and abilities, the level of satisfaction with characteristics of the prostheses and types of prostheses used.
Device/Product		Upper limb prostheses.
Users		n = 70 upper limb amputees (50 men, 20 women).
Method/Tool/Approach		Postal survey: 2 questionnaires were developed. The first had 17 questions and was designed to obtain basic information from amputees. It was sent to as many persons as possible who could be located through hospital clinics, prosthesis clinics and amputee associations. They included persons with both upper and lower amputations. 1,000 questionnaires were distributed, 485 responded (411 had lower limb amputations or deficiencies). Of the 74 upper limb respondents to the first questionnaire, 70 completed the second questionnaire. The second questionnaire had 38 questions. Nearly all the questions in both questionnaires were closed ones involving a choice of responses and most were taken from an earlier survey.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The respondents included 63 upper limb amputees and 7 limb deficient individuals. Trauma accounted for the highest incidence of all amputations (70%). 54% had suffered their amputations in the previous 10 years, 27% between 10 and 20 years previously and 19% more than 20 years before. 56% of amputees wore their limbs "once in a while" or "never". Prostheses were most often worn "all the time" for work and social activities. The amount of time amputees wore their prostheses was moderately associated with their level of satisfaction with their prostheses. The association between the amount of time amputees wore their prostheses and their level of satisfaction with their functional abilities was very low. Their prostheses were rated as "fair" or "not acceptable" by 64% of amputees. Sweating was rated as "not acceptable" by 55%. According to the authors this may well be a significant contributing factor to the low prosthetic use. Pain was a problem for 85% of respondents and 40% stated that pain interfered with their ability to wear a prosthesis. The amputees who did not wear prostheses did not have any greater satisfaction with their ability to do the tasks they wanted to do than the amputees who wore prostheses. The authors conclude that this study does not provide any clear evidence that upper limb prosthesis use increases patients' satisfaction with their ability to be functional in the community. They state that it is clear in terms of prosthesis use, optimum outcomes are not being achieved.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1497	**[TOOLS]**	Year/County: 2002 - USA
Reference		Mills T, Holm MB, Trefler E, Schmeler M, Fitzgerald S, Boninger M. Development and consumer validation of the Functional Evaluation in a Wheelchair (FEW) instrument. Disabil Rehabil 2002; 24(1-3):38-46.
Objective/Questions		The purpose of the study is to develop an outcome measurement tool to investigate functional performance of consumers using seating and wheelchair systems as their primary seating and mobility device. The instrument is undergoing systematic development in phases. The results of phase 1 will be reported. The objective of phase 1 is to: (1) select and evaluate existing functional measurement instruments with relevant factors to wheelchair users; (2) conduct videotaped interview with 20 manual and power wheelchair users with various causes of disability to determine what functional tasks are important for them to perform while seated in their wheelchairs and; (3) develop an item bank for the Instrument.
Device/Product		Mobility Devices including: manual and powered wheelchairs, crutches, walkers, standard canes and shower/commode chair.
Users		n = 20 [10 manual wheelchair users and 10 powered wheelchair users] who agreed to participate from a total of 30. Users are identified as individuals who use seating and wheelchair systems as their primary seating and mobility device. 10 males and 10 females with a mean age of 47.8 years. Length of time mobility device used ranged from 1 day to 20 years. Subjects were recruited from Three Rivers Centre for Independent Living, local advocacy groups, and from a roster of individuals who had previously participated in focus groups and mobility research at the Rehabilitation Engineering and Research Centre on Wheeled Mobility. Primary diagnoses included cerebral palsy, spinal cord injury, spina bifida, polio, multiple sclerosis, arthrogryposis, muscular dystrophy, and congenital limb anomaly. The average subject was a wheelchair user for 27.9 years and currently had 2.1 wheelchairs or mobility devices.
Method/Tool/Approach		Both the Canadian Occupational Performance Measure [COPM] and the Matching Person and Technology [MPT] models were used to develop Functional Evaluation in a Wheelchair [FEW], a tool that uses a consumer-responsive model, and addresses the three constructs of the MPT model: milieu (environment and psychosocial setting), person and technology. Phase 1 item development consisted of several incremental tasks. First, existing functional measurement instruments were evaluated. Next trained interviewers [not stated how many or how they were trained] administered a modified version of the COPM and interviews were videotaped [subjects paid $25 for the interview]. The modified version included a detailed demographic section to obtain information regarding consumers current seating-mobility system, and the service delivery process with their current seating-mobility system. Secondly, the modified version asked consumers to report the importance of each reported self-care, productivity, and leisure task relating to function in their seating-mobility system. The COPM has previously demonstrated a high degree of reliability and validity. Data from the interviews yielded 154 items across the 3 COPM categories of self care, productivity and leisure. Two clinicians sorted all items based on shared characteristics into 21 categories derived from literature searches and review of other functional assessment. The entire research team by consensus then used an item-fit approach to reallocate all items from the original 21 categories to 10. The number of categories were reduced to create a new outcome measure that is concise and easy to administer by practitioners, and reflects factors viewed by consumers as most affecting function in their seating-mobility system. Based on the 10 categories, questions for the new outcome measure were developed. Approximately 6 months after completion of the interviews, the 20 subjects were mailed a questionnaire asking them to prioritize the importance of the 10 categories relating to function for a seating-mobility system user and to validate the new categories. Subjects were asked to self-administer the FEW, Beta Version 1 consisting of 10 questions, and to provide feedback about the wording of the items, content of each item, and the scaling system. Additionally, they were asked to provide feedback on aspects of seating and wheelchair mobility that are important to them, but not included in the FEW, Beta version 1. For consumer validation of the FEW Beta Version 1, all subjects responses to the 10 categories on the questionnaire were assigned WRO values using a reverse rank order [e.g. 10=highest priority to 1=lowest priority]. The first author had responsibility for data collection. 17 subjects were contacted by telephone at their homes or workplace and the data was recorded onto identical forms. One subject died and two could not be contacted.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Subjects reported 154 self-care, productivity, and leisure occupational performance issues related to their current seating-mobility system, which were originally grouped into 21 categories. Based on their input, 10 categories [transfers, reach, accessing task surfaces, transportation-portability, human machine interface, architectural barriers, transportation-accessibility, transportation-securement, natural barriers and accessories] were validated for inclusion in the new outcome measure, Functional Evaluation in a Wheelchair [FEW Beta Version1]. Results from the consumer validation for category priority include: seating/mobility systems users ranked architectural barriers [mean 7], transfers [mean 7], and accessing task surfaces [mean 6.41] as the highest priorities. A comparison of consumer responses by WRO sum and ranks for items in the 10 categories the FEW categories and the FEW Beta Version 1. Transfers, transportation-portability, and transportation-securement were the only categories with no variation in rank order on both the consumer validation questionnaire and the FEW Beta Version 1. Consumer responses changed when they were asked to prioritize the importance of categories for wheelchair users in general versus themselves. The small sample size limits generalisability of the results, however, Phase 2 of the study will utilise a larger sample of seating/mobility system users to conduct test-retest validation of FEW. FEW should yield a reliable and valid outcome measurement tool that will help to validate outcome measurement tool that will help to validate the cost effectiveness and functional value of seating and wheelchair mobility systems to consumers and third party payers.
Researcher's Comments		Supported by a grant from the National Institute of Disability and Rehabilitation Research, United States Department of Education.

RefWorks Number: 1511 [ASSISTIVE DEVICES: MOBILITY AIDS]		Year/County: 2002 - USA
Reference		**VanRoosmalen L, Bertocci GE, Ha D, Karg P. Wheelchair integrated occupant restraints: feasibility in frontal impact. Med Eng Phys 2001; 23(10):687-98.**
Objective/Questions		To compare occupant injury measures of a fixed vehicle mounted wheelchair occupant restraint system (FWORS) to a concept wheelchair integrated restraint system (WIRS).
Device/Product		Mobility Device: Wheelchair integrated occupant restraints.
Users		Not appropriate.
Method/Tool/Approach		A 20g frontal sled impact test with a 30mph change in velocity with video recording. Neck loads, neck moments, head, pelvis and chest acceleration, sternum compression and knee and head excursion data were recorded from the wheelchair seated 50th percentile male hybrid III antropomorphic test dummy. A concept WIRS was developed at the University of Pittsburgh Injury Risk Assessment and Prevention laboratory. An SAE J2249 surrogate wheelchair (187lb) representing a powered wheelchair and equipped with a Tarsys WCSS was placed facing forwards on an impact sled platform and secured using a 4 point strap type tie down system. In the FWORS scenario the test dummy was restrained using a vehicle mounted surrogate pelvic and shoulder belt system. In the WIRS scenario the test dummy was restrained using an upper torso and pelvic belt mounted to 3 anchor points on the wheelchair.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The WIRS resulted in a lower head injury criteria value, lower sternum compression and a lower upper torso restraint load than the FWORS. Compared with the FWORS increased head, knee and wheelchair excursions and higher neck loads and moments were measured in the WIRS test. Both restraint scenario injury parameters complied with occupant injury criteria based on General Motors Injury Assessment Reference Values and occupant kinematic requirements defined by the Society of Automotive Engineers voluntary standard. A higher motion criteria index was calculated for the WIRS scenario and a comparable combined injury criteria index was calculated for both restraint scenarios. The authors conclude that the sled impact test showed WIRS concept feasibility, facilitating further development by manufacturers who may wish to pursue this restraint principle to increase wheelchair occupant safety and comfort during travel in motor vehicles. They argue that surveys have shown that FWORSs do not meet the needs of individuals because of poor belt fit, difficulties in use and discomfort therefore individuals currently using FWORSs are likely to be exposed to higher injury risks than found in this study. They argue that a WIRS should be integrated into wheelchair design and not seen as an add on feature to existing wheelchairs since loads and moments acting on the wheelchair system are different than when using a FWORS scenario and that alternative impact directions need to be evaluated.
Researcher's Comments		Grants from the Rehabilitation Engineering Research Center & the National Institute of Health

RefWorks Number: 1514	**[SKIN RELATED]**	Year/County: 2001 - The Netherlands
Reference		Jonker MJ, de Boer EM, Ader HJ, Bezemer PD. The oedema-protective effect of Lycra support stockings. Dermatology 2001; 203(4):294-8.
Objective/Questions		To investigate the effect of mild compression on the development of swelling of the legs and the effect on subjective complaints in healthy subjects.
Device/Product		Lycra support stockings (Dupont).
Users		n = 118 healthy volunteers (60 men & 58 women).
Method/Tool/Approach		161 individuals contacted the researchers, based on a questionnaire of medical and phlebological history, 153 were invited to be screened. 28 were excluded (118 completed the study). Cross over study with individuals randomly divided into 2 groups (X and Y) of equal size for a crossover between 2 types of support stocking. 1 group wore stocking X for at least 5 days and underwent volume measurements at the beginning and end of a full working day on 2 days. The other group underwent the same procedure wearing stocking Y. The following week group 1 wore stocking Y and group 2 stocking X. The control stocking was worn in the last week. The diurnal volume change of the lower legs during full working days was monitored with an optical leg volume meter (Bosl Medizintechnik, Cologne, Germany) in individuals without objective symptoms of chronic venous insufficiency. Individuals that agreed to participate were examined by 2 dermatologists, palpation and Doppler ultrasound was performed. Individuals with any degree of chronic venous insufficiency were excluded. Further exclusion criteria included pregnancy, disorders or medication usage that might cause oedema, a profession that required more than 80% walking in the course of the day and a physical build that would hamper fitting standard stockings. The diurnal volume changes after wearing 2 kinds of class I support stockings (X: average pressure at the ankle of almost 14mmHg; Y: almost 18mmHg) were compared with the diurnal volume change after wearing a control stocking (Z: almost 6mmHg). The effect on subjective feelings of the legs was also noted using a questionnaire that asked about complaints of tired/heavy feelings of the legs, swollen ankles and or feet, restless legs and or pain or cramps in the legs. Possible answers were no, sometimes or often, separately for the right and left leg. The comfort of the stockings was noted as well: whether they fitted well, felt too tight or if they slid down. The questionnaire was filled out after the initial consultation, after wearing stockings X and Y and the control stockings.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The mean age of the volunteers was 39.3 years (20-59). Prior to the volume measurements a size adaptation of the stockings was needed for 58 out of 118 individuals because they did not fit in the regular sizing table of the standard size stockings. Although a size adaptation was done (or perhaps because of it) many complained about the comfort of the stockings, in particular the control stockings. Most complaints were about "sliding down": with the control stockings this was 84% and with stocking X it was 43%. However a bad fit did not turn out to be a major influence on the diurnal volume changes. It appeared that healthy people have a mean daily volume increase in the legs of 2.3% in women and 1.6% in men. Mild compression stockings reduced this daily increase with 31 and 18% in males and females respectively, by stocking X and 37 and 32% by stocking Y. Subjective feelings occurred in 57% of all cases. A beneficial effect on subjective feelings, in particular tired and swollen legs was found. A difference in this beneficial effect between stocking X and Y was not obvious. The authors conclude that mild compression stockings reduce diurnal oedema and unpleasant feelings of the legs in healthy individuals. However they note that a problem with stockings is proper sizing. A size adaptation was needed in about 50% of the sample.
Researcher's Comments		All stockings were provided by Dupont de Nemours International SA, Geneva.

RefWorks Number: 1551	**["OUT OF THE MOULD"]**	Year/County: 2001 - USA
Reference		Fuhrer MJ. Assistive technology outcomes research: challenges met and yet unmet. Am J Phys Med Rehabil 2001; 80(7):528-35.
Objective/Questions		Current issues surrounding the assessment of Assistive Technology Services with reference to: special requirements, achievements and unmet challenges.
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		Deciding on the measures to use is one of the problematic aspects of planning an outcomes study of most assistive technologies. Three initiatives are discussed that attempts to fill the existing measurement gaps in the general-purpose instruments like the Functional Independence Measure [FIM]. These initiatives include: Psychosocial Impact of Assistive Devices Scale [PIADS]; Quebec User Evaluation of Satisfaction with Assistive Technology [QUEST]; "Cost Effectiveness Rehabilitation Technology" measurement developments undertaken by an interdisciplinary program. (The 'Cost Effective Rehabilitation Technology' [CERTAIN] program involves four centres in Sweden, Norway, The Netherlands and Italy. It is able to analyse both cost-utility and cost-effectiveness to assess the provision of assistive technologies). Three unmet challenges are also discussed: Operationalising a multiple-stakeholder approach to outcomes research; Formulating adequate treatment theories; Creating shared databases.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		1) Stakeholder diversity is a prominent theme in rehabilitation outcomes/literature. The identification of how homogeneous each party is and what the similarities and differences are will help to clarify its nature. 2) A long range goal is to develop relatively broad treatment theories that address commonalties among an array of specific interventions and that are applicable to diverse populations of service recipients. 3) To obtain systematic evidence about which rehabilitation interventions work best for the least cost, will depend increasingly on information from large databases that are contributed to by multiple service programs. 4) Use of clinical databases, constructed using Clinical Practice Improvement methodology, to obtain systematic evidence about which rehabilitation interventions work best for the least cost, shall depend increasingly on information from large databases that are contributed to by multiple service programs.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1585	**[TOOLS]**	Year/County: 2000 - Canada
Reference		Demers L, Weiss-Lambrou R, Ska B. Item analysis of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST). Assist Technol 2000; 12(2):96-105.
Objective/Questions		The purpose of this article is to present the results of an analysis of the 24 items comprising the Quebec User Evaluation of Satisfaction with Assistive Technology [QUEST] and to explain how a subset of items demonstrating optimal measurement performance was selected.
Device/Product		Assistive Technology Devices: primarily Mobility & Seating Devices.
Users		n = 150 who use assistive devices were recruited from assistive technology centres in three rehabilitation facilities. n = 5 trained interviewers. n = 12 international content experts representing 11 facilities in Canada, the US and The Netherlands.
Method/Tool/Approach		The criteria against which the items of the QUEST were measured were general acceptability, content validity, contribution to internal consistency, test-retest reliability and sensitivity. QUEST was administered in a face-to-face interview. Data from 2 sources were used in the item selection process: a Montreal sample and data derived from an International Content Validation Study [1999]. 1st source of data - Subjects recruited through assistive technology centres in 3 Montreal rehabilitation facilities. The assistive devices targeted were primarily seating and mobility aids, such as manual and powered wheelchairs and lower limb prostheses. QUEST was administered to the subjects by one of five trained interviewers on two separate occasions, with 7-11 days between evaluation sessions. To establish test-retest stability all subjects that were evaluated twice by the same rater n=85 was analysed. 2nd source of data - The second data source was derived from the International Content Validation Study [1999]. 12 international content experts were invited to participate in a multisite test and content validation of QUEST. They were each sent a test kit and were given 6-8 months to use the satisfaction tool with any number of devices available to them, which totalled 578 assistive devices, primarily seating and mobility aids [wheelchairs and scooters] but also including transfer aids [toilet adaptation, shower seats and chairs, stair-lifts], augmentative communication devices, lower limb prostheses, and environmental control devices. As content experts, the respondents completed a questionnaire on the instrument's content coverage and item relevance, the administration procedures, the instruction manual, the assessment materials, and the future commercial publication of QUEST. Only the results for content relevance are presented here. Item ratings relative to each of the measurement domains were used to eliminate the weakest items and retain the most appropriate subset for the revised QUEST. ITEM SELECTION PLAN: The item selection consisted of two parts, the first part was concerned with the criteria used to determine whether or not an individual item reached an acceptable level of response for each of the five measurement properties. The second part involved decision-making. It included establishing priorities among the measurement properties and conducting a factor analysis to refine and finalize the selection of items.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The first series of analyses reduced the item pool approximately by half. And the second series of analyses led to the final selection of 12 items. Factor analysis results suggested a bi-dimensional structure of satisfaction with assistive technology related to the assistive technology device: comfort, dimensions, simplicity of use, effectiveness, durability, adjustments, safety, and weight; and services: professional services, follow-up services, repairs/servicing, and service delivery. In terms of measuring satisfaction along these dimensions, a remaining challenge is posed by the sensitivity of the revised QUEST. In the present study this measurement property was not confirmed for the aggregated 12 items nor for the subscales. It is hoped that in future studies the 12 item QUEST resulting from this study's findings will discriminate among individuals with different satisfaction levels over a large spectrum of disabilities and assistive devices.
Researcher's Comments		Financial support provided by the Fonds pour la recherche en sante du Quebec, the Canadian Occupational Therapy Foundation, and the Universite de Montreal.

RefWorks Number: 1631	**["OUT OF THE MOULD"]**	Year/County: 2000 - USA
Reference		Malassigne P, Nelson AL, Cors MW, Amerson TL. Design of the advanced commode-shower chair for spinal cord-injured individuals. J Rehabil Res Dev 2000; 37(3):373-82.
Objective/Questions		2 Year development project's purpose was to design a new commode-shower wheelchair that can safely be used by patients with Spinal Cord Injury [SCI] and their caregivers.
Device/Product		Mobility Device: Commode-Shower Wheelchairs both self-propelled and assisted care chairs
Users		n = 147 survey of veterans with SCI to evaluate existing commode-shower chairs. Number of participants in clinical evaluation of prototypes not mentioned, however this sample included participants with SCI from the Milwaukee and Tampa Veterans Affairs Medical Centres. This pilot study was done by the authors in 1993.
Method/Tool/Approach		The need for this new design was consumer driven. Evaluation of existing chairs was undertaken as part of a pilot study, involving the design and clinical use of the chair by patients and caregivers. From this evaluation, functional and performance criteria were established in order to develop chair prototypes for clinical evaluation at the Milwaukee and Tampa VA Medical Centers. Typical of many such projects, an iterative process of prototype development, laboratory evaluation, and clinical evaluation was used to develop this new chair. The responses received from patients and caregivers were incorporated into the next prototype until the new chair design was complete. Patients and caregivers completed questionnaires addressing issues of their interaction with the new commode-shower chair. Primary Clinical Evaluation involved using one Questionnaire for the patients and one Questionnaire for the caregivers. The questions were related to the features of the chair relative to bowel care and showering, issues of seating, and transfer safety to and from the chair. [Not elaborated on]. Secondary Clinical Evaluation of prototype involved focus groups with patients and caregivers. [Not elaborated on]. The chair was designed based upon the following safety and performance criteria: overall chair safety; chair positioning over a toilet; seat design; seating position; hand access to the perianal area; caregiver friendly; durability/rust-proofing; propulsion pushrims; design of two versions.
Product Development Stage at which users were involved	Concept	Clinical evaluation.
	Design	Safety and performance criteria of the 2 versions- assisted and self-propelled.
	Testing & Trials	Prototype testing: "The long term clinical evaluation at the Milwaukee and Tampa VA Medical Centers".
	Production	X
	Deployment	Collaboration with manufacturers, some decided to commercialise.
Conclusions		Patients and caregivers identified the following flaws in the commode-shower chairs used in SCI centres: 1) Risk for patient falls during transfers, propelling, and while leaning over for showering; 2) Risk of pressure ulcers due to inadequate padding and seat positioning for lengthy bowel care regimes; 3) Inadequate caregiver access to the perianal area of the patient to perform bowel care procedures; and 4) Wheel-related inability to properly position the chair directly over the toilet. During the iterative process, several new features were invented: a new seat design, a foot-lift, oversized pushrims, swing-away pivoting armrest and new footrest featuring edgeless heel cups. Two chairs were designed, one self-propelled and the other assisted-care chair. Only the self-propelled design was clinically evaluated and prototypes tested. The self-propelled chair addressed the areas of concerns as highlighted by the patients and carers. The advanced commode-chair was successful after clinical evaluation and is being patented by the Department of Veterans Affairs. New suggestions by patients and carers for the design of a folding commode-shower chair for home use has led to collaboration between the Veterans Affairs Rehabilitation R&D Service and Everest & Jennings and the wheelchair is almost complete. The authors first collaborated with Milwaukee-based Ortho-Kinetics [OKI] during the development stages of the Advanced commode-shower chair. However, OKI decided not to commercialize this chair when it was completed. The chair was then presented to Invacare, Active Aid and Everest & Jennings. Although both Active Aid and Everest & Jennings were interested in the new chair for their product line, Everest & Jennings decided to manufacture and market the chair.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1638	**["OUT OF THE MOULD"]**	Year/County: 2000 - USA
Reference		Ramanathan R, Eberhardt SP, Rahman T, Sample W, Seliktar R, Alexander M. Analysis of arm trajectories of everyday tasks for the development of an upper-limb orthosis. IEEE Trans Rehabil Eng 2000; 8(1):60-70.
Objective/Questions		To help persons with Neuromuscular Disease [NMD] to pursue Activities of Daily Living more independently, research efforts have focused on developing orthotic devices. This paper focuses on the design architecture of an upper limb orthosis.
Device/Product		Upper Limb Orthosis - a device for mechanically guiding the arm while counteracting the effects of gravity & Wheelchair.
Users		n = 5 right handed males with normal neuromuscular functioning, age 34 to 41.
Method/Tool/Approach		The primary thrust of the study was the analysis of the arm trajectories of participants performing nine everyday tasks while in a wheelchair. These procedures were recorded using sensors placed at the wrist, elbow, shoulder and chest. Each of the nine tasks was executed 3 times normally- where subjects were asked to perform the specified tasks as naturally as possible. Then the tasks were repeated 3 times in a constrained manner that minimised elbow movement. The tasks included: picking up the phone, talking briefly, and hanging up; brushing teeth; combing hair [although they were wearing baseball caps the simulated the motions]; spooning water from a bowl; using a folk to eat two pieces of cheese; taking 2 sips from an 8 ounce cup of water; reaching to pick up 4 small metal objects; writing 'HELLO' on a sheet of paper; scratching the nose on both sides; and to reach their 'envelope', that is to trace out the limits of their reach in the horizontal plane at varying heights, torso movement was minimized. The recordings were imported into a computer programme [Matlab] where they were analysed and plotted, and on which the orthotic design parameters could be based.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		Envelopes for the nine everyday tasks were derived from all three trials for both normal and constrained conditions. However, only the third trial was extensively used to develop orthosis design parameters, under the assumption that it was the most practiced and representative. Currently, only simple unpowered orthotic devices have been commercialised. This may likely stem from issues of cost and acceptability more than lack on development and innovation. In their quest to develop a simple, inconspicuous and modular device, many tradeoffs were made, with few having greater ramifications than the size of spatial envelope to support. The decision to use the trajectory that encompassed observed normal task execution will likely result in a somewhat larger trajectory than the absolute minimum size required to perform the tasks. Besides allowing subjects greater flexibility and less contractures, the larger trajectories may enable some users, who may not have the trunk strength, required to carry out the contortions exhibited by subjects during constrained tasks. There were patterns in the plots that may be used to reduce the trajectories required for an orthosis. The range data obtained in this study may be applied to estimate spatial trajectory specifications for many disparate orthosis designs.
Researcher's Comments		Supported by grant from the National Disability and Rehabilitation Research, US Department of Education.

RefWorks Number: 1643	**["OUT OF THE MOULD"]**	Year/County: 2000 - India/Canada
Reference		Mulholland SJ, Packer TL, Laschinger SJ, Lysack JT, Wyss UP, Balaram S. Evaluating a new mobility device: feedback from women with disabilities in India. Disabil Rehabil 2000; 22(3): 111-22.
Objective/Questions		1 To gather the opinions of potential wheeled mobility device users at an early stage in the design process to ensure the development of technology which would meet their functional needs. 2 A feedback tool for data collection was also developed.
Device/Product		Mobility Device -GAD12 a ground-wheeled mobility device to perform activities inside and outside the house.
Users		n = 8 women with bilateral lower extremity disabilities living in Gujarat, India. Activities were predominantly carried out on or close to the ground, they were unable to walk in a fully upright position, they had functional upper extremity strength, range of motion and co-ordination and they were able to provide verbal feedback. These women were originally recruited in another study by the primary investigator.
Method/Tool/Approach		Problem: Women in India carry out their duties inside and outside of the house. Physical barriers to the use of 'normal' wheelchairs include slopes, mud, rocks and steps. Also, washing and cooking takes place at ground level. The design team comprised members from the technology group of the International Centre for the Advancement of Community Based Rehabilitation [ICACBR], Queens University Canada and the National Institute of Design [NID] India. The team included occupational therapists, physiotherapists, engineers, product designers and ergonomists. Feedback Interview Tool: this was developed based on the available literature, information gathered during the discussion group in Canada, results from the mobility needs assessment (India, 1998) and personal clinical (occupational therapy) experience. The resulting tool consisted of three sections. Section one consisted of 31 closed-ended questions soliciting feedback specifically on aspects of the device design, section two was to determine the participant's perception of the usefulness and potential function of the new mobility device. They were asked to 'go through the day from the time you get up until the time you go to bed to see where and what you think you would use this GAD12 for'. The investigator verbally guided the women through their activities of daily living and asked probing questions to clarify and provide detail when necessary. Section three photodocumented the woman sitting on the device in positions of comfort, propulsion, work (whereby various tasks were simulated) and transporting objects. All data was analysed using three broad predefined categories based on the interaction between the mobility and the user, the physical environment and the sociocultural environment. To establish the accuracy and trustworthiness of the qualitative data, Lincoln & Guba's (1985) criterion was used throughout the study. The data was collected in one 1.5 hours session during which a full scale working mobility device was introduced i.e. a rough prototype, tested for Approximately 20 minutes in the home environment [with verbal instructions and teaching], and the feedback interview conducted to determine to what extent their functional mobility needs were met. Interviews included primarily the subjects, with their families, extended families and community members participating in a spontaneous manner. Interviews were audio recorded and transcribed with a translator to ensure accuracy.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	Prototype testing.
	Production	X
	Deployment	X
Conclusions		The subjects were between 13 and 28 years old, having a range of formal education from 7th to 12th standard, and one having had no formal education. Seven had polio and one suffered spinal cord injury. In this study the users preferences often opposed what would typically be recommended when prescribing a wheelchair in a rehabilitation setting. For example they preferred to sit cross-legged versus the traditional upright sitting position. These conflicting design considerations and preferences present challenges for the design team in determining how new mobility technology could best meet an individual's and population's needs. 7 of the women stated that they would use the GAD12 but they also were able to recommend changes to guide further development. But the differing and sometimes conflicting opinions given are a further challenge to the ongoing design of the device. However, the authors did acknowledge that longer term field testing would enable the women to give feedback with Appropriate breath and depth, also the small sample size in one geographic region cannot be generalised beyond this study. The technical aspects of the device were addressed by other team members and are documented in additional sources i.e. 1999 paper. The interview process was used to initiate wider interest in the project and thereby nurture support from the community for future field-testing of a new mobility device and to eliminate fears or suspicions by facilitating an open forum for sharing information. This research has highlighted that: function and quality, when designing new technologies, should not get lost in, or overtaken by, mechanical and technical issues; the task is to always strive to design using local resources and with the absolute goal to meet the needs and preferences of the end user; to consider all design parameters and balance a product's options so as to meet both group and individual needs. Although data was collected using a case study approach, the resulting information was analysed, interpreted and presented using an across case comparison. The small sample size and lack of consensus in some of the results indicates the need for further research and field testing of this new mobility device design.
Researcher's Comments		Funded by the Canadian International Development Agency.

RefWorks Number: 1653	**[DENTAL & ORAL]**	Year/County: 1999 - USA
Reference		Kapur KK, Garrett NR, Hamada MO, Roumanas ED, Freymiller E, Han T, et al. Randomized clinical trial comparing the efficacy of mandibular implant-supported overdentures and conventional dentures in diabetic patients. Part III: comparisons of patient satisfaction. J Prosthet Dent 1999; 82(4):416-27.
Objective/Questions		To compare the benefits perceived by diabetic patients who received a new maxillary denture and a mandibular conventional denture (CD) and an implant-supported overdenture (IOD).
Device/Product		Dentures and mandibular implants: maxillary and mandibular conventional denture (CD) and implant supported overdenture (IOD) (No specific devices named).
Users		n = 89 patients (gender not stated).
Method/Tool/Approach		Randomised clinical trial: new maxillary and mandibular denture were delivered to 89 diabetic denture wearers with clinically acceptable metabolic control who treated their diabetes either with or without insulin. 37 received maxillary and mandibular CDs and 52 received a maxillary CD and an IOD. 2 questionnaires with categorical responses were used: the first contained 13 questions to ascertain a patient's absolute assessments of original dentures at entry and study dentures at 6 and 24 months after treatment completion (rating the patient's perceptions of their chewing function, speaking ability, social life, denture hygiene, self-confidence and overall satisfaction); the second questionnaire had 11 questions that assessed the relative change perceived by patients with study dentures (evaluated on a 7 point ordinal scale +3 to -3). Patients underwent detailed oromaxillofacial examinations, including clinical ratings of their dentures and denture bearing tissues and a series of masticatory performance and other sensorimotor function tests at study entry and at 6 and 24 months post treatment. The 2 questionnaires had been used in other outcome studies.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The participants ranged in age from 48 to 75 years. Of the 78 patients who completed the post treatment assessment at 6 months, 68 patients provided longitudinal data for questionnaire I and cross-sectional data for questionnaire II. In addition, 46 patients provided longitudinal data for questionnaire I at 24 months. Both mean scores and percentage distributions of longitudinal data for questionnaire I showed perceptual improvements with both types of study dentures. Improvements were higher in the IOD than in the CD group. Mean scores failed to show any significant differences between the 2 groups. More than 84% of the patients were fully or moderately satisfied and experienced little or no discomfort with CDs. The only significant difference was found in the change in percentage distributions for perceptual chewing ability in favour of the IOD group. Even this advantage was lost at 24 months. With the comparative questionnaire a higher percentage of patients in the IOD group than in the CD group perceived improvements with study dentures from their original dentures in chewing ability, chewing comfort and denture security. However mean differences were statistically significant in favour of the IOD group only for chewing ability and less difficulty to chew hard foods. The authors conclude that the IOD offers some advantage in terms of perceived chewing function over the CD.
Researcher's Comments		Dental Research and Department of Veterans Affairs Medical Research. The chairman of Removable Prosthodontics provided the dental laboratory and other financial support to complete the study.

RefWorks Number: 1660	**["OUT OF THE MOULD"]**	Year/County: 1999 - UK
Reference		Morris C. Patient pull: the changing influences on medical device design, Part I. Med Device Technol 1999; 10(4):30-3.
Objective/Questions		To outline the changing influences on medical device design.
Device/Product		Medical Devices.
Users		n = 0.
Method/Tool/Approach		Opinion article stating that the medical device industry is in the process of a major paradigm shift, driven by increasing levels of regulatory control, cost containment and patient involvement in treatment programmes. The role of the patient is stated as changing from passive participant to active partner, which the author states will have a significant impact on the design and development of devices.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The author states that the medical device industry is currently being squeezed on all sides with information technology increasing consumer expectations, growing ageing populations in industrialised nations, escalating healthcare costs and governmental pressure to contain expenditure. Companies are being required to improve not only efficacy but cost-effectiveness in real clinical environments. It is also stated that the emphasis on outcomes and the collection of data requires greater collaboration between companies, clinicians and patients however the current status quo in terms of who companies identify as the customer (the clinician) has in the past led to a neglect of the patient as the actual end consumer. Traditionally patients have gained access to care through their general practitioner however currently with the recognition of the sub-optimal healthcare management, particularly of chronic disease, healthcare reforms have been introduced to empower patients and provide them with more choice. For example, there has been a growth in self-diagnostic tests suggesting that individuals wish to take more active roles in their own management. It is argued that one of the keys to a consumer based market must be to focus on involving the consumers and other relevant stakeholders including manufacturers, clinicians, and regulatory bodies as early as possible in the device development process. This will help prevent situations such as with asthma inhalers where users have been noted to be unable to use their device correctly, with some too embarrassed to use it however they have stated a desire to be involved in the design of their device. It is concluded that the patient, the ultimate consumer of health care will assume an increasingly important role in healthcare, with the shift towards patient centred health care significantly influencing medical device design as consumers become more armed with good quality information, and demand choice and value for money.
Researcher's Comments		Funding not addressed. The author is responsible for market development at Team Consulting Limited, Barkway.

RefWorks Number: 1662 [TOOLS]		Year/County: 1999 - USA
Reference		Pruitt SD, Seid M, Varni JW, Setoguchi Y. Toddlers with limb deficiency: conceptual basis and initial application of a functional status outcome measure. Arch Phys Med Rehabil 1999; 80(7):819-24.
Objective/Questions		The objective of this paper is to describe the conceptual foundation, development, and initial psychometric analyses of a new outcome measure of functional status in toddlers with limb deficiency.
Device/Product		Upper & Lower Limb Prostheses.
Users		Participants were from a large sample of children, adolescents, and parents who volunteered for an investigation into biopsychosocial aspects of limb deficiency. Potential study enrolees were found from a systematic review of medical records, in two pediatric clinics, over three years. n = 20 mothers of children [8 girls and 12 boys, age 1-4 years old] with acquired or congenital limb deficiency from an outpatient orthopaedic clinic.
Method/Tool/Approach		The Child Amputee Prosthetics Project-Function Status Inventory for Toddlers [CAPP-FSIT] is a standardized instrument designed to assess functional status in toddlers aged 1-4 years who have either an upper or lower limb deficiency. Because of limited communication capacity of the children, parents serve as proxies in pediatric health care evaluation. The parents rate their child's performance of 37 developmentally appropriate behaviours using two scales- "does the activity' or 'uses a prosthesis' using a five point system. Parents completed the self-report measures during a routine medical clinic visit. TOOL DEVELOPMENT: The initial item pool of the CAPP-FSIT was created by soliciting written items from the Child Amputee Prosthetics Project clinicians [physicians, psychologists, physical therapists, and occupational therapists] experienced in the management of pediatric limb deficiency including rehabilitation and prosthesis fitting and training. The literature addressing pediatric prosthesis training and functional activities in children with limb deficiency was also reviewed. The group of clinicians generated 48 items that described everyday activities relevant to toddlers with limb deficiency. Item elimination procedures consisted of informal item content studies and formal, empirical strategies. If an item could not readily be identified as one that described an activity that required predominantly upper extremity function or predominantly lower extremity function, it was removed.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Cronbach Coefficients: Estimates of internal consistency [0.95], reliability of the measure are high [36 of the 37 items correlated above the priori established criterion of 0.25], suggesting conceptual congruence among the items. Initial validity studies confirm the CAPP-FSIT differentiates between toddlers with upper limb deficiency and lower limb deficiency in terms of functional activity and prosthesis use. The new measure does not appear to be contaminated by gender or socioeconomic status. To the authors knowledge, this is the first attempt to develop an empirically validated instrument to assess functional abilities specific to this very young population of children with limb deficiency. In addition, the descriptive data presented herein may be the first to objectively characterize the functional abilities of these children.
Researcher's Comments		Supported by grants from the Shriners Hospitals for Crippled Children Research Fund and the Milo Brooks Foundation for Limb Deficient Children. "…No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the authors or upon any organization with which the authors are associated…"

RefWorks Number: 1705	**[TOOLS]**	Year/County: 1998 - Australia
Reference		Walton TR. The outcome of implant-supported fixed prostheses from the prosthodontic perspective: proposal for a classification protocol. Int J Prosthodont 1998; 11(6):595-601.
Objective/Questions		Development of a classification protocol for the reporting of outcome on implant-fixed partial dentures.
Device/Product		Supported Fixed Prostheses (Dentures).
Users		n = 0.
Method/Tool/Approach		Background: both fixed and removable implant supported prostheses comparisons between reported studies are difficult because of a lack of uniform, well-defined evaluation standards. Thus a Literature review was undertaken on the accepted criteria for assessing and presenting outcome of osseointegrated implants. A 6 field protocol was developed by the author. These fields included: successful, surviving, unknown [lost to follow-up], dead, retreatment [repair] and retreatment [failed]. The fields are well-defined based on objective standards and accounts for retreatment as well as failures. The proposed protocol was applied where possible to reports on the outcome of fixed partial dentures in several published articles.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		It was difficult to find sufficient information in any study that allows a retrospective application of this protocol from the literature review. Many authors allude to complications associated with prostheses, but few provide comprehensive details. When sufficient information is provided, it is interesting to compare a 4 field protocol [success, surviving, unknown and failed], with the 6 field protocol. Allowing for some inaccuracy in interpretation of the data it showed a potentially deceptive nature in one of the criteria in the 4 field protocol. In all cases there was a stark difference between the authors claims of success and the outcome according to the 6 field protocol. Some illustrated examples show that "success" rates vary when replacement, modification and repair of prostheses are taken into consideration. It is accepted that the outcome of a given prosthesis does not necessarily correspond to the outcome of the overall prosthodontic treatment, as the latter also involves an assessment of outcome as perceived by the patient and accounts for planned revisions. A 1997 editorial [quoted] suggested that traditional decision-making in patient care is being challenged by insurance companies, government agencies, and other third party providers. They claimed that pressure is being placed on dental practitioners to produce the evidence upon which decisions are made and to demonstrate that treatment results in predictable and cost-effective outcomes. The costs associated with repairs, replacements, and failures of implant supported prostheses will obviously affect such outcomes. If adopted, the proposed protocol would allow meaningful comparisons to be made between prosthesis designs and between the capacities of different implant systems to support such designs. In addition, it would assist in evaluating the cost-effectiveness of implant-associated treatments. These outcomes could then be compared with more traditional tooth-supported treatment options.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1716	**[DENTAL & ORAL]**	Year/County: 1998 - Canada
Reference		Awad MA, Feine JS. Measuring patient satisfaction with mandibular prostheses. Community Dent Oral Epidemiol 1998; 26(6):400-5.
Objective/Questions		The aim of this study was to assess the magnitude and significance of the combined effect of different functional aspects of mandibular prostheses on patients' overall ratings of general satisfaction.
Device/Product		Dental Prostheses.
Users		n = 120 subjects who have been edentulous for at least 10 year, and wear their dentures on a regular basis, age 35-65 years old. These edentulous patients responded to an advertisement offering replacement of their current prostheses.
Method/Tool/Approach		The subjects were informed that a randomised control clinical trial was being conducted comparing two types of treatment for the mandible: conventional dentures and implant supported prostheses. Patients were offered a new replacement to their current prosthesis via an advertisement. They were informed about an RCT (Randomised Control Trial) where they would either get conventional dentures or implant prosthesis. Prior to randomization, patients were asked to complete a questionnaire designed to evaluate their current mandibular prostheses. The selection of items on this questionnaire was based on the results of qualitative research, in which patients were asked which features of prostheses they perceived to be important. Consultations with prosthodontists and a review of items cited in reports from other studies were also used to develop the measures. Using 100mm Visual Analog Scales [VAS], for which higher scores indicate greater satisfaction, subjects were asked to rate overall satisfaction with their current prosthesis. They were also asked to rate their level of comfort, ability to chew, stability, aesthetics, ability to speak and ease of cleaning their prostheses. They were also asked to rate their general satisfaction with their dentures. In addition, subjects were asked to choose from these six factors the one that they perceived to be the most important. Ratings of general satisfaction on the VAS were used as the dependent variable, while VAS ratings of level of comfort, ability to chew, stability, aesthetics, ability to speak and ease of cleaning their dentures were the independent variables. In addition, age, gender and ranking of the most important quality of prostheses were considered potential variables that could affect each independent variable on the general satisfaction ratings.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	Randomised Control Trial
	Production	X
	Deployment	X
Conclusions		Multiple regression methods revealed that gender, as well as patients ratings of comfort, stability, aesthetics, ability to chew and ability to speak with their prostheses contributed significantly to general satisfaction. Furthermore, 89% of the variation in ratings of general satisfaction was explained by these factors. In addition, patients who considered ability to chew as the most important factor associated with their dentures rated their general satisfaction significantly higher than the other subjects. Univarate analyses indicated that age is a significant predictor of overall significant predictor of overall satisfaction with mandibular prostheses, which suggest that as patients gets older, they become less satisfied with their prostheses. However, once level of comfort was included in the multivariate model, this effect was no longer observed. Females rated their overall satisfaction with their dentures significantly higher than did the males. The authors believe this to be due to the 'less biting force' produced by females resulting in less dislodging of their dentures and which will be more comfortable.
Researcher's Comments		Industrial Partners Nobel Biocare Canada Inc. & Laboratoire Dentachrome Inc. Funded by the Canadian Medical Research Council, Health and Welfare Canada and the Fonds de recherche en sante du Quebec.

RefWorks Number: 1722 [PROSTHESES: LIMB, FACIAL & PELVIC]		Year/County: 1998 - Turkey
Reference		Anafarta K, Yaman O, Aydos K. Clinical experience with Dynaflex penile prostheses in 120 patients. Urology 1998; 52(6):1098-100.
Objective/Questions		To present the authors experience with the Dynaflex self-contained inflatable penile prosthesis and define specific complication and patient dissatisfaction rates.
Device/Product		Penile Prostheses: Dynaflex (American Medical Systems).
Users		n = 120 men.
Method/Tool/Approach		Prospective study between 05/1990 and 01/1998 where 120 patients underwent implantation of this device. All patients attended regular visits during the first 2 months, with follow up ranging from 2 to 80 months (mean 42). After the 1st 2 months further information was obtained by direct questioning during follow up visits and in a telephone survey or by mail with standardised questionnaires (no further details provided).
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The average patient age was 52 years (30-790 with the following aetiologies of impotence: vascular disease, diabetes, Peyronie's disease, postprostatectomy, radical surgery and trauma. Specific complication rates observed after penile prosthesis implantation were: prosthetic infection 4.16% (necessitating explanation); mechanical device failure 7.5% (bilateral cylinder failure in 5 patients, requiring reoperation; and unilateral cylinder failure in 4, who were satisfied with their intact cylinder function and chose not to undergo reoperation); and patient dissatisfaction because of inability to work the pump 16.66%. After intensive teaching the dissatisfaction rate dropped to 0.83%. The overall complication rate was 14.15%. The authors argue that with several types of penile prostheses available Dynaflex can be regarded as an appropriate alternative with a relatively low mechanical failure rate. However they state that careful preoperative assessment and patient education in the use of the pump mechanism are essential to obtain a successful result.
Researcher's Comments		Funding not addressed.

RefWorks Number: 1869	**[TOOLS]**	Year/County: 1996 - Sweden
Reference		Oberg U, Oberg T. Worse functional status among old people when admitted for arthroplasty--an evaluation with a new assessment system. Scand J Caring Sci 1996; 10(2):96-102.
Objective/Questions		To discover whether there are age-related differences in functional status of patients referred to an orthopaedic clinic for total hip or knee joint arthroplasty, and, if so, to compare this age pattern with that of a healthy control group of approximately the same age. A "new" Functional Assessment System [FAS], including both impairment and disability variables was used in this study.
Device/Product		Total Hip & Knee Prostheses.
Users		n = 42 healthy subjects [Control Group]. 16 men and 26 women. Mean age 69.4 years. Comprised of hospital staff, relatives of patients, and from a pensioners association. n = 709 patients with osteoarthritis of the hip (426) or knee (283) were examined. 313 were men and 396 women, mean age 69.3 years. These patients were consecutively collected from the list of patients referred to the orthopaedic clinic, for total joint replacement. For patients with osteoarthritis of the knee the radiographical severity must be >=grade II [on a 6-grade scale], and show instability. Contraindications: infection, a non-cooperative patient, and a poor general condition. Age was not included in these criteria. The patients are considered to represent an average rural population with osteoarthritis in Sweden. None of the patients had serious heart or lung disease, or other diseases of the musculoskeletal system.
Method/Tool/Approach		All the patients and healthy subjects were examined using the FAS in the same way [time period not stated]. A physiotherapist carried out the rating. Clinical evaluations: Active range of motion of the hip and knee was measured with a standard manual goniometer with long telescopic shanks. Muscle strength, tested as isometric extension and flexion forces in the knee, was measured with a strain-gauge dynamometer at 45 degrees of knee flexion and with the patient in a sitting position. Rising/sitting down was recorded as the lowest possible sitting height of a chair with adjustable height and without armrests. Rising from a half-standing position was measured as the maximum number of times the patient could rise from a high chair in one minute, with a hip angle of about 135 degrees. Step height was measured using a platform with different step heights, corresponding to ordinary stairs, bus and train stairs, and so on. The time standing on one leg was tested as the number of seconds the patient was able to stand on his or her affected leg. Gait speed was tested on a 65m indoor walkway. The social variables were evaluated by a personal interview with the patient. Pain was evaluated in a manner related to standard clinical evaluation of the indication of surgery. The patients and controls were divided into three groups: <60 years, 60-74 year, and >=75 years. Age effects were explored by one-way analysis of the variance.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The age differences were statistically significant for the muscle force variables and for most of the physical and social disability variables i.e. older adults had lower functional status than younger adults. For the leisure time/hobbies variables, and the pain variable there was an inverse relationship, i.e. a decrease in the disability score with age. When hip and knee patients were analysed separately, the overall findings were mainly the same. An analysis was also performed with the patients divided into seven age groups, but the results were mainly the same. The control group had approximately the same age as the patient group, and scored zero with almost all patients for virtually all variables. When there is no variance in the dependent variable, analysis of variance cannot be performed. Older people showed higher dysfunction scores in almost all variables, with the exception of pain, where there was an inverse relationship i.e. old people had lower disability scores. This age related increase in disability scores was not observed in the control group. Old people seem to be referred for joint replacement on different grounds from those of younger people, despite the fact that age was not included in the criteria for arthroplasty. Most methods normally used for pre-operative evaluation of osteoarthritis patients do not include disability variables, and therefore age related disability had not previously been detected. The results may indicate a hidden, age related criterion in the selection of patients for arthroplasty. This could be due to prejudices among patients, general practitioners, and orthopaedic surgeons. The results suggest that earlier operation should be favoured. FAS was well suited to detecting age-related deterioration of functional status in osteoarthritis patients.
Researcher's Comments		Supported by a grant from the Research Committee, County Council of Jonkoping.

RefWorks Number: 1873	**[TOOLS]**	Year/County: 1996 - Canada
Reference		Demers L, Weiss-Lambrou R, Ska B. Development of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST). Assist Technol 1996; 8(1):3-13.
Objective/Questions		To develop a clinical instrument designed to evaluate user satisfaction with assistive technology devices. This paper describes the methodology used to develop the instrument entitled the Quebec User Evaluation of Satisfaction with assistive Technology [QUEST].
Device/Product		Assistive Technology Devices
Users		n = 11 team participants on a panel composed of both consumers and stakeholders of assistive technology. n = 5 users of assistive technology on which 4th version was pre-tested. n = 14 occupational therapists.
Method/Tool/Approach		Five principle steps constituted the construction of the QUEST: the development of the preliminary versions, the first validation of content, the pre-test, the second validation of content and the validation of the categories of variables. The variables were generated based on research findings as well as the clinical and research experience of the authors of the study, resulting in 3 preliminary versions. The three versions differed in the number of satisfaction variables, the scaling methods, the materials and procedures, but were similar in that they featured two principle tasks: the person is asked first to indicate the degree of importance he/she attributes to each of the satisfaction, and second, to rate his/her degree of satisfaction with each of the variables considered important. The panel was asked to examine the content of the variables, the proposed rating scales, and the assessment materials. During a half day session, the three preliminary versions of the instrument were demonstrated and then closely reviewed and criticized; the panel's recommendations resulted in a revised fourth version of the QUEST. This version was pre-tested [not piloted] on 5 users of assistive technology. This was conducted to verify that the language used for the satisfaction variables was clear and easy to understand, to re-evaluate the procedures and materials used in administering the instrument; and to check for any oversights or sources of error. As a result further refinement occurred creating a fifth version. This was validated by the panel creating the sixth and final version of QUEST [in French]. The occupational therapists and members of the panel then classified each of the 27 variables into one of three categories: the environment, the user, and the assistive technology device category, which led to 8 in environment, 15 in assistive technology device and 4 in user category.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		For each assistive device being examined approximately 30 minutely is required to administer the assessment. The QUEST form is to be completed by an evaluator and is divided into three parts: general information questionnaire, assessment of satisfaction, and summary sheet. The originality of QUEST lies in its interactiveness and user-directed approach to assessing satisfaction with assistive technology. From a set of 27 variables, the user is asked to indicate the degree of importance he/she attributes to each of the satisfaction variables and then rate his/her degree of satisfaction with each of the variables considered important. While QUEST remains a clinical instrument undergoing pilot testing, it holds much promise in our quest for a reliable and valid means of assessing assistive technology outcome from the user's perspective.
Researcher's Comments		Funded by the Fonds de recherche en sante du Quebec, the Reseau de recherche en readaptation de Montreal et de l'ouest du Quebec, and the Canadian Association of Gerontology.

RefWorks Number: 1912 [TOOLS]		Year/County: 1995 - Canada
Reference		McComas J, Kosseim M, Macintosh D. Client-centered approach to develop a seating clinic satisfaction questionnaire: a qualitative study. Am J Occup Ther 1995; 49(10):980-5.
Objective/Questions		The development of a program evaluation tool, using a client-centred approach, for service recipients in a paediatric seating clinic.
Device/Product		Mobility Devices including seating devices.
Users		n = 7 adult subjects, mainly parents of children who attend the seating clinic and agreed to participate in the study, and received at least two inserts through the clinic, and have received clinic services for their children in the past 18 months. All subjects were women, 6 were mothers and one was a group home supervisor. Ages of the children were 4 to 17 years old. n = 2 student research assistants. n = 5 professionals - who were employees at the Treatment Centre and were familiar with the seating clinic to varying degrees. The process items included all events leading up to, but not beyond, the creation of the seating inserts.
Method/Tool/Approach		The seating clinic's role is to evaluate need and prescribe seating and mobility devices for children with physical disabilities up to the age of 18 years. After an initial telephone contact, an information package was sent out. Subjects were given the choice of participation in the focus group or of having a personal interview at their location. Five chose individual interviews and two chose to come to the focus group. INTERVIEWS: one investigator and one of two student research assistants conducted each of the five interviews. The sessions were recorded on audiotape. The interviewers guided the participant with four open-ended questions: 1) What do you think of the seating clinic? 2) How can we make this service better for you? 3) What is your feeling about the seating inserts you have to had to date? 4) Suppose I was a parent with a child requiring seating clinic services, what would you advise me to do? The interviewer spoke only to clarify certain points or to prompt the participant for more details. Each interview lasted approximately 1 hour. FOCUS GROUP: the investigator, the two student research assistants, and an adult consumer who had used seating clinic services in another city as a child jointly led the focus group. The same questions were asked as in the individual interviews and the two clients were encouraged to interact with each other to compare and contrast their experiences with the services. This session was also recorded on audiotape. A conceptual framework was devised based on the initial data gathered, and were grouped into two large concepts: process and products. Aspects of the Process Concept included: communication, person in the clinic, time, choice for process or product, responsibility, organisation, quality, cost and value and choice of materials or inserts available. Aspects of the Product Concept included: quality, cost and value, and product choice. The questionnaire generated consisted of two sections: section 1 has 37 items using a Likert scale, formulated to reflect the chronological sequence of events typical of seating clinic services, and section 2 includes nine questions related to demographic variables. Validation of the questionnaire: all five professionals and seven participants were sent a draft copy of the questionnaire for review and feedback. All evaluators were asked to comment on four aspects of the questionnaire- format, reading ease, clarity and time to complete. In addition, participants were asked how well the questionnaire reflected the information and issues they raised during the interview.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The satisfaction questionnaire was developed through a process that included client involvement. The questionnaire that resulted is different from other client satisfaction questionnaires in three aspects: 1) It asks about value for cost; 2) It focuses on interpersonal communication and quality of product; 3) It addresses competence of professionals in terms of effort and understanding of clients needs by professionals and quality of final product. Product Limitations: 1) The limited number of participants in the interviews and focus group may mean that some concerns are not addressed in the questionnaire; 2) The process did not involve asking the children themselves if they were satisfied and including their concerns in the questionnaire; 3) The usefulness of the questionnaire for other services and settings has not been established. It is important to test the questionnaire in the seating clinic and to determine test-retest reliability.
Researcher's Comments		Partially supported by a grant from the Neurodevelopmental Clinical Research Unit which is funded by the Ministry of Health of Ontario.

RefWorks Number: 1951	**[TOOLS]**	Year/County: 1994 - USA
Reference		Kroll M, Ganz S, Backus S, Benick R, MacKenzie C, Harris L. A tool for measuring functional outcomes after total hip arthroplasty. Arthritis Care Res 1994; 7(2):78-84.
Objective/Questions		The purposes of this paper are: 1 To describe/develop a tool for measuring functional progression during hospitalization after Total Hip Arthroplasty [THA]. 2 To demonstrate that this scale meets the accepted standards of scale construction.
Device/Product		Total Hip Prostheses.
Users		n = 20 physical therapists whose experience in orthopaedics ranged from 1-15 years, with a mean of 5 years experience. n = 30 patients who had undergone THA [used to assess inter-observer reliability] n = 45 patients who were instructed in the use of the modified Functional Status Index pre-operatively. Patients whose peri or postoperative course included cardiac dysfunction, urinary infection, pulmonary embolism, symptomatic deep vein thrombosis, or any other medical condition that resulted in an interruption in routine in physical therapy was classified as having a complicated course of stay and were not included in this sample.
Method/Tool/Approach		Tool Development: The Functional Milestone Scale [FMS] is a discriminative scale used to differentiate between THA patients whose functional improvement post-operatively followed the normal rate of progression and those whose improvement did not. The FMS was designed by and for physical therapists. 20 physical therapists determined by consensual agreement the functional milestones selected for the FMS. FMS was to include specific functional milestones that patients were routinely expected to achieve prior to discharge from the hospital. In general all THA patients are required to (1) transfer in and out of bed; (2) ambulate with external support on level surfaces and stairs independently prior to discharge from the hospital. Based on these, the five milestones selected for inclusion in the FMS were: transfers, walker, crutch, cane ambulation and negotiation of stairs, with post-operative discharge being another milestone. Each milestone was scaled into two levels of achievement, either assisted [requiring aid from another person to perform the milestone] or non-assisted [successful achievement of a functional milestone with an ambulatory aid]. A grid format was devised with a vertical axis containing the hierarchically arranged milestones and the horizontal axis listing the postoperative day, so that functional progression can be seen at a glance. The FMS has been used in The Hospital for Special Surgery, by the authors, for over 6 years representing over 4000 THAs. It takes less than 2 minutes for the physical therapist to complete. A power study determined that 30 patients were required to ascertain inter-observer reliability. One physical therapist was assigned to treat the patient while another physical therapist observed each treatment throughout the patient's hospital stay. Each therapist scored the patient independently on their functional level for that day and remained blinded to the other's scores until the patient was discharged. Agreement between the pairs was assessed using the kappa coefficient of concordance for ordinal data. A power study determined that 45 patients were required for concurrent criterion validity, and was carried out prior to surgery using the Functional Status Index [FSI, a modified version], a patient self-assessment that has similar items to the FMS. At completion of each post-operative physical therapy treatment the therapist filled out the FMS. Then an independent observer [another physical therapist who did not have routine access to the patient's chart] met with the patient and assisted them to complete the form without assistance regarding Responses. Although the independent observer was present at the time the modified FSI was completed, no assistance regarding the responses selected by the patient was provided.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		A high level of agreement existed between therapists for each milestone. And was almost perfect according to the criteria of Feinstein [1987]. The results of the criterion validity evaluation demonstrated that there was moderate to substantial agreement between the therapist's decision on the patients need for assistance. The milestones with only moderate agreement were walker ambulation and stair climbing. In most cases [74 of 93 disagreements] the patients felt as if they were unassisted while the therapist felt that they required assistance. This disagreement may reflect the definition of the word 'assist'. Agreement between therapist and patient responses was assessed for 589 pairs of observations using the kappa coefficient, which indicated that there was substantial agreement for transferring and crutch ambulation and moderate agreement for walker ambulation and stair ambulation. In a compilation of data from the FMS using large numbers of patients with osteoarthritis, permitted standards of functional recovery to be developed. In 309 unilateral THA patients who had an uncomplicated post-operative course, the average day of attainment of each functional milestone +/- 2 Standard Deviations was determined. The FMS correlates to length of stay and exhibits substantial interobserver reliability and moderate to substantial validity. The authors believe that they have demonstrated its clinical applications as well as showing it to be a useful management and research tool.
Researcher's Comments		Funding not addressed.

RefWorks Number:1955 [TOOLS]		Year/County: 1994 - Greece
Reference		Vernardakis N, Stephanidis C, Akoumianakis D. Rehabilitation technology product taxonomy: a conceptual tool for analysing products and extracting demand determinants. Int J Rehabil Res 1994; 17(3):201-14.
Objective/Questions		The Development of a conceptual tool, the Rehabilitation [Assistive] Technology [RT] Product Taxonomy, as a framework for analysing rehabilitation technology products and extracting demand determinants.
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		The ultimate objective is to provide demand and supply-related actors with a meaningful tool for identifying and focusing on specific aspects, which may be directly or indirectly related to existing or new products, so that demand and consumption allocation decisions can be targeted, evaluated and/or predicted. Tool Development: The tool should be sufficiently expressive to accommodate a relevant subset of the critical issues related to demand forecast in the RT market. Thus it should be flexible to enable assessment of existing product lines and reveal the reasoning behind their relative success. In addition, it should be able to predict, qualitatively, the relative potential economic activity of new RT products, on the grounds of some distinctive characteristics. Finally, the tool must be formal enough to facilitate a consistent and systematic approach to the ongoing work in the RT field. The tool consists of a set of criteria addressing: 1 The economic environment: competitive strategies, prices, level of competition, and intensity of competition; 2 The market structure: size of firms and type of structure [i.e. monopoly, oligopoly, free-market conditions etc]; 3 The product itself: the type of product [tool versus appliance], the purpose, the form of support a product is associated with [i.e. tangible versus non-tangible], the method of provision [i.e. loan, subsides &/or tariffs], and the intensity of care that the product is aiming to provide; 4 The underlying technology: type of technology, innovation type and direction, existing versus non-existing technology, enabling versus disabling technology, and technology maturity stage [i.e. technology push versus technology pull].
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		The RT product taxonomy provides a conceptual tool that can accommodate many different perspectives of analysis depending on the criteria to be applied and the target objectives of the analysis. Four Constructs of the taxonomy include: the economic environment, market structure, product-based criteria and significance of present or anticipated future economic activity and technology based criteria, which have all been described/defined. The taxonomy can be quite useful in analysing a particular product, in terms of: 1 the product's market structure e.g. oligopoly; 2 importance and performance levels; 3 whether or not economies of scale for the particular product exist; 4 what are the underlying technologies 5 whether or not innovation is critical to the product process; 6 the type of innovation. The paper also discusses end-users having an active role in the selection of a preferred solution/device, and highlights some of the limiting factors that may restrict the users involvement. The taxonomy is proposed as a flexible tool that can be appropriately reconstructed to accommodate the objectives of a specific analysis. It can also be used as either an evaluative or predictive tool.
Researcher's Comments		Partially funded by the TIDE programme of the Commission of the European Communities.

RefWorks Number: 2029 [INFUSION DEVICES & INTRAVENOUS CATHETERS]		Year/County: 1992 - The Netherlands
Reference		Borst CG, de Kruif AT, van Dam FS, de Graaf PW. Totally implantable venous access ports - the patients' point of view. A quality control study. Cancer Nurs 1992; 15(5):378-81.
Objective/Questions		To evaluate patients' experiences of totally implantable venous access ports.
Device/Product		Intravenous catheters: Port-a-Cath (PAC) a totally implantable venous port.
Users		n = 40 patients (15 men & 25 women.)
Method/Tool/Approach		Telephone interviews. At the time of the study 44 patients attached to a single hospital were living with PACs. 2 patients were too ill to be interviewed, 1 refused for personal reasons and 1 could not be reached. The first author using a questionnaire that was adapted from a study where the instrument was used to assess the satisfaction of patients with the Hickman catheter interviewed patients. Specific questions regarding the PAC were added.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The median age of the patients was 56.5 years (19-73). The PACs had been in place for a median of 6 months (1-33), for 36 it was their first PAC. All except 6 of the PACs were placed under local anaesthetic. All the patients were receiving or had received chemotherapy for non-resectable advanced cancer, 26 of them by means of a portable pump. Almost all were very satisfied with the PAC and thought that the advantages of the PAC outweighed its disadvantages; they were not hindered in their daily activities; and none of the patients experienced problems with sexual intercourse because of the PAC. Drawbacks of the device are that 40% of the patients found the operation for insertion of the PAC more painful than they had expected. Although PAC reduced the fear of repeated peripheral venous puncture, puncture of the PAC was viewed as painful by 15 of the 40 patients. The authors conclude that PAC appears to be preferable to an external catheter but that information needs for patients need to be improved.
Researcher's Comments		Funding not addressed.

RefWorks Number: 2153	**[TOOLS]**	Year/County: 2002 - Canada
Reference		Demers L, Monette M, Lapierre Y, Arnold DL, Wolfson C. Reliability, validity, and applicability of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) for adults with multiple sclerosis. Disability & Rehabilitation 2002; 24(1-3):21-30.
Objective/Questions		The applicability of the Quebec User Evaluation of Satisfaction with assistive Technology [QUEST-version 2 -12 items] for assessing satisfaction within a specific diagnostic group of users has not been explored. The purpose of the study is to: 1 Examine the reliability of the QUEST 2 instrument at the scale and sub-scale level including test-retest stability and alternate form equivalence. 2 Examine the relationship between satisfaction results, as measured by QUEST 2, and the quality of life impacts of using assistive technology. 3 Gain insights on the applicability of the QUEST 2 for community-based Multiple Sclerosis [MS] patients who are users of mobility assistive devices.
Device/Product		Mobility Devices- standard walker, four wheeled walker, manual wheelchair, powered wheelchair and scooter.
Users		n = 81 individuals with confirmed diagnosis of MS who use mobility assistive devices. Ages between 18-65 years old. Primarily recruited from Jan 1999 to Nov 2000, through the MS Clinic of the Montreal Neurological Institute [n=74] and the Department of Neurological Sciences of the Jewish General Hospital [n=9]. And had an Expanded Disability Status Scale score of 6.5 or more. This cut-off point indicates that constant bilateral assistance is minimally required for walking. Both French and English speaking patients were eligible for the study. 119 patients were initially contacted. Reasons for non-inclusion: lack of interest 19, failure to get in touch with candidate 10, and sickness or hospitalisation 7. EDSS scores indicated that non-participants had higher disease severity. 2 subjects excluded because of a lack of variability in responses. n = 3 interviewers collecting data. One had extended knowledge of the evaluation instruments prior to the study implementation and was involved in the study design. The remaining two interviewers received a formal six-hour training session on the administration of the scoring of the QUEST 2 and PIADS assessment instruments.
Method/Tool/Approach		81 individuals provided data using the QUEST 2.0 and the Psychosocial Impact of Assistive Devices Scale [PIADS]. At the beginning of the study the subjects were randomly assigned to one of four groups, G1 to G4. These groups differed with respect to the questionnaire format- either self administered or interviewer administered and also differed in the order in which alternate forms of the QUEST 2 were presented. The first evaluation was conducted at home, with an interviewer being present. Those assigned to G1 & G2 were asked to complete the self-administered QUEST 2 questionnaire while those assigned to G3 & G4 were asked to undergo the interview based version. AT Time 1 all participants also completed the PIADS. Before leaving, the interviewer discussed the second testing. Depending upon group allocation, the procedures differed. With G1 & G3 received a self-administered version and a self addressed envelope. G2 & G4 were informed that the interview based version would take place one week later during a home visit. In the middle of the study, interviewers feedback led to transgressions in random assignments mainly to accommodate the subject's specific disabilities and needs. For instance, several subjects assigned to G1 [self administer questionnaires] were not able to write and were given an interview. That led to disparities in sample size. A second QUEST 2.0 was administered one week later. Measures of association were calculated between QUEST 2.0 and PIADS and between QUEST 2.0 and alternate forms [i.e. self administered and interview administered].
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		The device subscales, services subscale, and total QUEST 2.0 scores achieved good test-retest stability. Alternate-form equivalence was lower for services. The positive correlations between QUEST 2.0 and the three PIADS dimensions were fair to moderate for device and total QUEST 2.0 and fair with services. The tool was positively received with some restrictions for the services subscale. The interview based format of QUEST 2.0 was meant to be marginally used, and the material optional. However, with some MS respondents, it became evident that this format was more convenient. The study results are robust with respect to test-retest stability, alternate form reliability, and validity to recommend the use of the QUEST 2.0 tool for assessing community-based MS users of assistive technology. However, because the results on the services are marginally acceptable, it is recommended that future studies address this particular subscale's measurement properties using different sampling and design strategies. In a subsequent step, it would also be relevant to examine the responsiveness of the QUEST 2.0 to satisfaction changes and its ability to discriminate among different categories of assistive technology. With this study population, the adherence to a strict research protocol was challenging because of important fluctuations in symptoms. Accordingly, assessments at time 1 were frequently postponed and assessments at time 2 cancelled. Moreover, the protocol for group allocation could not be entirely respected. For these reasons there was a substantial proportion of missing data, leading to smaller than expected sample sizes.
Researcher's Comments		Financial support provided by the Multiple Sclerosis Society of Canada.

RefWorks Number: 2155 [TOOLS]		Year/County: 2001 - USA
Reference		Parker M, Baker PS, Allman RM. A life-space Approach to functional assessment of mobility in the elderly. Journal of Gerontological Social Work 2001; 35(4):35-55.
Objective/Questions		The purpose of this paper is to: 1 Emphasise the importance of mobility as an aspect of functional and disability assessment for social workers. 2 Description of the application of a new strategy of mobility, Life-Space Mobility Assessment [LSMA], that enhances standard approaches in the detection of functional problems and disabilities. First used 1985.
Device/Product		Assistive Technology Devices.
Users		n = 0.
Method/Tool/Approach		First, a literature overview is provided that emphasises the clinical relevance of mobility within the context of functional and disability assessment. Second, an application of the LSMA with seniors is described as complementing the more traditional but less precise and sensitive methods of functional assessments typically used by social workers and other health care practitioners. Theoretical links to person-in-environment and ecology models are reviewed, and the implications for training, practice and research for social workers are discussed. A person's Life-Space is the area through which one routinely and purposely moves. Conceptually, Life-Space is a concentric pattern of zones radiating from a person's usual abode. It not only measures elder travel patterns over a specific time period, but qualities and patterns of life style indicative of physical, mental and social health. Thus, Personal Life Space is an approach that allows clarification of mobility changes, predictors, and outcomes. The Life Space Questionnaire [LQS], adapted in 1999 from the 1985 version, is a self-administered instrument consisting of 9 questions that measures movement patterns over 3 days. The limitation to a 3 day time span is suggested to establish a consistent pattern of daily activities without permitting unusual circumstances to influence their routine. Each question establishes movement in a life-space zone ranging from one's dwelling to travel outside of a region of the country in which one lives. Each question has a yes/no answer and uses a points system for easy interpretation of scores. In 1999 test-retest reliability was found to be 80% overall, with questions 1-5, and 8 and 9 having 90% agreement, and questions 6 and 7 having between 70-73%. Data from the Alabama Statewide Survey [1987] suggests that persons who have mobility limitations within a specific Life-Space zone have a high prevalence of both ADL and instrumental ADL difficulty.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	X
Conclusions		"…Since 1945 over 75 instruments has been developed to measure functional limitation and disability…" Most of these have addressed change from one state to another, or addressed just one Activity of Living [ADL]. Social workers strive to develop interventions that result in an optimum fit between an elder's capacity and his or her environment. Life-Space mobility provides a more accurate picture of the senior's life style, including essential adaptations conductive to homebound independence. The LSMA enhances social work practice with older persons: 1 It is theoretically grounded in traditional social work models 2 It emphasizes mobility and its complex relationship with the environment and bio-psycho-social factors 3 It helps illuminate cultural and racial issues related to mobility and life style 4 It helps social workers on geriatric teams emphasize factually the psychosocial implications of mobility limitations and trajectories 5 It improves the precision of assessment and the timeliness of efficacious supports and interventions. A great advantage is its preventative quality that can be used to enhance traditional assessment methods. This method also facilitates communication between disciplines.
Researcher's Comments		Supported in part by grants from the AARP/Andrus Foundation and National Institute of Aging.

RefWorks Number: 2179	**["OUT OF THE MOULD"]**	Year/County: 1999 - USA
Reference		Riemer-Reiss ML. Applying Rogers' diffusion of innovations theory to assistive technology discontinuance. Journal of Applied Rehabilitation Counselling 1999; 30(4):16-21.
Objective/Questions		To determine the factors that are associated with discontinuance of assistive technology by individuals with disabilities.
Device/Product		Assistive Technology Devices.
Users		n = 115 individuals with disabilities who received funding toward 136 assistive devices through the Colorado Assistive Technology Act.
Method/Tool/Approach		The research is guided by Everett M Rogers theory, diffusion of innovations, which offers a comprehensive philosophy regarding the processes involved in accepting or discontinuing use of technology. A qualitative, correlation research design was used to analyse the relationship among the independent variables of: relative advantage, support, consumer involvement, trialability, changes in consumers needs, re-invention, compatibility of assistive technology devices and the dependent variable of discontinuance of assistive technology devices. Telephone interviews [lasting 10-20 mins] conducted by the investigator with participants using a survey instrument [not elaborated on]. A script was utilized to introduce each section and to affirm consistency in the administration of the survey. Then, logistic regression was conducted to determine which combination of independent variables was the best predictor of discontinuance of AT.
Product Development Stage at which users were involved	Concept	X
	Design	X
	Testing & Trials	X
	Production	X
	Deployment	Post-market surveillance.
Conclusions		Examination of the results led to the preliminary speculation that the diffusion of innovations theory may be applicable to assistive technology discontinuance. This study showed that the variables of relative advantage and consumer involvement were associated with the criterion variable, that is, these attributes have a significant relationship with discontinuance. The authors stated that this was consistent with the variables related to assistive technology use identified in other research findings. This study did not provide enough evidence to conclude that support, trialability, changes in consumers, and re-invention were significant predictors of assistive technology. There are several possible explanations for a lack of relationship among the variables and assistive technology discontinuance: 1) Support- may not have been significant in the sample where 77.3% were living with family, friends, roommates and care-givers; 2) Trialability- if an individual's need for the technology was not apparent after an assessment, the technology would not be provided through this project; 3) Changes in Consumers- classified devices that were replaced by superior devices were identified as "continued use" as opposed to "discontinued use"; 4) Re-invention- most assistive technology is designed to accommodate specific disabilities, an in a sense are customised devices. Therefore, re-invention may not have been needed for the technology that was provided as part of this project. Consumer involvement demonstrated a significant negative relationship to assistive technology discontinuance. This is consistent with the literature on assistive technology and the diffusion of innovations theory. These results suggest that assessment practices for assistive technology should concentrate on involving the consumer as extensively as possible. Additionally, assistive technology devices prescribed must offer more advantage than burden to the users. Therefore, careful evaluations to determine the costs and benefits of using assistive technology devices from the consumers' perspective are crucial to avoid future discontinuance of assistive technology.
Researcher's Comments		Funding not addressed.

PART A APPENDIX D: FRAMEWORK ANALYSIS

D.1 THE CONTEXT OF USER AND END-USER REPRESENTATION

Key: (#) – respective Refworks reference number of study (the Refworks numbers are linked to the complete references at p62)

Thematic Framework Category **The Users**	*Issues Raised*	*Consequences and Conclusions*
	There are varying interpretations and definitions of users and end-users. Varying forms of user and end-user information. The nature of the device and its function determine the primary user and the type of user information generated. Assistive technologies are a particular category of medical devices where a client-centered approach is crucial and the methodologies for engaging with clients appear to be mature and in use, as evidenced in most of the literature surveyed (#326, #994, #1305, #1482, #1631, #1643). Example 1: pre and post surgical implantation of a device, clinicians may be interpreted as the user and therefore assess the device from the clinical perspective. The end-user information comprises objective measurements (e.g. visual acuity) and subjective end-user perspectives on vision (e.g. awareness of glare at night and fixation) (#1126). Example 2: user-centered approach to assess effectiveness of outdoor mobility devices and services (#119). Example 3: failure to adopt a user-centered approach is associated with discontinuance of device use (#2179).	There is a need for clarity in defining the user and end-user of a particular class of device and therefore the nature of user information required in the device technology cycle. This could be characterised as physician driven measures (physical examination, radiographic findings and complications), and patient/client derived measures of outcome (pain, mobility, utility of mobility devices etc).
	Sampling from a heterogeneous population when the focus is a single intervention. Example intervention-Total Hip Arthroplasty, outcome measures- standard scoring system and self administered questionnaire. Sample of 103 patients with an average age 60.1 years, 67 females and 36 males. 84% had a preoperative diagnosis of degenerative joint disease, 3% rheumatoid arthritis, 5% avascular necrosis and 8% other causes. All procedures were performed through a standard posterolateral approach. Discrepancies were found between the standard scores and the self-administered questionnaire responses, which may have resulted from the co-morbid conditions (#1391). **Sampling from a cohort with an element of opportunistic access.** Example in a study that developed a shoulder pain index associated with wheelchair use, wheelchair users were recruited at a wheelchair athletic event (#1045).	The prevalence and incidence of user populations of specific devices may be unknown, creating methodological issues related to potential recruitment and the resulting sample. Sampling within heterogeneous user populations of specific devices suggests the need for sampling strategies that can control for co-morbid conditions. Issues of access and sampling bias also arise.

Thematic Framework Category **The Users**	***Issues Raised***	***Consequences and Conclusions***
	Post-marketing surveillance studies and tight exclusion criteria. #1163 – In a study examining outcomes post total hip arthroplasty all individuals that had undergone previous surgery to the hip were excluded. #1355 – In a study of changes in the life situation related to an implantable cardioverter defibrillator all patients with psychological and/or medical complications were excluded. #1869 – In a study of age-related differences in functional status of patients undergoing total hip or knee joint arthroplasty it was stated that "…*the patients are considered to represent an average rural population with osteoarthritis in Sweden. None of the patients had serious heart or lung disease, or other diseases of the musculoskeletal system*…" #1951 – In a study examining functional progression during hospitalisation after total hip arthroplasty individuals experiencing any condition that interrupted routine physiotherapy or complicated the course of stay, such as a urinary tract infection, were excluded. Conversely, some studies include the more complex clinical cases. **Exemplar study of inclusion of clinical complexity:** #231 - In a study assessing the impact of total hip arthroplasty as a treatment for osteoarthritis, patients who had received revision procedures and those with co-morbidities were not excluded. Studies may be performed in highly specific user populations. **Exemplar studies of specific populations:** #238 – Evaluation of total hip arthroplasty in individuals with aplastic anaemia. #617 – Evaluation of total hip arthroplasty in individuals with ankylosing spondylitis. #1202 - In a postal survey regarding assistive device utilisation in various social settings and perception of devices, scientists and engineers with disabilities were purposefully sampled.	Exclusion criteria can fail to include the more needy individuals who are users of devices and the "real life" users of medical devices. Questions are thus raised regarding representation and the influence of exclusion of the more complicated cases on study outcomes. Sampling bias? Where is the balance in representation to be achieved? This is another indication of the need for particular sampling strategies in medical device evaluations and raises important generalisation issues.
	There has been an **increased promotion of user involvement** over recent years, particularly patient/client involvement in the UK National Health Service, for example with *patient centred care* and *the expert patient*.	There is value in sampling experienced users. However there may be practical difficulties in identifying and targeting such populations and incorporating them in an ethical framework of research and development. This suggests the need for core methodologies and databases from which generalisable information can be extracted by key stakeholders.
	Issues of access to end-user information to inform device design and evaluation.	There are ethical and governance issues in carrying out research within the clinical environment.
	Expert user involvement in undertaking research. Example: A model of involving researchers with disabilities to train and inform disability groups in research methods and conducting research to bridge the gap between end-users and researchers (#1406).	There is value in sampling experienced users. However there may be practical difficulties in identifying and targeting such populations and incorporating them in an ethical framework of research and development. This suggests the need for core methodologies and databases from which generalisable information can be extracted by key stakeholders.

Thematic Framework Category **The Users**	***Issues Raised***	***Consequences and Conclusions***
	Healthy volunteers used to test devices to the exclusion of the real end-users. #1317 – In a study testing a curb-climbing aid for wheelchairs able-bodied volunteers were used. #1514 – In a study testing the effects of lycra support stockings healthy volunteers were used. The volunteers were screened to exclude those individuals with objective symptoms of chronic venous insufficiency; however support stockings are required in this context. #1638 - In a study looking at the development of orthotic devices, a sample of 5 right-handed males with normal neuromuscular function, aged between 34 and 41, was recruited. Their arm trajectories were then analysed whilst they performed "everyday tasks", such as spooning water from a bowl and simulation of hair brushing whilst wearing a baseball cap, whilst in a wheelchair with their elbow movement minimised in a "constrained manner". **Exemplar study of a healthy, medical device user population:** #29 – In a single case study involving a healthy and fit transfemoral amputee, a prosthetic limb was tested, with the individual performing six repetitions of each task, such as ascending and descending a slope and stairs, where she chose to take two stairs at a time when ascending [with her sound leg] and descending [with her prosthetic leg].	The problematic assumption made is that "healthy" populations can be used to satisfactorily generalise to the end-user population. This raises questions regarding the value of sampling from healthy populations including 'extreme case' sampling and potential barriers to accessing actual end-users.
	Recruitment of users and non-users of a device: #439 – Both users and non-users of electronic aids to daily living were recruited to develop the Measure of Control Using Electronic Aids to Daily Living (MCEADL). #664 - In a study regarding use of electronic aids by individuals with muscular dystrophy half the sample used such devices, whereas the other half did not.	What impact does non usage and lack of experience using a particular device have on the data received within a study? Sampling directly from disabled groups both end-users and non-users results in comparative data, but what is the value of these data?
	Where end-users are not involved in selecting a device for their own use, the likelihood of non-usage of the device or discontinuance increases (#2179).	The potential for non-usage or discontinuance of device use which links to the need for involvement of professionals with end-users in needs assessment, device selection and training.
	Self-selected user samples. #208 - In a study of impact of implant-stabilized prostheses on the health status of complete denture wearers, patients that were reporting difficulties with conventional dentures were recruited through hospital departments and dental practitioners. #1716 – In a study to assess the magnitude and significance of the combined effect of different functional aspects of mandibular prostheses on patients' overall ratings of general satisfaction, edentulous patients were recruited who had responded to an advertisement offering replacement of their current prosthesis.	Opportunistic sampling with outcome measures attributed to the sample. Bespoke devices. This type of sampling targets actual end-users? However it will be open to the criticism that the method lacks rigour.
	End-user safety issue using physical models. #1511 - In the testing of wheelchair occupant restraint systems anthropomorphic test dummies were used #1662 – In a study of functional status in toddlers with limb deficiency, their mothers were used as proxies for data collection.	Appropriate proxies need to be sampled in particular situations, such as the use of anthropomorphic test dummies for wheelchair crash testing.

Thematic Framework Category **The Users**	***Issues Raised***	***Consequences and Conclusions***
	End-user and user involvement in pre and post-operative assessment using multiple methods. #97 – A study comparing patient and clinician responses to a total hip arthroplasty clinical evaluation questionnaire during 2934 clinical assessments between 1991 and 1996. For 12 of the 16 items the patient responses had acceptable agreement with the doctor responses. Some important differences between patient derived and doctor derived data were found. If the patient had other joint or health problems, had a revision total hip arthroplasty or reported mild or moderate pain, there was a greater chance of reduced agreement on the pain items. Where there was disagreement the patient often reported a greater degree and frequency of hip pain compared to those reported by the doctor. Younger patients demonstrated better agreement with doctors than older patients did. The authors conclude that patients' perceptions of symptoms and outcomes after total hip arthroplasty are relatively similar to those of their doctor. They argue that the selective use of patient completed questionnaires has the potential to substantially reduce the costs of outcomes evaluation programmes by minimising doctor input and pending revision of some of the items the use if this patient completed questionnaire is advocated.	Impact on outcomes of co-morbid conditions. End-users perceived to be a robust and cost-effective source of post-operative evaluation data.
	Impact of patient expectations on medical device outcomes. Example in a study evaluating patients' experiences of totally implantable venous access ports, 40% of patients receiving a Port-a-Cath (n=40) found the operation more painful than expected and although the device reduced the fear of future peripheral venous puncture, puncture of the skin/device was viewed as painful by 15 of the 40 individuals #2029.	The phenomenon that patient expectations can influence outcome assessment measurement indicates the need for accurate transfer of information to and from professionals in order to understand patient expectations and reconcile differences. Important contextual issues which can be overcome by a consensus process of data capture.

D.2 THE LEVEL OF INVOLVEMENT OF USERS AND END-USERS IN THE MEDICAL DEVICE DEVELOPMENT

Key: (#) – respective Refworks reference number of study (the Refworks numbers are linked to the complete references at p62)
($) – repeatedly observed in studies reviewed
(~) – observed gap in studies reviewed

Thematic Framework Category	*Issues Raised*	*Consequences and Conclusions*
The Level of Involvement of Users and End-Users According to the Stages of Medical Device Development	In an opinion article the status quo for user involvement was identified as involving the clinician and trends were cited indicating an increasing consumer led market where the end-user is the patient (#1660). However the majority of the studies reviewed demonstrate user-involvement solely in the post-marketing stage of product development. However, the exemplars (Part A Appendix E:) drawn from the assistive technology device group appear to indicate well established models of end-user engagement throughout device development. The following exemplars are the exceptions found demonstrating aspects of good practice in user involvement within medical device assessment. **Exemplar study in terms of the level of involvement of users:** #22 – End-user (individuals over the age of 65) focussed involvement in the assessment of assistive devices, specifically walkers. Data were captured from a representative sample of end-users, in interviews in subjects' homes by 2 expert clinicians, with no by-proxy information giving from others. The findings indicated that 57% of the sample had walking aids that not only did not meet needs but that were potentially dangerous. Recommendations were made for improved assessment of needs as opposed to new designs although intelligent and more high technology designs were also proposed. Furthermore, this work is part of a much wider study examining the use and need for assistive devices and environmental interventions in the elderly population in the US. **Exemplar studies in terms of user involvement through the stages of medical device development (Please refer to Part A Appendix E: for the Model Components of the following Exemplary Cases):** #640 – Provides a model of product development based on neuroprosthesis user and therapist involvement, to generate a second generation neuroprosthesis and evaluate its performance. The design criteria for the device was developed from a survey of neuroprosthesis users and therapists to identify how the first generation technology could be improved, the product was then developed and tested functionally on a small sample of participants (n=4). #934 – Describes a model of user involvement through the stages of medical device development. The aim of this technology transfer model is timely transition of prototype developments into commercially viable products and techniques that can be readily available and accessible to benefit veterans and non-veterans with disabilities. This is accomplished through the funding of R&D proposals that will improve treatment, management and rehabilitation of veterans within the following defined priority areas: prosthetics, amputations, orthotics; spinal cord injury; sensory, cognitive and communication aids; and ageing. The process attempts to bridge the gap with the manufacturing sector by use of the procurement contract to purchase pre-commercial	The global shift towards focusing on individuals requires major changes in a number of processes in medical device development and manufacture, including regulatory processes. The predominance of post-marketing surveillance studies may be perpetuated by the existing regulatory framework of such studies as a legal requirement of market listing and usage. Thus a focus is placed on these studies or trials by companies, perhaps at the cost of involvement of users at earlier stages in medical device development. Where this occurs devices may lack user involvement in their development, consequently the product may partially meet user requirements for the specific product, or fail to meet user requirements. This suggests a major shift in culture which needs to be matched by changes in methods, methodologies, regulatory, marketing and purchasing frameworks in order to embed end-users. #22 – This exemplar from the US (University of Buffalo Consumer Assessments Study) was a post market surveillance study which focused on the end-users and identified substantive contextual issues around understanding of the elders' feelings around their own disability, assessment of needs, matching the device to accurately assessed needs and training. The study indicates that high technology solutions were not required to meet needs, what was needed was appropriate attention to detail at the end-user interface. #640 – In this small study social science method (survey) was used to identify limitations in a first generation device. Users and end-users were involved in designing the second generation device. No indication for commercial exploitation was given but the end-users were followed up for 4 years. From a methodological perspective this study appears exemplary in embedding end-users in the design and follow-up stage. The commercial aspects are not addressed. # 934 – An exemplar from the US (Department of Veteran Affairs Rehabilitation Research and Development Service Project) again focusing on consumer driven assistive technologies. End-users are embedded throughout the stages of device development in an

	models as an enticement to attract companies. A national clinical evaluation on these models is then performed to validate the product or technique's success in meeting the specified clinical need, and defining readiness for commercial production and marketing. The manufacturer is identified in the early stages and is committed to the future production and marketing of the product/technique. The process begins and ends with a clinically defined need and in turn can significantly improve the availability of products and techniques with the potential outcome to impact the lives of individuals with disabilities. The authors conclude that "locking-in" a manufacturer early in the process and utilising clinical evaluation from an objective environment, apart from the developer's lab, are major elements that assist in ensuring the process can affirm market opportunity for the final product. #1482 – End-user (individuals with spinal cord dysfunction using prone carts and their caregivers) focussed involvement in an iterative process of product development. During the concept stage of medical device development the end-user was the concept originator evaluating existing prone carts. In the design stage of the cycle the end-users generated ideas for both manual and motorised carts. In the testing and trials stage the end-users tested the developed prototypes. In the production stage the research team collaborated with manufacturers to commercialise the product, to facilitate the final stage of the device development, including deployment and use of the product. #1631 – End-user (individuals with spinal cord injuries and their caregivers) driven product development. During the concept stage of medical device development clinical evaluation was performed to evaluate existing commode-shower chairs. During the design stage safety and performance criteria were defined from the clinical evaluation for two versions of a commode-shower chair, both assisted and self-propelled. In the testing and trials stage prototypes of the chairs were developed and tested by the end-users. In the production stage there was collaboration by the research team with manufacturers, some of whom made the decision to commercialise the product. # 326 - End-users and their carers in the home environment. Interactive Design Process. Specification agreed with end users, and appropriate care professionals e.g. specialist therapists. Iterative process of prototype testing and evaluation with marketing of the final product by a UK company. # 1643 – An international study between Queens University Canada and The National Institute of Design, India. A multi-professional team of engineers, ergonomists and designers together with professionals allied to medicine, Occupational Therapists and Physiotherapists. Cultural, environmental and end-user driven design, including family and community members. Use of local materials and resources included in the contextual assessment of long-term need. Multiple methods employed including social science methods. Issues around reaching consensus with a multi-faceted sample. Generalisation issues from a specific cultural and disability group. #1305 – Individually inspired end-user driven service delivery (orthopaedics), culturally and environmentally sensitive product development i.e. using local products and artisans. Robust methodologies for evaluating product performance (double-blind study) to compare the Jaipur design with the Western design. Strong rebuttal to Globalisation. Extensive end-user (rehabilitation service users) population sampled involving over 5000 amputees requiring artificial limbs in rural Northern India.	iterative process of design and development. Of particular interest is the commercial exploitation of the research outputs through a particular model of technology transfer through a commercial section (TTS) of the Department of Veterans Affairs which engages or “locks in” manufacturers at an early stage of device development. #1482 – Another exemplar from the US (Department of Veteran Affairs Rehabilitation Research and Development Service Project) again focusing on consumer driven assistive technologies. The features of this study are end-user involvement at every stage of product development from concept to manufacture. Carers were also involved and a range of methods were adopted including social science methods (questionnaires, interviews, informal discussions and visual techniques- photography). #1631 – Another exemplar of consumer driven assistive technologies from the US (Department of Veteran Affairs Rehabilitation Research and Development Service Project). In addition to embedding end-users and carers in needs driven design and development the process embedded commercial companies and was a rich source of information leading to three potential products. The methods were again a cluster of social science, ergonomics and engineering methods. # 326 – A UK university research team (Brunel) example of consumer driven assistive technologies using multi-methods including questionnaires to determine design priorities. Similar process to the Veterans Model, without the commercial “locking in” process. # 1643 – An academic and design team exemplar from two countries demonstrating that the combination of perspectives on the device performance from both end-users and their carers provides added value in assessment. Furthermore involvement of caregivers and/or family members in assessment may increase device acceptability and usage. Methodologically the challenges are to achieve consensus in a timely fashion. The methodological processes and methods may be generalisable as opposed to the specific findings regarding the device. #1305 – An outstanding holistic model of embedding end-users in the delivery of a service, the context of device use, device development including manufacturing processes that are sensitive to both local materials and skills. This exemplar case provides lessons to Western exporters of devices: local end-user needs need to be embedded in products for export to avoid discontinuation of device use (Healthcare Industries Task Force 2004, #2179). The model is one of ongoing research and development for service delivery to geographical population of amputees.

D.3 THE CONTEXT OF MEDICAL DEVICE USAGE

Key: (#) – respective Refworks reference number of study (the Refworks numbers are linked to the complete references at p62)
($) – repeatedly observed in studies reviewed
(~) – observed gap in studies reviewed

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	The context of medical device usage in the western world involves a number of pertinent factors that require consideration (#1660): Ageing populations Increasing healthcare costs National healthcare policies that promote user involvement Increasing end-user management of their own diseases and conditions Increasing consumer expectations	Increasing expectations are placed upon medical device manufacturers to develop via on-going processes, appropriate technologies that facilitate end-user involvement in care, at the lowest cost for the best technology.
	The range of medical devices in existence is vast. Assistive Technologies area a separate class of medical device, and it is in this group that models for embedding the end-user, and that embrace human factors design, in device development appear to be well developed. Example a high number of assistive devices may be used by a single individual, in a study of assistive technology use in older adults with cognitive impairments (n=20) an average of 5.35 devices per person were used #320.	The plethora of devices in existence raises particular issues and challenges in relation to methodologies for device development and evaluation, including training requirements.
	Training and device use. **Exemplar study related to training issues:** Example in a study evaluating the experience of men (n=120) with the Dynaflex self-contained inflatable penile prosthesis, patient dissatisfaction because of inability to work the pump was originally 16.66% but after intensive teaching the dissatisfaction rate dropped to 0.83% #1722. Another example illustrates user satisfaction with physical devices increases with training and support #320.	Provision or lack of device related training may greatly affect device related outcomes and usage.
	Survey designs for large scale surveillance of range of assistive technologies and end-users. Example in terms of assistive devices alone out of 2002 individuals responding to the Quebec User Evaluation of Satisfaction with Assistive Technology questionnaire 2002 various assistive devices were in use #541.	Questionnaires may be a cost-effective tool for accruing post-market data in the assistive technology user population.

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	Transferability of devices across cultures and contexts of usage. Example, inappropriate transfer of designs from one cultural context to another. In this example prostheses from the west were discarded in India. Once this was recognised user needs, including contextual and environmental needs, were factored into designing low cost and durable usable alternatives that additionally employed local artisans and materials #1305.	Context of device use: Controversial questions result from transferability issues. For example, are appropriate technologies about meeting the needs of the most vulnerable populations, facilitating cultural appropriateness and self-reliance in the product design, such as the development of the Jaipur limb? This was fashioned out of durable and readily available vulcanised rubber for amputees in rural Northern India, enabling limb-wearing in the fields and the ability to sit cross-legged (#1305). Is it possible that manufacturers inadvertently exacerbate difficulties in relation to the transferability of devices by promoting high technology products? It has been noted by some that function and quality of a new device should not get lost or overtaken by mechanical and technical issues (#1643). A balance is required between both individual requirements for a device and requirements at the group level that will facilitate transferability of devices. This is an issue for the HITF agenda informing the UK export strategy and international trade initative so that it is sensitive to local needs and resources (HITF 2004).
	Medical devices are frequently used in a system, with one device necessitating the use of another. Such an example includes the use of restraint systems with wheelchairs. However the devices are commonly not developed and tested in combination. #1511- In a study examining occupant injury measures of a fixed vehicle mounted wheelchair occupant restraint system found that that the system did not meet the needs of individuals because of poor belt fit, difficulties in use and discomfort. Therefore the authors recommended that restraint systems rather than being solely tested with wheelchairs should be incorporated into wheelchair design.	Context of device use: Recommendations should be made that devices are both developed and tested in conjunction with other devices that they are likely to be used with in practice.
	The common need to utilise one device to assess the effectiveness of another. Example, an optical leg volume meter was required to assess the effects of lycra support stockings, #1514, and a transducer was used to measure the forces and moments applied on the socket of an amputee when wearing a transfemoral prosthetic limb and recorded at distance using a wireless modem to transmit the data #29.	Context of device use: Relationship between a diagnostic and therapeutic device. What affect does the use of a further device have on the assessment of the device under focus? Is the evaluation consequently affected by this additional device, for example in terms of its usage and calibration? Could the evaluation explain more about the additional device than the device under investigation?

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	Testing of combined implantable investigational/therapeutic devices. Issues arise regarding the classes of devices and the nature of invasive procedures around class I devices. #1157 – When testing an implanted defibrillator in 20 patients with recurrent ventricular arrhythmias 26% of the shocks given by the device were found to be inappropriate. **Use of data captured via telemetry to inform patient diagnosis, and concurrently device performance.** The use of enhanced telemetry, in the newer anti-tachycardia devices, with stored or real time patient data to assess device efficacy as well as provide information on device use and function. The devices are designed to detect arrhythmias and deliver the appropriate therapy which may range from anti-tachycardia pacing to low-energy cardioversion to high-energy direct current shock. During follow-up the device was used in 11 of 20 patients. In the entire group anti-tachycardia pacing was activated on a mean of 44 occasions per patient with shock delivery occurring on 8 occasions (mean) per patient. 26% of shocks were not appropriate and were due to atrial arrhythmias in 2 patients and dysfunction of the sensing lead in 3. Anti-tachycardia pace acceleration occurred in 5.3% of cases, 7% of attempts at pacing were unsuccessful and needed shock therapy. The authors concluded that enhanced telemetry in newer devices enabled more accurate assessment of device use and enhanced diagnosis of inappropriate therapy delivery.	Particular measurement challenges and measurement issues related to testing of safety and efficacy in highly invasive devices such as implantable anti-tachycardia devices. Information other than symptoms can be used in the assessment of an anti-tachycardia device (defibrillator). Using ambulatory telemetry real-time or stored data can be used to reconstruct the events leading to device activation. This data together with the associated patient's symptoms and other current therapies e.g. drugs can then be used for effective patient diagnosis
	What is acceptable in relation to complication rates and outcome measures in palliative care? Complex and invasive medical devices also raise issues regarding what is acceptable in relation to complication rates and outcome measures particularly in palliative care. #719 – In a study examining the role of self-expanding stents endoscopically implanted for the palliative treatment of malignant oesophageal stenosis complications occurred in 9 out of 40 patients. In 3 of the 40 patients it was not possible to implant the stent because the guide wire could not be passed through the stenosis. The 9 complications comprised 2 bleedings, 3 neoplastic obstructions, 1 food obstruction and 3 distal dislodgements of the stent.	In the stent study, despite difficulties with the procedure and device the authors conclude that endoscopic placement of metallic self-expanding stents is safe and to be preferred to plastic stents for easier implantation and lower morbidity.
	Effects on usability of medical devices where users are not involved in the device development arise. Example in a study to design and test a prototype curb-climbing aid for wheelchair bound paraplegic individuals 2 channel shaped ramps were attached to the wheels of the wheelchair and telescopic control rods had to be manipulated into position by the wheelchair user, so as to manipulate the ramps into position across the curb for ascent and descent #1317.	Sampling end-users. Device usability issues are affected where users are not involved in the device development process.

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	Problems related to device performance, safety and use surface in the post-market surveillance stage. Devices may have performance related issues when in use. In some studies high levels of device performance issues are raised (#878), indeed some studies may demonstrate unclear efficacy of certain medical devices (#561). #22 – In an analysis of walker problems encountered by subjects in the University of Buffalo Consumer Assessments Study high levels of performance problems, non-usage of the devices and device failures in terms of difficulties and dangerous aspects when in use were found. Out of 69 individuals 42 reported problems with their walkers. Of the 42 individuals reporting problems they reported a total of 46 "problem walkers", 33 were no longer being used and 9 were in use. 57% of the problems were categorised as "difficult and/or dangerous", highlighting a need for careful professional assessment and follow up. #470 – In a study evaluating two 1-channel volumetric infusion pumps extensive usability problems were identified related to the pumps. For example pump 1 had 89 usability problems identified and pump 2, 52 problems. #561 – In a study examining the possible relationship between temporomandibular joint (TMJ) implants and persistent pain, responses to sensory stimuli, quality of life and systemic immune dysfunction, the authors concluded that TMJ implant surgery for TMJ disorders should not be performed until new compelling evidence for the efficacy of implant surgery is obtained. 25 of 32 implants in the sample were removed because of pain and mandibular dysfunction. #1514 – In a study investigating the effect of mild compression on the development of swelling of the legs and the effect on subjective complaints in healthy subjects, despite a young healthy sample (mean age 39.3), size adoption of lycra support stockings was required for 58 out of 118 individuals. This was because the individuals did not fit the regular sizing stable of the standard stockings. 43% of the sample complained about the comfort of the 14mmHg stocking and 84% with the 6mmHg stocking. The authors noted that proper sizing of the stockings was a particular problem in the study.	The fit and performance of medical devices may be problematic even in healthy population samples. Such usability problems raise issues of patient safety. These studies suggest that human factors/usability methodologies are indicated to improve medical device design and usability. In addition, studies such as #22 highlight that improved designs should go hand-in-hand with professional training in assessment and methods, for longitudinal follow-up/post-market surveillance, which embed the end-users.

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	What is acceptable in relation to complication rates and outcome measures in countries where health provision is less globally harmonised? Raises issues regarding access to diagnostic and measurement devices to tailor implantable devices to end-user need. #1185 – In a study evaluating the results of extracapsular cataract extraction with posterior chamber intraocular lens implantation (n=49) in an outpatient clinic in Ghana, performed by 5 American surgeons, biometry was not available therefore intraocular lenses were randomly selected. Compared with the preoperative status, visual acuity without correction improved in 41 patients (84%), remained the same in 5 (10%), worsened in 3 (6%); with correction, the visual acuity improved in 44 patients (90%), remained the same in 3 (6%) and worsened in 2 (4%). Intraoperative complications included vitreous loss (in 5 patients), posterior capsule rupture, and iris prolapse. Several postoperative complications were noted. The most serious was diffuse corneal oedema in 4 eyes. Glaucoma developed in 2 of these eyes. Other postoperative complications included 2 cases of updrawn pupil, 1 case of vitrous in the anterior chamber, wound problems, iris prolapse, endophthalmitis and retinal detachment. The intraocular lenses were "well tolerated" except for: 1 anterior chamber device decentred, folding the iris and was removed; 1 posterior chamber device decentred by 2mm; and 1 posterior chamber device was partially anterior to the iris. **Time and cost issues related to high volume provision of an implantable device.** Example in a study reporting the short and medium term outcomes of a prospective series of sutureless manual extracapsular cataract extractions (ECCE) and intraocular lens implantation (n=500) at a high volume surgical centre in Nepal, the mean duration of surgery was 4 minutes and the average cost of the consumables including the lens was less that $10 US. Visual acuity declined in the year post surgery and poor visual outcome of less than 6/60 occurred in approximately 2% and intraocular complications in 9.4%. The authors conclude that rapid recovery of good vision can be achieved with sutureless manual ECCE at low cost in areas where there is a need for high volume cataract surgery #539. Can it be questioned as to whether reducing cost and increasing volume leads to poorer outcomes, in this case increased rates of post-operative astigmatism?	In the intraocular lens study, despite high rates of complications the authors conclude that outpatient surgery may be a safe and practical alternative to in-patient surgery in developing countries. Given that biometry exists generally in this clinical application though not in the particular of Ghana its non-use and consequent random selection of implants could be questioned on ethical grounds. This raises issues regarding global harmonised standards of medical device availability including processes and procedures. High volume low cost provision may be associated with avoidable side effects. The side effects may not be significant when weighed against the benefit gained such as site and astigmatism. Value issue.

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	Assessment of safety issues in medical device evaluation. Example in a study of seating problems in patients with Duchenne's muscular dystrophy 63% (60 out of 95) could not lift their heads by themselves when they were tilted backwards whilst seated in their wheelchairs. This could lead to asphyxia if unnoticed which was reported in 2 patients. Of 60 caregivers, 58% experienced trauma related to the seating systems, such as difficulty in making bodily contact with the patients when lifting them from behind the wheelchair #509.	Evaluation of devices within the context of usage is essential for evaluating in-use issues, such as safety. The authors of the exemplar noted that studies involving expert assessment and patient and caregiver interviews can benefit care management and device usage. For example they suggested practical solutions to the safety issues identified, such as ankle-foot orthoses, trunk support, pressure relieving cushions, powered wheelchairs and adjustable systems.
	Cohort sampling method. Example total hip arthroplasty inpatients with aplastic anemia. The study evaluated the results of total hip arthroplasty in patients with aplastic anaemia who received one of the following prostheses:1 bipolar prosthesis fixed with cement, 2 bipolar prostheses fixed without cement, 3 hybrid total hip prostheses, and 22 total hip replacements fixed without cement #238.	Clarity needed in sampling in medical device user groups even within cohort groups.
	Satisfaction and its relevance as an outcome measure to medical device performance. Example in a study of 70 upper limb amputees in Australia, 56% wore their limbs "once in a while" or "never". The amount of time amputees wore their prostheses was only moderately associated with their level of satisfaction with their prostheses. The association between the amount of time amputees wore their prostheses and their level of satisfaction with their functional abilities was very low #1489.	This exemplar raises 2 important issues: How useful is satisfaction as a concept to inform about device performance and usage? What do high levels of non-usage of devices inform about device performance? For example were the high levels of non-usage related to the experiences of pain and sweating? 40% stated pain interfered with their ability to wear a prosthesis and 55% rated sweating as "not acceptable" whilst wearing the device. A second study is required to explore sub-optimal outcomes.
	Changing technologies -including methodological challenges of accruing meaningful longitudinal data. Example, outcome data between 1993 and 1999 were reported for metallic self-expanding oesophageal stents used in palliative care using three different manufacturers' stents #719.	The way in which this study is reported makes it problematic to drawn conclusions between the performance of one stent and another. Suggests the need for a protocol for reporting changing technologies for the benefit of manufacturers and providers. Suggests a need for a more rigorous and universal post-market surveillance methodology.

Thematic Framework Category: **The Medical Devices**	***Issues Raised***	***Consequences and Conclusions***
	Complicating disease processes and care effects in relation to outcomes: The complexity of the context of medical device usage raises methodological issues not only in terms of the difficulties in differentiating between care and treatment effects and the actual device performance, but also in terms of potentially profound effects of underlying diseases and conditions. #202- For example, variables such as age at surgery and pathological diagnoses have been found to be highly significant p= (0.0001) in terms of outcomes following knee arthroplasty. #144 – In a study evaluating revision hip arthroplasty (n=609) in the first year after surgery, dislocation of the new implant occurred in over a quarter of patients who had undergone two or more previous total hip arthroplasties and over a third needed a further operation. #689 – In a paper reporting a series of saddle prostheses (n=17) inserted following resection of pelvic malignant tumours, complications such as nerve damage and infection were observed in 11 patients and functional results were available for only 9 patients as 6 had died, 1 was lost to follow up, and 1 was excluded because of removal of the prosthesis secondary to deep infection.	Device performance and outcomes are complexly intertwined with numerous variables, some of which may be clinically unknown. Medical device evaluation requires methodologies that facilitate assessment of devices within the context of their usage, reflecting and capturing issues of aetiology, co-morbidity, treatment and care. Furthermore the exemplars raise issues of acceptable outcome standards (see below). In the saddle prostheses study, despite a complication rate of 65% it is stated that "…*the prosthesis provided in all cases an early pain free weight bearing reconstruction with minimal limb shortening, but the functional results remained fair in most patients due to a limited range of motion and a poor abductor strength*…" Methodologically, small group-work such as in #689 suggests that case study methodologies may be appropriate with inclusive sampling strategies to maximise understanding in complex cases.

D.4 THE CONTEXT OF TOOLS USED IN MEDICAL DEVICE EVALUATION

Key: (#) – respective Refworks reference number of study (the Refworks numbers are linked to the complete references at p62)
($) – repeatedly observed in studies reviewed
(~) – observed gap in studies reviewed

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Issues are raised because of the plethora of tools in existence. For example, one study states that since 1945 over 75 instruments have been developed to measure functional limitation and disability alone (#2155).	Questions arise regarding which tools should then be selected for usage in a study when so many exist. Should choice be related to the validity and reliability of the tool and/or the study aims? Furthermore, given the number of tools in existence is a lack of sensitivity to user need and outcomes implied? The development of selection criteria for tools would be useful for harmonisation to approaches for medical device evaluation.
	Where tools are to be used routinely in practice they are required to be concise, and possess an acceptable completion time and simplicity of valid assessment of user need, facilitating data collection and collation (~).	Where such tools can be introduced to routine practice large data sets can be obtained which may then be used to direct policy, service provision and product development where appropriate.
	Tools may not focus solely on outcome measures. #1955 – For example, a conceptual tool, the Rehabilitation Technology Product Taxonomy, developed as a framework for analysing rehabilitation technology products and extracting demand determinants. The tool promotes examination of: 1) the economic environment - competitive strategies, prices, level of competition, and intensity of competition ; 2) the market structure - size of firms and type of structure [i.e. monopoly, oligopoly, free market conditions etc]; 3) the product itself - the type of product [tool versus appliance], the purpose, the form of support a product is associated with [i.e. tangible versus non-tangible], the method of provision [i.e. loan, subsides &/or tariffs], and the intensity of care that the product is aiming to provide; and 4) the underlying technology - type of technology, innovation type and direction, existing versus non-existing technology, enabling versus disabling technology, and technology maturity stage [i.e. technology push versus technology pull].	Such a tool may aid analysis of a particular product but some of the taxonomy issues raised may not have known answers such is the context of medical device development. Indeed the intended use of a developed product may be yet to be determined, and even where the use of the product is known and developed, the size of the potential market may be unknown because of a lack of epidemiological data regarding particular conditions for which the device may be beneficial.
	Issues are raised relative to the lack of internationally standardised clinical outcome measurement systems (~). For example there has been a call for a standardised hip score (#875).	There is a need for the development of such systems.

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Issues arise because of the lack of formalised frameworks for producing device-specific outcome models, which will be applicable to multifarious types of devices and their outcomes. Currently the development of device-specific models is motivated by utilitarian, clinical concerns such as comparing the outcomes of competing devices of different but related types (#1329).	Device-specific outcomes models require careful selection of the variables to include in them, and designation of the user population to which they apply. Such models will facilitate the research agenda for medical device evaluation in terms of for example, the manner and duration of device usage. In a study developing a framework for producing assistive device specific outcome tools the following aspects were discussed: procurement of a device-type; introductory use; shorter term outcomes; longer term use; moderating co-factors; longer term outcomes; continued use; and discontinued use (#1329). The framework highlighted the need to examine outcomes over time in both the short and long term, the need to include the multiple stakeholder perspectives and consideration of all stages of medical device development. [major themes include multiple-methods and the need to include the context of device use]
	Measuring Outcomes: Multiple tools for the same condition. #930 – See above example. In this study 15 different tools for assessing knee arthroplasty procedures were analysed. The results contradicted the opinion that the outcome differences between knee evaluation systems were small. The notion that different knee evaluation systems measure different underlying factors was supported. More detailed operative specifications for the different systems were suggested as a first step to decrease the variability among assessment systems. Reasons given for the wide spread of the results were: different demarcation of categories, the indices measure different factors, poor operating instructions.	Different tools used for the same clinical condition may actually be measuring different outcomes, making comparisons between similar studies problematic. Highlights the need for harmonised tools.
	Measuring Outcomes: Variation in measured outcomes may arise between various tools. #117 - Four commonly used scoring systems for knee arthroplasty: the Hungerford Score, the Hospital for Special Surgery score, the Knee Society knee and function scores, and the Bristol Knee score revealed considerable differences in outcome scores. The median total score outcome, as averaged for both observers and for all the knees was 74 points [range 15-100 points], the median for the Hungerford score was 75 [range 23-97points]; for the Hospital for Special Surgery score 58 [range -17-92 points]; for the Knee Society score 50 [range -10-100 points]; and for the Bristol score 71 [range 21-98 points].	Not only may variation in scoring ranges and scales potentially cause confusion in practice but the exemplar revealed significant differences among the mean total score outcomes causing questions to be raised regarding the reliability of the measures.
	Measuring Outcomes: The choice of measurement scales contained within tools may have an impact on study outcomes. In the case of medical device evaluation the commonly used visual analogue scale may be problematic, lacking sufficient meaning at specific points, for example on a 10cm scale anchored from “no difficulty” to “so difficult require help” (#1045). Another commonly used measurement mechanism is the Likert scale which was found to vary both across and within studies in terms of the number of points on the scale, with some scales containing mid-points whereas others did not.	Do measurement scales contained within tools provide sufficient meaning when it comes to evaluation of device performance?

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	How effective are tools in informing the user or healthcare professional regarding the effectiveness of the device? **Exemplar study regarding device effectiveness and outcomes as measured by a tool:** #401 – The authors of a study investigating the long term changes in the Harris Hip and Knee Society scores to determine whether they result from overall functional decline rather than actual changes in the condition of the prosthesis, concluded by questioning the effectiveness of these tools in the evaluation of long term mechanical outcomes of total hip and knee arthroplasties. For example, they state that "…*the combination of functional and pain scores within the Harris Hip Score system leads to inaccurate decline in the entire score*…"	What can tools inform the user regarding the effectiveness of a particular device? Sensitivity and specificity of the tools.
	How useful/valid are psychological dimensions which are contained within some tools regarding the effectiveness of the device ($)? For example, the domains of depression and cognitive ability may be measured.	It can be questioned as to what such dimensions inform about device performance and whether it is appropriate to measure them. Cognitive ability, for example, may be an important contextual dimension of device usage but it may not inform about device performance per se.
	Generic Tools used to assess device performance. Issues will arise where general assessment tools are used to measure the general condition of respondents rather than device performance. #687- The Barthel Index, Sickness Impact Profile and Functional Independence Measure have been used to measure general disability levels within studies rather than specific medical device related goals.	What do generic tools inform regarding device performance? Validated and accepted tools that facilitate the measurement of specific device related goals are required.
	Generic Tools - transferability and sensitivity issues. Issues may be raised where generic tools such as functional assessment tools are applied to varying areas of clinical practice and medical device usage, for example hip and knee arthroplasties (#1869).	The application of generic tools to specific areas of care and medical device usage raise potential issues of reliability, validity and sensitivity.
	Generic Tools - sensitivity between clinical condition/disease and device performance. Issues can be raised regarding the sensitivity of generic tools to changes in not only the disease and underlying condition but the performance of the device. For example, the SF-36 has been used to establish outcomes following total hip arthroplasty and is perceived as a well established assessment tool in clinical studies (#231). Furthermore it was used as a "benchmark" with which to compare the outcomes of other tools such as the London Handicap Scale and the Nottingham Extended Activities of Daily Living (#231). However in this particular study comparing the size of benefits resulting from a hip replacement using a multi-dimensional health profile - the SF-36, the London Handicap Scale and the Nottingham Extended Activities of Daily Living scale the 3 various tools calculated different sizes of benefits.	How sensitive are generic and specific tools to changes in disease status and device performance? Different tools may measure varying sizes of benefits in relation to outcomes because they focus on and measure varying aspects of functional recovery.
	Generic Tools applied to specific device groups. Issues raised where general purpose instruments are applied to outcome measurement in specific device groups and populations, such as assistive technology (#1551).	There may be an inherent difficulty in applying generic tools to specific areas of device usage, raising issues of lack of sensitivity of the tool.

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Specific Tools used to assess device performance. Issues arise where tools are designed to examine specific populations, such as the self-administered hip-rating questionnaire, developed for the assessment of patients who have arthritis of the hip (#1163), or alternatively specific groups of medical devices, such as the Quebec User Evaluation of Satisfaction with Assistive Technology which is used to assess seating and mobility aids, transfer aids (toilet adaptation, toilet seats/chairs and stair lifts), communication devices, lower limb prostheses and environmental controlled devices (#1585). Some tools are highly specific, for example the Child Amputee Prosthetics Project-Function Status Inventory for Toddlers is a standardised instrument designed to assess functional status in toddlers aged 1-4 years who have either an upper or lower limb deficiency (#1662).	The use of tools for specific populations and specific groups of medical devices suggests that in medical device evaluation the use of generic tools may not yield informative data of device performance and patient outcomes. This raises a number of issues regarding sampling of medical device user populations or groups and the need to generate device and context specific tools.
	Specific Tools - training requirements. The use of specific tools raises issues regarding training requirements for potential assessors in their use. #2153- It has been found that the mechanism or format of administration of the tool may be pertinent. Multiple sclerosis participants found an interview based format of the Quebec User Evaluation of Satisfaction with Assistive Technology (version 2) to be the most convenient, with robust test-retest stability.	Device and context specific tools raise training issues for the assessors
	Specific Tools- transferability to other clinical areas. Issues raised where specific tools are applied to alternative clinical areas from which they were developed. #628 - The Nottingham Extended Activities of Daily Living scale is a popular outcome measure in stroke research. Its psychometric properties have not been tested in other conditions and in one study the tool was assessed in conjunction with others in the context of total hip arthroplasty. #60 – In a study evaluating whether dissatisfaction with the artificial limb and/or body image relate to achieved mobility following lower limb amputation in established limb wearers, a questionnaire on body image from an eating disorders instrument was adapted	It can be questioned in terms of validity as to whether specific tools are transferable to other areas of care and device usage from which they were initially developed. Methodologically new applications of existing tools require piloting and validation. Transferring tools to contexts outside those in which the tool was developed and intended raises questions regarding the validity of such use.
	Specific Tools- transferability with other clinical assessors. Issues of transferability of specific device related tools may be compounded where tools are designed for a specific professional assessor group. For example, OTFACT, an assistive technology outcomes assessment protocol is used by occupational therapists (#571).	Highly specific tools via their inherent nature will lack the ability to be transferred to various areas of medical device use and be used by varying groups of users

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	How sensitive are generic and specific tools in detecting clinical nuances in outcomes research? **The use of both generic and specific tools within a study.** #219 – In a study designed to assess the reliability of the Pain and Function of the Hip Scale [PFH] and its degree of association with other instruments as well as its ability to measure clinical change (responsiveness) in patients undergoing total hip arthroplasty it was found that Cronbach's alpha reliability coefficients were 0.81 for the PFH and 0.91 for the Nottingham Health Profile [NHP]. Data presented in this study showed that the PFH scale is responsive to clinical change. The amount of improvement detected by the PFH scale was higher than that of the NHP, indicating the PFH to be more sensitive. Also, the PFH showed a moderate to high level of correlation with patients' perceived health status as measured by the NHP. However only moderate correlation was observed between the PFH scale and clinical examination. **Do tools detect clinical nuances in device performance (using both a general and a specific tool)?** #875 – In a study assessing patients with a primary total hip arthroplasty using the Harris Hip Score and the Nottingham Health Profile at 1, 3 and 5 years post surgery to compare the specific and general outcomes measures in evaluating total hip replacement the authors concluded that the tools were not able to detect subtle differences in the performance of 2 different types of hip replacement at 5 years post operatively.	Are specific tools where available more sensitive to clinical change? Is clinical change measurement sensitive to changes related to device performance as opposed to other factors such as the surgical procedure? In the exemplar only moderate correlation was observed between the PFH scale and clinical examination, is it likely that the tool misses data obtained via clinical examination? Does a battery of tools yield information about device use? Are tools sensitive to nuances in device performance and outcomes? Overall the approach to tool usage whereby multiple tools and data triangulation are adopted can still miss the goal of generating valid and reliable outcome measures of medical device use, unless the tools are 'fit for purpose'.
	What effect does tool age have on its sensitivity as a means of evaluating device performance? #32 – The authors outline the development and testing of the reduced Western Ontario and McMasters Universities Osteoarthritis Index [WOMAC] functional scale, of which the original tool was first used in 1988. In practice the stiffness score was found to be largely redundant and commonly excluded from the questionnaire, thus this element of the tool was eliminated as well as other items reducing the tool to 7 items from the original 24.	Does greater tool age imply lack of sensitivity to device performance given the fast pace of technological development or does it in fact imply greater reliability of a tool, ability to generalise and ability to perform meta-analysis where the same tool is used in studies over time? Furthermore the exemplar raises issues of the need for pragmatic lengths of tools when applied in practice and the possible redundancy of items contained within older tools. However it could be questioned as to whether reduction in tool length is offset by losses in sensitivity and detail in outcome measures.

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Extensive tools usage. The number and extent of tools and evaluation systems that are used in the context of medical device evaluation precludes cross-study comparison and meta-analysis for groups of devices. #561 – In a study examining temporomandibular joint implants the participants were asked to rate their usual level of orofacial pain during the month preceding their visit as well as their present orofacial pain. Separate visual analogue scales for pain intensity and pain unpleasantness were used (100mm line from no pain/not bad at all to worst pain possible/most unpleasant feeling possible). Environmental exposure was evaluated using the Quick Environmental Exposure and Sensitivity Inventory. Psychological and quality of life issues were evaluated using the Minnesota Multiphase Personality Inventory, Millon Multiaxial Inventory-II, the Symptoms Checklist-90, Medical Outcomes Study Short Form Health Survey (SF-36) and the Sleep Quality Index. #930 – In a study analysing the 'performance variability' of 15 different knee assessment scales after knee arthroplasty, the 15 evaluation systems which had been revealed in a literature search were applied to the same sample of a cohort of 52 patients. In order to compare the different rating systems a common scale was developed. The results contradicted the opinion that the outcome differences between knee evaluation systems are small. The notion that different knee evaluation systems measure different underlying factors was supported. The reasons given for the wide spread of the results were: different demarcation of categories, indices measure different factors, and poor operating instructions.	Such studies display the inherent difficulties in cross-study comparison of results where various tools and evaluation systems are used. Furthermore the results of studies that compare the outcome measures of various systems suggest there is a great need for studies of the conformity and consistency of the evaluation systems. Indeed, internationally accepted systems are required that are applied and developed across studies. Does the need for a range of tools within a single study imply a lack of sensitivity and generalisability of outcome measures in capturing needs and issues?
	The length of time for tool completion may affect response rate. Where multiple tools are used the effects may be compounded, particularly if the sample comprises an elderly population (#22). #203 – In a study testing various outcome questionnaires in order to determine which is the best for patients who have had knee arthroplasty it was found that on average the 12 item Short Form health survey took 7.7 minutes to be completed, the Algofunctional Index for the Knee took 8.2 minutes and the Oxford 12 item Knee Score took 9.6 minutes.	Where a number of tools are used within a study and on a repeated basis longitudinally the length of time required for completion may be a factor affecting reliability and arguably sample attrition.
	Use of tools across participant age divides. #611 – In a study evaluating patient satisfaction and quality of life after bone-anchored hearing aid implantation using a patient orientated post-interventional questionnaire (the Glasgow Benefit Inventory) both paediatric and adult patients were recruited (n=312), with an age range of 2-67 years.	Can such tools be successfully used across age divides? Have validation issues been addressed at the various ages?
	Issues arise regarding tool validation in various languages and for particular populations ($).	Questions may arise as to whether the tool has been validated for a certain study population, within the respective language.

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	The development and use non-validated tools. Exemplar study of non-validated tool usage: #1474 – In a study examining the experiences of women receiving bilateral breast augmentation the women completed a 2 page questionnaire designed to assess their reasons or expectations for the surgery and their concerns about perceived risks of both surgery and the implants. At 6, 12 and 24 months postoperatively the women completed another 2 page questionnaire, rating on a 5 point Likert scale their satisfaction with surgery and its specific psychosocial outcomes, their concerns and their benefits-to-risk appraisals of the augmentation. The questionnaires were adapted from an existing survey instrument and from information obtained from focus group research with women who had sought breast implants.	Is it appropriate to use non-validated tools within a study and if so can the results be successfully generalised?
	Questions raised regarding the validity of some tools. #689 – In a study examining saddle prostheses inserted following resection of pelvic malignant tumours the Toronto Extremity Salvage Score (TESS) was used for functional analysis. However its validity was questioned because 1 patient aged 17 years had a TESS of 95 points which represented a patient aged 50 years. This patient was a student who walked without aids. Furthermore, the best functional outcome was obtained for a 56 year old patient who had a TESS of 73 points; however he walked using a crutch and was unable to return to work.	If validity is accepted to be an ongoing process then the validity of individual tools needs to be examined in a continuous process over time, within the context of the studies in which they are used. The clinical relevance of the findings from this study is called into question because of the analysis of the function did not take into consideration the relevance to the individual concerned.
	Issues of validity relating to modification of tools. #57 - Modification of a tool from an assessor administered tool to a patient self-administered one raises issues regarding validation. For example, in a study examining outcomes post total hip arthroplasty a self-reported version of the Patient-Specific Index was created. The original Patient-Specific Index reflects how individual patients weigh concerns in rating the outcome of total hip arthroplasty and is administered by an interviewer. #580 - In a study assessing the Brooker Classification (1973) used in assessment post Hip Arthroplasty, modification of the tool occurred. The assessors included physicians with different training backgrounds. The Brooker classification was modified as the classification was found lacking adequate inter-observer consistency. The new classification showed adequate inter-observer reproducibility, less variability, and improved consistency for classification of significant HO.	Such changes require further validation of the tool post-modification and additionally tool utility is confined when self-administered to individuals who have appropriate reading and writing skills. #580 – is an example of a tool being validated post-modification.
	Do missing responses to questions or high rates of "not-applicable" responses impact on the validity of tools? 541# - In a study that compared the Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology with a modified version containing "not-applicable" responses, it was assumed that respondents answering 'not applicable' would not have answered at all in the original version. The authors concluded that including the non-applicability option improved the feasibility of the instrument without affecting content validity.	What do either missing responses or "not-applicable" responses in relation to questions contained within tools tell us? Do they reflect a lack of sensitivity, relevance of the questions to the pertinent issues of the respondent, and/or respondent irritation or offence at the question for example?

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	The validity of a tool itself may be questioned in relation to non-response bias. For example in a study that developed the Individually Prioritised Problem Assessment to assess the extent to which the problems in daily activities, identified by the client, diminish as a result of the provision of a mobility device and/or transportation service, three-quarters of the sample (n=69) were female and the mean age was 75 (#119).	The sample used for development of a tool may have an important effect on the validity of the tool. In this example because of the response rate there are limits to generalisation beyond the actual respondents who were female and elderly.

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Process of tool development. The initial formation of items for a tool may involve a process of generation, such as a literature review, existing instruments review, expert knowledge, consensus generation and end-user review. The process used by researchers may be called into question, for example in the development of the Seating Identification Tool, a screening tool designed to identify the need for formal seating and wheelchair intervention among institutionalised elderly, the generation of items was performed by two clinicians, an occupational therapist and a physiotherapist, utilising their clinical experience and a literature review (#402). Tool development may often involve extraction of items from existing tools. For example, the Wheelchair Users Shoulder Pain Index was developed from the Shoulder Pain and Disability Index (#1045). The following exemplars display thorough processes. #379 – In this study the purpose was to construct a reliable and valid instrument to identify problem areas in the broad range of activities within the capability of lower extremity amputees with prostheses. Maslow's Hierarchy of Needs and Roy's Adaptation Model were used as a conceptual framework in developing the Prosthesis Problem Inventory Scale. Items were selected from a comprehensive literature review, existing instruments assessing other disabilities, and the clinical experience of the authors. The instrument was reviewed by a diverse range of instrument reviewers, content experts from the fields of nursing, rehabilitation medicine, sex therapy, sports medicine, and sports and physical fitness. The suggestions of the content experts were then incorporated in the instrument. A pilot study was then conducted with 26 amputees to develop the content validity of the instrument. The instrument was further revised and then given to 131 amputees. #663 – In a study that developed an interactive training programme and interpretive guidelines for professionals administering the Assistive Technology Device Predisposition Assessment [ATD PA] consumer form an iterative user involvement process was used. 22 professionals representing diverse geographical regions, cultural backgrounds, a range of ages and both genders were exposed to the new, pre-pilot, interpretive guidelines. The participating professionals and consumers who were exposed to and used the ATD PA were asked to complete a survey on their experiences with it. The advisory committee members read summaries of the responses to the survey and identified the essential content for the ATD PA interpretive guidelines and interactive training programme. This information was used by the advisory committee using a modified Nominal Group Technique. All responses were summarised and distributed to the advisory committee members until the group was unable to provide additional responses. Finally, all acceptable topics were redistributed to participants to rank-ordered the ones they believed were most important in: a) the process of matching person and assistive technology; b) to include in computerised interpretive guidelines; and c) to include in the interactive training programme.	The processes required for validating tools require a degree of stability for coding, for example to ascertain inter-rater reliability, however, the very nature of disease processes that underpin medical device usage fluctuate over time. Indeed stability in coding over a period of time could reflect a lack of sensitivity of the particular tool in capturing changes. Thus the issues of validation required for tools used in the context of medical device assessment are inherently complex. In addition, end-user involvement is essential. Extraction of items from existing tools may imply a lack of sensitivity of tools to specific areas of medical device use; however such tool development necessitates further processes of validation. The exemplar study developing a tool for amputees using prostheses found that piloting of the instrument was essential, increasing the instruments validity and internal consistency which was then demonstrated by further testing with 131 end users. In both studies a diverse range of professionals were used to review the respective tool and their feedback was appraised so as to be incorporated systematically into the tools.
	Issues may be raised regarding the timing of publication of a tool during the research process (#1873).	For example, is it appropriate to present a tool prior to piloting?

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Terminology used within tools. For example, a rating scale may range from "marvellous to no improvement or worse" (#231).	Could such terminology potentially introduce bias? Such subjective terminology arguably does not generate valid or comparative data.
	The need for guidelines by which to interpret data arising from tools. For example, one study highlights the lack of guidelines to interpret QUEST (Version 1) data (#664).	The ability to interpret data arising from tool usage is as fundamental as collection of the data itself via the tool.
	The impact of different professional groups and individual levels of clinical skills and experience in assessment. Intra-observer reliability may be a problematic issue where tools are completed by clinicians with varying levels of experience. #220 – In a study examining the reliability of the American Knee Society Score intra-observer reliability varies according to the experience of the assessor. The assessors who evaluated the subjects included 1 consultant with an interest in knee surgery, 2 registrars with at least 3 years experience in orthopaedics, 1 senior house officer with 3 months experience in orthopaedics, and 2 arthroplasty nurse practitioners whose responsibilities occasionally included clinical assessment. The more experienced observers had greater intra-observer reproducibility. Notably, there was moderate agreement between observers in the subjective variables, while the objective variables produced lower levels of agreement. The authors noted high levels of inter- and intra-observer variations in scoring of the tool and concluded that reliable use of the tool would necessitate repeated evaluation by an experienced observer. #580 – In a study examining use of the Brooker Classification [1973] used post Hip Arthroplasty, physicians with different training backgrounds were assessed for the intra-observer and inter-observer reproducibility. They included 3 orthopaedic research fellows to act as observers, were trained in Argentina and Italy. 3 observers trained in North America: an operating surgeon, a 4th year orthopaedic resident, and a musculoskeletal radiologist. Reliability in tool outcomes may be raised where variation in measurement of outcomes occurs between various professional assessor groups. #273 - For example, in a study that examined a model developed to systematically evaluate the specific functional needs of the person with disabilities as these needs relate to technological interventions, it was found that quantification of the data was impossible because the different members of the interdisciplinary team interpreted the components of the model differently.	Both inter-rater and intra-rater reliability may be of concern with relation to tool usage. This example (#220) raises 3 pertinent contextual issues to tools that are used by varying professionals: Cross-disciplinary working issues may arise Professional variation in opinion can occur both within and between professional groups There is a need for robust, observable, single-meanings for components of any tool, with terminology defined #580 is a further example of the above

Thematic Framework Category: **The Tools**	***Issues Raised***	**Consequences and Conclusions**
	Discrepancies or variations between clinical assessors and subjects perceptions in response to tools. #782 - For example the Functional Independence Measure and Instrumental Activity Measure have been found not to cover all aspects of significance for community living young adults with cerebral palsy or spina bifida. It was found that these tools exclude aspects that these individuals with potentially high levels of need consider to be of importance such as personal care and occupational and leisure domains (#782). #1951 - Differences have been observed in tool ratings between patients and clinicians. In a tool assessing function post total hip arthroplasty, patients rated themselves more favourably than physiotherapists, with the some patients perceiving that they did not require "assistance" while the physiotherapists did. The authors concluded that this disagreement may reflect variation in individual definitions of the word "assist". Assessment of responses made by both users and end-users in relation to hip arthroplasty. #97 - A study comparing patient and doctor responses for a hip arthroplasty procedure, using a evaluation questionnaire comprising of two components, one requiring the patient to complete and the other the doctor's clinical evaluation. It was found that 12 of the 16 items the patient responses had acceptable agreement with the doctor responses. However, some important differences between patient derived and doctor derived data were found. The authors conclude that patients' perceptions of symptoms and outcomes after total hip arthroplasty are relatively similar to those of their doctor. They argued that the selective use of patient completed questionnaires has the potential to substantially reduce the costs of outcomes evaluation programmes by minimising doctor input, and pending revision of some of the items, the use if this patient completed questionnaire is advocated.	Differences in perceptions between clinicians and end-users may be highlighted when completing tools, such perceptions require acknowledgement in order to meet end-user requirements for medical devices. Essentially differences in perceptions between clinicians and end-users need to be understood and the context in which end-users are living needs to be taken into account.

D.5 THE CONTEXT OF METHODOLOGIES FOR MEDICAL DEVICE EVALUATION

Key: (#) – respective Refworks reference number of study (the Refworks numbers are linked to the complete references at p62)
($) – repeatedly observed in studies reviewed
(~) – observed gap in studies reviewed

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Issues arising due to the fast-paced nature of technological development. Issues arise in medical device evaluation because of the fast-paced nature of technological development. Products are frequently introduced into the market and newer versions of devices evolve continually. Traditionally, research studies usually take a matter of years from the beginning of the research process until the publishing of results.	Methodological issues arise within this context because of inherent difficulties in evaluating continually developing devices ($) (Lilford, Braunholts, Greenhalgh et al 2000).
	The influence of commercial funding on research outcomes. For example, it may be more likely that a single manufacturer's device is evaluated without cohort groups of other manufacturers' devices or comparators. In addition commercial research companies may be employed to perform research on behalf of a company, which raises questions regarding the potential for bias and recruitment related issues where the external companies lack insight into the healthcare environment and medical device usage. #1321 – In a review of the prevalence of corporate funding in hip and knee arthroplasty of 603 consecutive articles reviewed, the presence of commercial funding in these studies was 50%. The authors reported that adult lower extremity orthopaedic research reports, upward of 90% of studies reporting positive outcomes when carried out by commercial industry, and 30-60% of studies reported bad results or cause for caution when carried out by independent researchers. They also found an important influence of implant registries. In the US 17% of Medicare beneficiaries received revision total hip replacement, compared with 8% from the National Swedish Hip Registry. They concluded that it is possible that the Swedish Registry has allowed the dissemination of objective implant information to all surgeons in Sweden, and has led to improved implant selection in these surgeons. In the US there is no such registry, and information on the performance of implants is via research literature. The available literature may be provided by surgeons who have been funded by corporations, and because the criteria for disclosure vary from one format to the next, the same investigator presenting the same research may fail to disclose a relationship in another format.	Controversially, commercial funding may be associated with a bias towards reporting of positive outcomes. The exemplar raises the additional issue of the inability to analyse how often there are failures to disclose commercial relationships. (See new policies in relation to International Federation of Pharmaceutical Manufacturers and Associations and disclosure of clinical trials information in particular).
	Lack of agreed and/or uniform outcome measures and defined end-points. Issues arise because of the lack of agreed and/or uniform outcome measures and defined end-points for specific medical device areas, with a lack of established standards. It has been argued for example, that the results obtained with physical status measures including goniometry, muscle force measurement and radiographic examination, commonly used for orthopaedic device evaluation to reflect relevant aspects of quality of life, should also be related to the physical and social ability of the patient (#1086).	Uniform outcome measures and defined end-points for specific device areas require on-going development, incorporating consensus generation so that the measures are comprehensively accepted across studies. Lack of clarity and consensus on what constitutes appropriate outcome measures for medical devices.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Lack of predictive algorithms for device assessment. Issues arise because of a lack of predictive algorithms by which to assess medical device effectiveness, and facilitate decision making (~).	There is a great need for studies to develop and evaluate models of device performance which could be used to aid decision-making and procurement choices in practice.
	Lack of formalised processes for deciding the appropriate data collection points throughout the pre and post intervention stages. Issues are raised in relation to the timing of data collection points, particularly post-intervention follow up points. A question may be raised for example, as to whether 3 months as the last data collection point is satisfactory in terms of assessing patients with both conventional dentures and implant stabilised prostheses (#208). **Exemplar study regarding the timing of data collection points including the absence of baseline data:** #611 - In a study evaluating patient satisfaction and quality of life after bone-anchored hearing aid implantation, patient benefit was found to be significantly improved following implantation, and when the participants were asked about the success of their bone-anchored hearing aid, the response was extremely positive. However, no baseline data prior to implantation were collected, so assessment relied on retrospective recollection by the participants. #1355 – In a single study, post pacemaker implantation assessment (n = 93, 56 Swedish patients & 37 US patients) was performed at 3 months in a Swedish sample and at 6 months in a US sample, with comparisons made.	What effect do varying data collection time points have on study results and outcomes? Suggests a need for robust protocols in post market surveillance studies.
	The opportunistic use of pre-existing data, where the data has been collected for alternative purposes, for retrospective analysis ($).	It may be appropriate to question for example the age of the data, the methods and tools of collection, the number of individuals involved in data collation and whether the data collectors were additionally the care providers.
	A tension between the prevailing paradigm embracing statistical methodologies and alternative ways of judging effectiveness of medical devices e.g. universal design. Issues are raised because of the requirement in medical device evaluation of the device industry as a whole, particularly manufacturers and regulators to be convinced of the value of specific methods, in order to go on to adopt the concepts of research findings and possibly change the way in which the industry operates where appropriate. For example, it has been noted that traditionally industry needs statistical justification for practicing universal design as a method and that they also need a set of universal design performance indicators against which to judge their designs for use by a diverse consumer base (#292).	Where methodological development is performed the utility and value of the methods have to be demonstrated to medical device stakeholders before findings and outcomes are accepted.
	Need for methodological development. Issues are raised regarding the need for methodological development (~). At present disparate methods are used across numerous and diverse contexts of medical device usage ($).	Defining and validating methods that are then used systematically within specific device related groups and populations would facilitate mapping of device performance, which currently only occurs sporadically as the use of disparate methods prevents mapping across studies.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Need for methodological development in terms of highlighting and predicting possible device related hazards or events (~). #1349 – In a study that sought to determine whether computer-based surveillance can reliably identify medical device-related hazards (no known harm to patient) and adverse medical device events (patient experienced harm) and to compare alternative methods of detection of device-related problems, two pertinent issues were highlighted: currently there are poor predictive detection strategies; and potential hazards or events are not regularly assessed.	Methods for predicting possible device related hazards and events require development. This is of particular importance because reporting of actual events and hazards by users may be based on voluntary systems e.g. yellow card system for adverse drug reactions in the UK.
	Methodologies for testing theoretical risk of two devices where one could have an influence on the vital functioning of the other and patient safety. #846 – Warnings regarding a heart rate monitor affecting pacemaker function stimulated the respective manufacturer to part-fund a study conducted by a clinical/academic collaboration to investigate whether any interactions occur between a heart monitor and the implanted pacemaker that might affect the function of the pacemaker or the accuracy of the monitor.	The theoretical risk was not substantiated in this exemplar, which demonstrates a practical approach to investigating interactions between devices leading to safe practice with implications for a number of contextual uses, example in a public gym.
	Need for development of comprehensive clinical databases. Issues arise regarding the need for the development of comprehensive clinical databases to obtain systematic data regarding devices and their performance and to inform study design and sampling methodologies (~).	There is a profound need for routine data capture in healthcare practice regarding medical device performance. Such data capture would create databases that could facilitate mapping of device performance, and would be of benefit to national regulators and providers.
	The need for user-focused methodologies. Issues are raised regarding the need and value for user-focused methodologies. #858 – This study outlines how the concepts of user centred design and usability engineering, have been applied to develop a methodology called USERfit. This is a tool which was designed to ensure that human issues are adequately considered through the development process of an assistive device. The techniques used to gather information are brainstorming, task analysis, interview techniques and user trials, which force design issues to be made explicit and developers to justify any design assumptions they have made, either about technology or users. Some of the elements of USERfit include: environmental context, product environment, user analysis, user activities, product analysis, product attribute matrix, requirements summary, design summary, and usability evaluation. It includes the selection of methods for evaluation as well as establishing suitable evaluation criteria. The documentation of the results of such evaluation activities is supported, along with action points for the necessary improvement of the product before full commercial release. Interestingly a low response rate was found in a survey on usability of the handbook for the USERfit method, which could be indicative of its length. Out of 114 UK developers and academics who requested the USERfit manual 25 responded to a postal questionnaire, 16 of whom had read some part of it, with only 5 making use of the methodology.	The exemplar demonstrates the utility of a flexible user-focused methodology that enables different elements of the framework to be applied at different times in product development. However successful use of any method requires careful selection dependent upon the context of the device usage and is additionally predicated by the actual implementation of the method, for example who is selected to do the initial proposed brainstorming. The exemplar also raises issues regarding interest towards and acceptance of newer methodologies.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Value of involving multidisciplinary professionals in methodological development, and medical device design (~).	Multidisciplinary working for the purposes of methodological development and device design can facilitate novel development and beneficial insights through collaboration that would not develop by single disciplines alone (#1643, #1305, #326, #1482, #934, #1389).
	The importance and value of experiential knowledge on the part of the clinician and end-user. #1305 – Outlines 24 years of experience providing rehabilitation aids such as artificial limbs and callipers for individuals in Northern India, highlighting appropriate identification of population needs and device design to the extent that "…*our rural amputees now no longer are required to migrate to urban areas, seeking and learning sedentary occupations*…"	Involvement of experienced clinicians and end-users is essential to the appropriate and successful use of methods and device development (#1305).
	Who is best placed to assess medical devices? Does the use of non-clinical evaluators in assessing medical devices, for example in terms of usability inspections have an influence over findings (#470)?	Are "naïve" evaluators of benefit because they may not have expectations regarding the device and may be more likely to think of out-of-the box solutions and approaches to design? Do such evaluators also increase the simplicity of the design for example, preventing the use of medical jargon? Conversely, non-clinical evaluators may not be aware of the context of device use, for example the possibility of patients tampering with infusion devices, and may not consider these implications fully.
	Need for combined and triangulated data collection methods (~). **Value of using comprehensive, interventional methods.** Interventional studies that focus on phases of assessment, individualised interventions, training and follow-up raise issues of their potential value. #320 – In a study assessing the impact of professional intervention on the use of, satisfaction with and effectiveness of assistive devices amongst older adults with cognitive impairments (n=20), based on assessment results and interviews with the participant and care provider, assistive devices and environmental interventions were provided or existing assistive devices were adapted to meet specific individual needs. The participants received individualised training on the use of the devices by an occupational therapist. Support was provided by telephone follow up at 2 week, 4 week, 2 month, 4 month and 6 month intervals.	The use of a combination of data collection methods, such as clinical evaluation by expert clinicians, radiographic evaluation and patient completed questionnaires to combine perspectives of outcomes may facilitate comprehensive assessment. In appropriately designed studies interventional methods may be particularly beneficial in revealing the value of specific devices and the associated requirements for individualised assessment and training.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Potential value of using appropriate, user-focused methodologies in product development. Methods that facilitate device development raise issues of their potential value. The following exemplars illustrate valuable use of such methods for product development. **Exemplar studies of methods utilised to facilitate device development:** #326 - Home visits were performed with individuals with motor neurone disease to discover what items of equipment would enable them to live more independent lives. These visits produced a list of over 30 items which were then prioritised via the use of a questionnaire. One item was chosen from 30 and the Autosip device, a device that removes the need for a carer having to assist a person with motor neurone disease, and who has minimal sucking ability and/or arm strength to have a drink, was designed. Consultations were held with potential users, and the appropriate care professionals, at every stage in the development of the Autosip, and prototypes were frequently tested. Nevertheless, this study raises issues regarding successful commercialisation of products that have been developed entirely through research processes because in 1995 only 60 devices had been placed with individuals despite the potential transferability of the device to other disease groups. #564 – Illustrates the value of obtaining user feedback, in this case from older people, in focus groups, identifying problems and solutions with respect to their indoor mobility difficulties which may in turn be addressed by innovative assistive devices, before designing solutions. #878 – Describes the use of a focus group and consensus generation model for systematically transforming end-user requirements into a form that is useful and accessible to product designers and manufacturers. The model was used to examine battery chargers for wheelchairs and identified low cost improvements that could be made and highlighted issues not normally considered in product evaluations such as warranty lengths. #994 – Usability tests defined product design criteria, for an affordable pressure relieving device that is adaptable for wheelchairs which allows individuals with quadriplegia to relieve the pressure from the ischial tuberosities, generating first and second generation prototypes, with facilitation of simplicity of design, and real life observation and testing resulting in pressure relief systems that function without the assistance of another individual. #738 – A custom made sacral prosthesis was developed using extensive clinical analysis, CT and MRI imaging, 3D modelling and wax models, in conjunction with engineers from a manufacturing company.	The exemplars highlight the particular importance and value of carrying out tests and feedback for device development in real life environments, related to everyday tasks. Contextual detail is all important. Exemplars illustrate the use of a range of methods for example, clinical imaging and engineering (#738), social science methods (#564, #868) comprising focus group and consensus building methods, and ergonomics methods (#994).
	The potential benefits of university related educational programmes: The promotion of methodologically-related issues such as the production of well-tested prototypes, engagement with users and awareness and sensitivity to the requirements of design for specific groups (#1389).	Educational programmes can be utilised to promote methodological awareness, awareness of issues of medical device usage and the stages of medical device development, user involvement and product development (See a holistic model (#1389) in Exemplary Cases: Part A Appendix E:).

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	The potential value of a novel theory for medical device evaluation: #470 – In this study heuristic theory (Nielson-Shniederman) was applied to the evaluation of volumetric infusion pumps. Of two pumps, Pump 1 heuristics were violated a total of 192 times for 89 usability problems. Consistency & standards and visibility were the two most frequently violated heuristics, with feedback and match the next most common. These four heuristics accounted for 64% of the violations. With Pump 2 heuristics were violated a total of 121 times for 52 usability problems. Visibility was the most frequently violated heuristic, with memory and consistency & standards being the next most common. These three heuristics comprised 54% of the violations. #2179 – In this study diffusion of innovations theory (E M Rogers) underpinned work illuminating the factors that are associated with discontinuance of assistive technology by individuals with disabilities.	The application of heuristic theory to the evaluation of infusion pumps in the first exemplar enabled the identification of extensive usability problems including discontinuance.
	The potential value and need for longitudinal studies. In a study examining satisfaction of 3 treatment modalities in resolving lower denture related complaints patients (n=90) were followed for ten years post-treatment (#1337). Such length of follow-up was infrequently found.	Longitudinal studies have value in ascertaining the impact of medical device usage over sustained periods of time. However methodological issues may be raised as a result such as the difficulties of patient recruitment for longitudinal studies and issues of sample attrition.
	Issues are raised relative to the need for outcome measures that are both specific and appropriate to device performance ($).	Such outcome measures need to be observable and objective, but may vary widely according to the device. For example, heart rate may be an appropriate measure of physiological strain when using an arm propelled 3-wheeled chair in the context of the developing world (#772).
	Incorporating patient choice around treatment options/specific devices will have an impact on study outcomes if not taken into account in the research design. #1337 – In a study examining satisfaction of 3 treatment modalities in resolving lower denture related complaints, patients (n=90) were randomised into one of 3 groups: overdenture retained by dental implants in the lower jaw (implant retained overdenture group, IRO); patients treated with a vestibuloplasty and lowering the floor of the mouth before insertion of a new conventional complete denture (pre-prosthetic surgery group, PPS); and patients treated with a new conventional complete denture alone (complete denture group, CD). After 1 year patients in the CD and PPS groups who were not satisfied had the opportunity to switch to an implant retained overdenture, with 20 out of a possible 60 patients switching over the study period. The authors concluded that both short and long term denture satisfaction appeared most favourable in the IRO group when compared with the PPS and CD groups.	Is it possible in the given exemplar that the ethical inbuilt study design that allowed patients from the other treatment options to switch to the implant retained overdenture increased the satisfaction rates within this group?

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Issues are raised regarding the transferability of methods across diverse groups of devices, populations, settings and cultures ($).	Methods such as case studies, interviews, photo documentation and observation may demonstrate transferability. For example, they were used to obtain opinions of potential wheeled mobility device users, Gujarati women aged between 13 and 28 with physical disabilities whose level of formal education varied, at an early stage in the design process to ensure the development of technology which would meet their functional needs (#1643).
	The population sampled can have a profound effect on the efficacy of a medical device. Issues arise as to whether functional outcome measures that are commonly used in medical device evaluation preclude assessment with less functionally achieving groups ($). For example, if the performance of ascending and descending slopes and stairs is used as an outcome measure are individuals that cannot meet these criteria are excluded from the study?	A focus on functional achievement may exclude the more needy populations, arguably with the greatest requirements for medical device use.
	Contextual issues regarding the methods implemented in research design. Methodologies in device assessment need careful selection regarding the context of their use. For example, expert panels are frequently used in the early stages of medical device development. Such by-proxy data collection can raise issues regarding the selection of the experts, the quality of the information they provide, and the use of the information that is provided ($).	Methodologies are required to be selected to be appropriate to the medical device under evaluation, the context and populations of the study.
	Appropriateness of outcome measures for the setting and country of the study. Issues arise regarding the appropriateness of outcome measures for the setting and country of the study. For example, visual acuity may be appropriately used as the sole outcome measure following intraocular lens implantation in Nepal (#539) whereas in the developed world more complex outcome measures may be utilised within this context such as best corrected Snellen distance acuity and Miller-Nadler glare testing (#1126).	Outcome measures require defining to be appropriate to the country, cultures and population of the study.
	Use of statistics to produce a model for evaluating new coronary artery stents. Evaluation of coronary artery balloon expandable stents, where multiple stents were evaluated, all of which were made of the same material, stainless steel 316L, with the assumption that there was "…*no effect of stent within trial*..." #1418. **Issues are raised due to the difficulty of assessing some clinical outcomes objectively without the use of invasive procedures**. For example, the outcome of re-narrowing post coronary artery stenting may arguably only be assessed with precision via angiogram (#1418).	New technologies are needed to prevent the necessity for using invasive procedures as a method of assessing clinical outcomes. Objective measurement of device outcomes may require invasive procedures, but issues can be raised in relation to the ethics of performing additional procedures particularly those that are invasive. Development work proposing alternative outcome measures such as sensitive imaging are required to prevent additional invasive interventions.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Ethical issues arise in relation to the methods utilised in studies, particularly where western trained clinicians have performed procedures and interventions abroad. #1185 – In a study examining the results of extracapsular cataract extraction with posterior chamber intraocular lens implantation in an outpatient clinic in Ghana, performed by 5 US trained clinicians, the authors state that "…*preoperative refractions could not be performed because of the dense cataracts, and biometry was not available therefore intraocular lenses were randomly selected*…"	Questions can be raised where western trained clinicians travel to other countries to perform procedures and device implants. The recipients may receive treatment that they may not have otherwise received but the potential lack of resources may profoundly affect both the study and device outcomes. This issue relates to global harmonisation of procedures and standards (Healthcare Industries Task Force, World Health Organisation, Global Harmonisation Task Force and the European Union's New Approach Directives).
	Possible effects of ethical and governance procedures on research. It is to be questioned as to whether ethical approval and research governance procedures are influencing methodological issues. For example, in a study assessing seating and mobility devices for children with physical disabilities in the context of a seating clinic, parents and caregivers were used as proxies for children even those up to the age of 17 (#1912).	Arguably, current ethical approval and research governance procedures in the UK in particular are deterring well-designed studies from being performed because of red-tape issues delaying research processes. In addition, ethical committees may hold particular views regarding the efficacy and utility of certain methods and approaches, at times influencing study designs.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	To what extent is a measure of satisfaction a measure of device performance? #52 - In a study assessing patients' (n=336) satisfaction with the process of total hip arthroplasty older individuals and those who did not live alone tended to be more satisfied. #1391 – In a study evaluating cementless total hip arthroplasty with an anatomically designed femoral stem (n=103) 96% of the patients were either very satisfied or satisfied with their surgery. #1202 – In a study of assistive device performance professional scientists and engineers with disabilities (n=595) were sampled using a postal questionnaire. The findings displayed general user satisfaction with devices, and also variations across social settings and disability types. In addition, 32% said devices were often restricting and 32% said they were often inconvenient. #1474 – In a study examining the experiences of women (n=360) receiving bilateral breast augmentation very high levels of satisfaction were found in 90% of the sample, even where significant capsular contraction occurred 71% of those women remained satisfied with the outcomes. **Problematic issues arise regarding the assessment of satisfaction with regard to the process of service or care delivery as opposed to device performance and vice versa.** For example, studies may question participants regarding "what is the overall level of satisfaction with your device?" and "what is your overall satisfaction of service delivery as a whole?" (#541). **Difficulties with measuring device satisfaction using different products with similar end-points.** For example, a single rod implant will not be a fair comparator with a contraceptive pill. #1388 – Respondents in a contraceptive implant study (n=75) compared the implant favourably, "better" or "the same", with their experiences of other methods of contraception, despite the fact that only 17% of the sample experienced no side effects. Bleeding irregularities were experienced by 41% followed by weight gain, moods and headaches. 19% had their implant removed during the study period mainly for bleeding problems, and the wish for pregnancy was not stated as a reason for removal.	These exemplar studies raise a number of issues in relation to the use of satisfaction as an outcome measure. Where the device is an implantable and part of a surgical intervention end-user satisfaction may only be measurable on the parameters of the process (#52, #1391). Other studies have measured outcomes in relation to surgical implantation on functional measures of for example mobility and pain reduction (#52, #875, #1391). That said in the particular cosmetic surgery study the obvious signs of device failure did not correlate with outcome satisfaction (#1474). In the situation of assistive device performance it appears possible to design questions related to satisfaction with the device as opposed to more global intervention satisfaction measures. In practice it can be problematic for individuals to distinguish satisfaction levels related specifically to the performance of their device from their overall satisfaction levels with the care and services they have received, thus raising issues of validity related to such measures. Postal questionnaire relying on retrospective recall of one contraceptive implant compared with other contraceptive methods previously used. This type of post market surveillance relies heavily on memory and lacks accuracy of measurement.
	To what extent do psychological outcome measures inform device performance? Issues regarding what psychologically orientated outcome measures can inform regarding device performance. #60 - In a study seeking to establish whether dissatisfaction with the artificial limb and or body image relate to achieved mobility following lower limb amputation in established limb wearers (n=107), body image disruption, anxiety and depression were measured. The authors concluded that body image disruption, anxiety and depression were not common in established limb wearers.	Psychological issues may not be related to device performance and additional issues may be raised regarding the measurement sensitivity of these outcomes and whether individuals find such measures inappropriate or intrusive.

Thematic Framework Category: **The Methods**	***Issues Raised***	***Consequences and Conclusions***
	Issues arise where levels of dependence or need for assistance are taken as indirect assessments of medical device need or usage. #439 – In a study reporting the development of the Measure of Control using Electronic Aids to Daily Living [MCEADL], a tool that measures the functional changes specifically related to the use of electronic aids to daily living devices, it was found that the level of spinal cord injury was in fact not reflective of the use of electronic aids to daily living.	Specificity and validity of measures of device need or usage. The exemplar provided challenges the assumption that higher levels of functional dependence or requirements for assistance relate to higher levels of device usage.
	Issues arise regarding the plethora of influencing factors over the ability to perform activities of daily living. #697 - In a study that collected empirical data to support the contention that the Individually Prioritised Problem Assessment [IPPA] is a valid measure of the change caused by assistive technology service delivery as perceived by the service delivery client/end-user, the assumption made was that the difference between the total IPPA score before and after provision of assistive technology represents the effectiveness, thus indicating the degree to which the perceived inconvenience with respect to problems diminished.	Contextual variables. Numerous factors, not only the effectiveness of assistive devices for example, influence the ability to perform functional activities, thus the assumption made in the given exemplar may be a simplistic representation.
	The potential influences of response rates and attrition rate. #1163 – In a study following patients for up to 12 months after total hip arthroplasty, the initial patient population was 98, by 6 months this had fallen to 62 and 42 patients remained at 12 months. #231 - In a study evaluating total hip arthroplasty the authors concluded that care must be taken in interpreting results of intervention studies where the response rate is less than 100%, stating that patients least pleased with their results may also be the least likely to respond to requests to complete questionnaires, with an additional element of acquiescence bias also possible, where patients grateful for any help that they get are reluctant to declare poor outcomes.	Both response rates and sample attrition raise questions regarding potential non-response bias. It is possible that those individuals who do not respond are indicative of those who are frustrated by their treatment or device outcomes.

PART A APPENDIX E: THE EXEMPLARY CASES – MODEL COMPONENTS

Nochajski S M, Tomita M R & Mann W C (1996) The use and satisfaction with assistive devices by older persons with cognitive impairments: a pilot intervention study Topics in Geriatric Rehabilitation 12(2): 40-53 (#320)

Model Components: Extensive data collection from a defined population to generate a comprehensive dataset enabling data mining regarding particular device related issues; and intervention with individualised assessment, training and follow up.

Users: Individuals with cognitive impairments

User Issues:
Individuals with cognitive impairments can experience a decline in physical and cognitive functioning. Cognitive impairment can lead to functional decline due to loss of ability in performing activities of daily living.
Individuals with cognitive impairments may lack the ability to make appropriate judgements and decisions about safe and unsafe situations.
Care providers need to ensure safe environments for those with cognitive impairments. This includes the use of assistive devices and home modifications that enable the users to maintain their daily living skills.

How it works:
A pilot intervention study was conducted with individuals with cognitive impairments receiving a comprehensive assessment, individualised interventions, training and follow up over a 6 month period.
The Consumer Assessment Study (CAS) is a longitudinal study designed to determine the needs of older persons for assistive devices and environmental interventions. One of the purposes of CAS was to collect and analyse data, over a 5 year period. The CAS data was from the Rehabilitation and Research Center on Aging at Buffalo and from referrals from the Alzheimer's Disease Assistance Center of Western New York.

Application: 20 participants meeting the study criteria (of a score of between 10 and 23 on the Mini Mental Status Exam) were randomly selected from the CAS sample pool.
Data were collected by an occupational therapist who assessed participants and their care providers in their homes. The purpose of the assessment was to gather information about the use and satisfaction with assistive devices and the problems in daily living experienced by the participant and their care provider.
The average length of time of the assessments was 2 hours 29 minutes. The tools used were:
Mini Mental Status Exam (refer to Glossary of Tools).
Functional Independence Measure (refer to Glossary of Tools).
Multidimensional Functional Assessment of Older Adults (refer to Glossary of Tools).
Care Provider Burden Scale, Environment Survey (refer to Glossary of Tools).
Two instruments developed for this study: Activity Performance Worksheet (used to summarise the types and probable causes of problems experienced by the participant and care provider in daily activities and routines) and the Assistive Device User Survey (based on the assistive device survey in the Consumer Assessment Study, used to measure the participants' and care providers' level of satisfaction with the assistive devices they used and the reasons for their satisfaction or dissatisfaction, devices were rated on a 5 point Likert scale for satisfaction, effectiveness, ease of use, physical discomfort, compatibility with other devices, durability and maintenance).
Based on assessment results and interviews with the participant and care provider, assistive devices and environmental interventions were provided or existing assistive devices were adapted to meet individual, specific needs. The participants received individualised specific training on the use of the devices by an occupational therapist. Support was provided by telephone follow up at 2 week, 4 week, 2 month, 4 month and 6 month intervals.
Findings included:
Participants initially used a range of 0-18 devices, with an average of 5.35 devices per person. The majority of devices were used to facilitate performance of tasks that the participants had difficulty completing due to physical limitations (74%). Participants also used devices to compensate for cognitive impairments (22%).
Although individuals and their carers used more physical devices rather than cognitive devices, there was greater satisfaction with cognitive devices.
User satisfaction with physical devices appeared to increase with training and support. Many of the stated reasons for dissatisfaction with physical devices were related to improper use. Participants did not know how to use the device correctly or the device was installed incorrectly.
The overall dissatisfaction with cognitive devices appears to be related to the loss of cognitive capabilities of the participants rather than a function of training, support or the devices per se.
The authors state that early intervention is the key to acceptance and satisfaction with devices and home modifications by persons with cognitive impairments and their care providers; and that coping with functional decline with the use of assistive devices not only helps maintain the individual's functional capabilities but also the benefits of the intervention outweigh the costs.

Burkitt J, Torrens G E, Kay G H, Sandbach D & Sutherland I A (1995) The development of the Autosip: a hygienic, self-operated, drinking device for people with minimal sucking ability and/or minimal arm strength Journal of Rehabilitation Science 8(4): 115-8 (#326)

Model Components: End-user focused involvement in product development

Users: Individuals with Motor Neurone Disease (MND) and their carers

User Issues:
Difficulty with minimal hand or arm movement in carrying out simple daily living activities, thus requiring the assistance of another person. This and minimal sucking ability for drinking was highlighted as a particular problem which required frequent carer intervention/assistance for these disabled individuals to have a drink.

Device Design:
A hands-free pumping device controlled by means of a single switch, which acts as a liquid feeding device (Easy to use).
The tube for drinking can be refitted and the material used can be repeatedly sterilised or boiled to ensure hygiene (Easy to clean).
The flexible tube-holder is long enough to have the liquid container at a safe enough distance from the user. An extra long tube is also provided. This is useful especially for bedside use (Portable).
A dial allows the pre-selection of volume of liquid to be delivered, which is extremely important to reduce the risk of aspiration pneumonia (Safety).
Caters for MND end users with varying abilities by using:
A variety of switches, examples include special cheek, chin, activated switches, as well as commercial switches that involve hand and foot activation.
A selection of mouthpieces, examples include silicone rubber tubing and a special narrow mouthpiece that stops any liquid dribbling out when the pump is not running.
The Autosip drinking and liquid feeding device was manufactured.

User Involvement:
Firstly, 15 MND end users and their carers were visited in their homes to establish a range of devices that could enable them to live more independent lives, with over 30 items being chosen. Secondly, 2000 questionnaires were sent out to Motor Neurone Disease Association Members, in order to prioritise the chosen items. One of the prioritised needs required the development of a piece of equipment for the ingestion and swallowing of liquids, with the end users highlighting specific concerns in the questionnaire.
A design specification of the device was drawn up in consultation with end users and appropriate care professionals.
A Prototype was trialled by MND volunteers and their feedback was incorporated in the new design e.g. wider selection of switches and mouthpieces.

Zhang J, Johnson T R, Patel V L, Paige D L & Kubose T (2003) Using usability heuristics to evaluate patient safety of medical devices Journal of Biomedical Informatics 36(1-2): 23-30 (#470)

Model Components: Novel application of theory to medical device evaluation

Users: Stakeholders concerned with the safety of medical devices.

Concept: Medical device related errors are a common source of patient injury and death. Many of the errors are attributable to poor product design especially with user interfaces. Thus, the identification of usability problems can highlight potential problems.
This paper identifies heuristic evaluation, as a possible method of eliciting usability problems.
A modified version of the heuristic method addresses three main issues:
It is used to identify usability problems that are likely to cause medical errors.
The nature of the method may be useful in comparing medical devices.
The method may be a useful tool for manufacturers to improve current or future device designs with respect to patient safety features.

How it works: The Nielsen-Schneiderman Heuristics (based on the work by Nielsen 1994, Schneiderman 1998 and the authors own considerations) consists of 14 heuristics (each judged by a severity rating scale), which are applied typically by 3-5 usability experts to evaluate the user interface of a product, with each evaluator generating a separate list of heuristic violations.
The authors state that 2-3 hours of training combined with clear examples and a practice evaluation with feedback is often sufficient for using the technique.
Firstly, each evaluator identifies in a written tabular format:
'Place of occurrence' - where the problem occurs e.g. Opening screen.
'Usability problem description' – e.g. Displayed for only 15 seconds.
'Heuristics violated' – e.g. Visibility.
'Mean severity rating.'
Once the evaluators have identified potential usability problems, the separate lists are compiled into one master list by eliminating duplicates. Another method is to have the evaluators sequentially evaluate the interface, with each passing the list on to the next. The master list is then given back to each evaluator who independently assesses the severity of each violation. Finally, ratings from the individual evaluators are averaged.

Application: The evaluators 'walked through' the interface of both infusion pumps to identify elements that violate usability heuristics.
They identified usability problems in various areas/sections of the pumps, and identified one or more heuristic violations for each usability problem. A list of usability problems was generated, heuristic violations were ascertained for each problem, and each evaluator independently assessed each problem for severity.
The authors concluded that as a usability technique, heuristic evaluation could be used to identify the great proportion of major usability problems with a product in a timely manner at reasonable cost.

Limitations of Heuristic Evaluation: It does not indicate what is right with the system i.e. the elements of the interface that correctly follow usability guidelines.
It does not reveal major missing functionality, especially when compared to other engineering techniques, which can identify the most appropriate functionality.
Evaluators need some understanding of the heuristics method, as well as minimal training in human factors. Their level of domain knowledge will impact on the problems identified.
Heuristic evaluation focuses on a single device or application at a time and may not identify problems that are reflective of the user's environment e.g. when an infusion pump is used in a clinical setting, light, noise and other devices in the room may affect the usability of the device.

References:
Nielsen J (1994) Usability Engineering AP Professional, Boston.
Schneiderman B (1998) Designing the user interface (3rd Edition) MA: Addison-Wesley, Reading.

Hefzy M S, Nemunaitis G & Hess M (1996) Design and development of a pressure relief seating apparatus for individuals with quadriplegia Assistive Technology 8(1): 14-22 (#994)

Model Components: Usability tests to develop adaptable and affordable devices

Users: Individuals with Quadriplegia

User Issues:
Individuals with Spinal Cord Injury above C7 (Quadriplegia) lack the ability to produce elbow extension, finger flexion, finger extension, and wrist flexion as their triceps, forearm and hand muscles are non-functional due to their injury. Thus, when seated, they are unable to press down to shift their weight to relieve pressure on their ischial tuberosities. This can cause pressure ulcers to develop.
This problem can be prevented with the use of the electric power recliner wheelchair. Unfortunately, not all individuals with quadriplegia will be able to afford these devices.

Device Design:
The designers therefore sort to design and build an affordable apparatus that was adaptable to wheelchairs which utilises mechanical rather than electrical power, and which could be independently controlled by the limited hand musculature of an individual with quadriplegia.
Four methods were considered to allow the individual to relieve pressure on the ischial tuberosities. These include:
Elevating one side of the buttocks at a time.
Reclining the entire body by either reclining the back of the wheelchair or reclining the whole chair.
Lifting the entire body completely out of the seat just enough to raise the buttocks of the seat.
Finally, returning the individual to the seated position after he has levered himself forward out of the seat.
Different mechanical systems were considered in order to adapt each of these methods e.g. pneumatic, pulley, and linkage systems. Each method was judged on 10 specific criteria using the Pugh method (Lumsdaine & Lumsdaine 1993). The Pugh method was used primarily to select the most practical design concept without building and testing the other concepts. It involves an iterative process. During each repetition, the best concepts are carried forward utilised as datum for the next iteration. The evaluation process ends when it is no longer possible to improve the best concept.
10 criteria were used to judge each idea:
Does it relieve the pressure? A design concept was considered to relieve the pressure if it could shift the weight of the individual with quadriplegia, not necessarily lifting the ischial tuberosities completely off the seat but enough to allow pressure to be relived.
Does it provide the person with quadriplegia with exercise? Pneumatic systems were considered better at providing exercise because they could be set up to provide as many repetitions as wanted.
Is it safe? Designs were considered unsafe if the user had to go through a large range of motion or if they operated using mechanisms that could pinch or cut the user.
Is it affordable? Is it made from standard parts? Gas springs for example are more expensive than pneumatics or a pulley system.
Does it interfere with other wheelchair functions? Each design concept was evaluated as to whether it would be too large and interfere with the range of motion of the user's arm, or whether it was located in an inappropriate place preventing the chair arm from being removed.
Can the person with quadriplegia use it independently?
Can it be instrumented onto the standard manual wheelchair? The concepts were evaluated as to whether they could be attached to standard wheelchairs, based on the size of the basic components.
Is it too heavy/bulky/large?
Is it simple to install and remove from the wheelchair? This was measured by the number of pieces necessary for each design concept and the nature of the mechanism involved.
Does the system need to be maintained frequently or is it reliable?
This process culminated when the best solution was found. An inflatable air cushion using a pneumatic system was selected. After completing the first generation prototype several possible improvements became evident and a second generation prototype was designed. For example the apparatus could only initially be used on wheelchairs that utilised the same armrests (the same diameter of tubing and same space), so the pneumatic system was then placed at the base of the wheelchair and attached with cinching straps.
The Pneumatic system utilised two inflatable air bladders. One cushion was placed under each buttock and inflated separately to tilt the user from one side to another. The inflated cushion elevated one side of the buttock, which relieves the pressure on the other side. The power required to operate the system is generated using repetitions of elbow flexion.
According to the authors, the cost of a typical manual wheelchair is approximately $1000. The cost of the universal base including the pneumatic system is approximately $600. Thus the total cost of $1600 is less expensive than an electric wheelchair with a powered recliner or tilt system, and manual tilt chairs.

User Involvement: The system was evaluated by a 35-year-old male with C6 quadriplegia, who used a manual wheelchair and had frequent pressure ulcer development on his buttocks. He relied on others to tilt his chair to help him relieve the weight on his buttocks. When others were not around, he levered his body forward to try to shift his weight off his ischial tuberosities. He was interested in any adaptations that would allow him to shift his weight without intrusion on independence, function, cosmesis or cost.
During the evaluation of the system the user was able to perform 20 repetitions of elbow to pump each cylinder until 10psi was reached in the storage cylinder, which took 5 minutes. He was then able to flex his elbow to fill the cushion under his right ischial tuberosity to 2 inches and after one minute to depress the switch and then elevate the right side. This procedure was repeated four times in a 1-hour trial. Following each trial, the skin of his buttocks was examined and no breakdown was noted. A pressure monitor and a 2.5cm sensor were placed under each ischial tuberosity, one at a time, to monitor the interface pressure during the trials.
The subject demonstrated independent pressure relief without the assistance of another person while he was

sitting in an upright position. He was also able to transfer on and off his chair without any problems. The arm-rest with an air pump attached to it was simply swung away for easy side-to-side transfer; however the latch to release the arm rest had to be released by another person.
Other benefits noted from the evaluation included:
The individual was able to exercise in the chair in an upright seated position without assistance. In order to relieve the pressure every 15 minutes, the user adapted a regimen of 20 repetitions per arm to provide the required pressure to inflate the cushions.
The system was found to be safe because the user did not lose his balance during the tests. Also, the pivot arm did not pinch or cut the user.
The system did not interfere with other wheelchair functions.
The system can be instrumented on different standard manual wheelchairs.
The weight of the system is about 10 lbs, and individuals who can lift 10-15 lbs can operate the system. It is compact and takes almost the same space as normal armrests. The pneumatic cylinders are tucked below the armrests, and the storage cylinder is located below the seat. The pivot takes up a small extra space compared to the standard manual wheelchair.
The system is simple to remove and install from the wheelchair. Only four velcro cinching straps are used to attach the system to the seat rails.
It requires minimal maintenance, especially if industrial-grade pneumatic cylinders are used. It is recommended that the system be checked once a year for wear.

Reference:
Lumsdaine E & Lumsdaine M (1993) Creative Problem Solving (2nd Edition) Mcgraw-Hill, New York.

Sethi P K (1982) Appropriate technology for rehabilitation aids in developing countries Annals of the National Academy of Medical Sciences (India) 18(2): 34-42 (#1305)

Model Components: Extensive end-user population through service delivery access; appropriate product development for cultural context; value of extensive end-user expertise; and value of artisan skill

Users: Individuals with amputations requiring assistive technology devices in North India

User Issues:
The author established an orthopaedics centre in Jaipur in the late 1950s. At the time there was a lack of rehabilitation facilities to provide aids such as artificial limbs or callipers for polio children. The added difficulty was that at the time rehabilitation facilities were thousands of miles away, resulting in only the affluent being able to travel there.
He noted that some of the first service users, amputees, were using crutches and had discarded the artificial limbs. The reasons for abandoning the devices included:
In the West (where the original device designs were conceived) it is customary to wear closed shoes due to the climate, however the Indian climate is warm and people wear well-ventilated footwear or walk barefoot.
In the West tables and chairs are used for sitting and working. In India the working level is predominantly the floor where people squat or sit cross-legged to perform activities of daily living.
In the West paved roads are available for walking. In India farmers may not afford to wear shoes when tilling fields, and they are usually walking in mud and water. In addition, shoes are not worn inside homes or in places of worship.
The western design of artificial limb has a foot-piece that need not look like a human foot because it is inside a shoe, which in addition protects the delicate material. The limb cannot therefore be used without a shoe. There is no provision in this design to permit squatting or sitting cross-legged on the floor. In trying to squat with an artificial limb unbearable pressure is put on the stump.

Device Design:
Thus, the design criteria needed to take into account the context of the users. This included that the limb should permit barefoot walking, have a natural looking foot-piece that was made from a durable and waterproof material, and should allow squatting and cross-legged sitting, as well as being adaptable to walking over rugged terrain.
Vulcanised rubber was used to reproduce the shape of a human foot because "…*every town in our country has re-treading shops where worn out tyres are reconditioned; rubber is easily available and the technology of vulcanisation is known to our people*…" (p35). The rubber was packed into a specially designed 'die' and vulcanised in a simple steam sterilizer used in the hospital, resulting in a foot-piece resembling a normal foot. Traditional village craftsmen (artisans), proved innovative, producing the die using their typical sand casting methods in which the foot-pieces were moulded.
This design however proved heavy. The author then broke with conventional (western) designs to provide a large sponge rubber universal joint located in the hind-foot region. A proximal wooden block was used for the carriage bolt with which the foot-piece is secured and a distal wooden block was used to provide rigidity for the take-off stage of the gait cycle. This provided the mobility the designers were striving for. The design was then modified by replacing the rigid forefoot block by a supple block, adding to the adaptability to uneven surfaces.
The initial fitting of the prosthesis takes less than 45 minutes. No plaster moulds are needed. The artisan uses a tape measure and draws a pattern on an aluminium sheet (cheaper than polyesters), cuts it with hand shears, beats it on an anvil to make it into a tube, welds the seam, and then with hand tools shapes the limb.
Formally educated prosthetists were compared to the traditional uneducated craftsmen with two separate workshops being set up in the rehabilitation department. Their performances were monitored for over ten years and a study conducted revealed that the artisans output was more than twice that of the prosthetists and the investments were less than half. The skills displayed by the artisans were superior and the patients more satisfied.

User Involvement: The individual requiring the prosthesis is able to closely work with the artisan guiding the artisan in the fit of the prosthesis. 5000 amputee subjects have undergone rigorous monitoring in field trials.
Findings included: The appearance of the limb was found to be acceptable and it was difficult for trained observers to spot the artificial limb at a casual glance.
Squatting was easy to perform as was sitting in a cross-legged fashion.
Farmers could do a full day's work, walking on uneven surfaces, without the skin over their amputation stump becoming bruised or painful. A double-blind study comparing the western foot and the Jaipur foot showed that amputees were more comfortable while walking on uneven terrain with the Jaipur design and at the end of a day's work there was much more bruising and pain using the western design.
The limb is waterproof, allowing our farmer to work in their irrigation channels without fear of spoiling it.
Heavy manual work can be done at ease. Amputees work as rickshaw pullers in Jaipur and as farmers, on the traditional open wells, lifting the heavy water containers and emptying them to water their fields.
The amputees can climb trees, with the foot-piece gripping and adapting itself to the convex contours of a tree trunk.
During testing rubberised tyre-cord was added to reinforce the foot because walking and field trials caused a number of broken foot-pieces. The breaking load rose to 6 tons and the durability of the foot-piece is up to 5 years in a rural environment (Jaipur design).
Other advantages of the Jaipur design: the "…*rural amputees now no longer are required to migrate to urban areas, seeking and learning sedentary occupations*…" (p37). The point is made that complex, sophisticated and expensive technology does not necessarily imply that 'high science' content is involved. While attempting to work out alternative designs the author argues that his perceptions and value systems were challenged with regard to technological choices, demystification of professional knowledge and peoples' participation in a health delivery system, so as to reach the un-reached. He questions whether with 80% of the population living in remote villages and a third of who live below the poverty line can a capital intensive technology imported from abroad be justified? As a result appropriate technologies are defined as meeting the needs of the neediest, generating endogenous self-reliance, being environmentally sound and rooted in the culture of the people.

Barrett S F, Laurin K M & Bloom J K (2003) University of Wyoming, College of Engineering, undergraduate design projects to aid Wyoming persons with disabilities Biomedical Sciences Instrumentation 39: 597-602 (#1389)

Model Components: Device technology improvement through university related educational programmes

Users: Individuals with disabilities or those receiving medical care requiring medical device intervention

Concept:
The University of Wyoming College of Engineering curriculum is designed to prepare students for engineering practice, culminating with the students completing a meaningful design project based on the knowledge and skills acquired from earlier coursework. The College has approximately 130-180 graduates per year. Due to Wyoming's geographical scale and small population, access to assistive device technologies and services are limited. There are over 50,000 individuals with diverse disabilities and needs in the state of Wyoming. The program is thus a link between the Universities's engineering students and individuals with assistive technology needs. Students create and provide prototypes, custom-made assistive devices to improve the daily lives of individuals with disabilities, and the program educates new design engineers on the special needs of community members with disabilities.

How it works:
To accomplish program objectives the College of Engineering joined with Wyoming Institute for Disabilities [WIND], Wyoming's Assistive technology program, Wyoming New Options in Technology [WYNOT] and its Sports an Outdoor Assistive Recreation [SOAR] program, as well as with the university's Special Education Department.
The WYNOT project director serves as the co-ordinator with the community to identify specific assistive technology needs. WYNOT also provides training to the engineering students regarding assistive devices and services. In addition, the project assists students with research activities through their AT Information and Referral program.
Project proposals may be initiated by the individual with a disability, his/her family members, caregivers, teachers, or any of the service agencies in the state of Wyoming.
A short project application is used to identify the desired assistive device and the special needs of the individual. A project director from one of the organisations and a named Principal Investigator meet on a regular basis to evaluate the suitability of the submitted projects and if necessary interviews are conducted.
One student or a small group of students select a project from a specified list which needs to be completed within a year. Each project is aligned to a discipline-specific faculty mentor. Since these projects involve the use of human subjects, students are required to complete an Institutional Review Board (IRB) application prior to initiating a specific project. These studies are completed and submitted to the IRB per federal and university guidelines. "....*Furthermore, projects are delivered to the recipients only after extensive testing*…" (p601)
All the engineering design students are provided with disability awareness training. This is to sensitise the students to the needs and challenges of individuals with disabilities.
The program provides the following potential benefits:
Prototypes, one-of-a-kind assistive devices for persons with disabilities.
Meaningful, challenging, multi-disciplinary senior design projects.
Awareness and sensitivity training for the next generation of Wyoming engineers towards the needs of others.
Projects that serve as a springboard to graduate work in biomedical engineering.
Opportunities for participation in biomedical related symposia.

Application:
During Autumn 2002 semester five projects were successfully completed including:
Star Writer learning disability demonstrator.
"Life is a Switch"- adapting off-the-shelf toys for children with learning disabilities.
Non-invasive Infant Respirator and Temperature Monitor.
Automatic Casting Device for Fishing.
Specialized Tricycle for Osteogenesis Imperfecta Type 111.

Malassigne P, Nelson A L, Cors M W, Jensen R P, Amato M & Schnurr E S (2002) Iterative design and evaluation of new prone carts for individuals with SCDs: a technical note Journal of Rehabilitation Research and Development 39(1): 127-39 (#1482)

Model Components: End-user focused involvement in product development

Users: Individuals with Spinal Cord Dysfunction (SCD) and their carers

User Issues:
Individuals who use prone carts report that prolonged use results in chronic neck, shoulder and back pain.
Existing prone carts problems identified by users include:
Interferes with socialisation.
Causes discomfort, pain and fatigue.
Presents safety risks.
Limits independence in activities of daily living.
Motorised prone carts are needed for individuals who are not able to self-propel a manual cart because of limited arm-hand function, fatigue, or other medical conditions.

Device Design:
A prone cart is a flat horizontal stretcher, propelled by a patient while lying in a prone position. Individuals with SCD who cannot use a wheelchair use prone carts for mobility.
Existing prone carts were evaluated, to reveal functional and performance criteria on which to base the new prone cart designs, through a pilot study, by a team of clinicians and designers.
The development of the prone carts followed an iterative process of design, where design suggestions, observations, and responses received in the clinical evaluation from patients and caregivers were incorporated into the next prototype design until the new design was completed and met the established performance goals and design criteria.
This iterative process allowed:
The design of a new manual prone cart.
The design of a new motorised prone cart.
Collaboration with manufacturers to market and commercialise the new prone carts.
Short and long versions of manual and motorised prone carts were produced to accommodate different body sizes. The motorised prone cart was tested at the Pittsburgh VA (Department of Veteran Affairs) Human Engineering Research Laboratory for compliance with applicable ISO electric wheelchair standards, since there are no specific standards for prone carts.
The design team first collaborated with Ortho-Kinetics Inc, a durable medical equipment manufacturer, for the frame fabrication of all new prone cart prototypes, which resulted in the manufacture of 6 prone carts. Four were purchased by the Milwaukee Veterans Affairs Medical Center (VAMC), the Wisconsin Paralysed Veterans of America, and the Medical College of Wisconsin, and two were used for the motorised prone carts [whose body support is identical to the manual version].

User Involvement:
Concept: "…*The original impetus for designing a new prone cart was given by Mr Emil (Sammy) Schnurr, a Milwaukee VAMC patient with SCD and a double above- knee amputee who had 'lived' on a prone cart for many years. Mr Schnurr formulated the idea for a cart for which the body support would be angled up as opposed to being horizontal. The angled up prone cart would help him look up without developing neck and shoulder pain, thus improving his quality of life and other's who use a prone cart. The first conceptual design for a new prone cart, a 1992 student project at the Milwaukee Institute of Art and Design, received the prestigious 'Industrial Design Excellence Award' from the Industrial Designers Society of America*…" (p128)
Users were involved in the evaluation of the existing prone carts. The first cart the Sammy LS which Mr Schnurr has used extensively since 1993, and two other Sammy LSs, were used for several months at the Milwaukee and Tampa VAMC.
Designing and testing of the prone cart prototypes. Based on user feedback evaluation results of the Sammy LS, another prototype named the SCI-PC 22 was designed and fabricated in 1994. Re-design then took place which incorporated the evaluation findings of the users in the design of the Tubular Manual Prone Cart and the motorised version, producing short and long versions.
Four Tabular Manual Prone Carts were continuously used for 2 years and evaluated at the Milwaukee and Tampa VAMCs by 12 patients. One Motorised Prone Cart was used for one year and evaluated by 13 patients and 26 caregivers at the Spinal Cord Injury Center of the Tampa VAMC.
Patients and carers were provided with questionnaires that addressed issues of their interactions with motorised prone cart. The questions related to the user's body positioning on the cart, the physical characteristics of the cart, the cart's manoeuvrability and performance, and the user's access from the cart. Informal discussions as well as interviews with patients and caregivers also took place. In addition, photography was used to provide valuable information to the designers.
During the clinical evaluation of the motorised prone cart, caregivers made suggestions for another design that would include a body support that elevated patients vertically. This could lead to the improvement of several physiological parameters and improve bladder function, decrease calcium in the urine, increase bone density, decrease leg spasticity, decrease number of pressure ulcers, and improve bowel function. This stand-up prone cart has been designed by the Veterans Affairs Rehabilitation and Development Service.

Malassigne P, Nelson A L, Cors M W & Amerson T L (2000) Design of the advanced commode-shower chair for spinal cord-injured individuals Journal of Rehabilitation Research and Development 37(3): 373-82 (#1631)

Model Components: End-user focused involvement in product development

Users: Individuals with Spinal Cord Injury (SCI) and their carers

User Issues:
A common problem for individuals with SCI is bowel incontinence. While some are able to transfer to the toilet for bowel care others may need to use a commode-shower chair.
Most of the existing commode-shower chairs were designed for the elderly, and do not meet the needs of the younger SCI population managing a neurogenic bowel.
A previous survey by the authors (Nelson et al 1993; Malassigne et al 1993) of 147 veterans evaluated existing commode-shower chairs and numerous safety-related problems were highlighted:
66% felt unsafe self-propelling.
47% felt unsafe while transferring to an existing commode-shower chair
42% indicated brakes were unreliable.
24% reported development of pressure ulcers and cuts from the seats, due to inadequate padding and seat positioning for lengthy bowel care procedures.
35% indicated falling from commode-shower chairs. Of these patients 23% were hospitalised for injuries ranging from one month to four years.
Patients reported flaws in the chairs that negatively impacted on their quality of life, self-esteem, and physical well-being.
Inadequate carer access to the perianal area of the patient to perform bowel care procedures.
Wheel-related inability to properly position the chair directly over the toilet.

Device Design:
Evaluation of existing chairs was undertaken as part of a pilot study, involving the design and clinical use of the chair by patients and caregivers.
From this evaluation, functional and performance criteria were established in order to develop chair prototypes for clinical evaluation at the Milwaukee and Tampa VA (Department of Veteran Affairs) Medical Centers.
The safety and performance criteria were based on user input, data from pilot studies and International Standards Organisation (ISO) American National Standards Institute/Rehabilitation Engineering Society of North America (ANSI/RESNA) wheelchair standards.
An iterative process of prototype development, laboratory evaluation, and clinical evaluation was used to develop the new chair. The responses received from patients and caregivers were incorporated into the next prototype until the new chair design was complete.
The new chair features included: Lockable swing-away pivoting armrests and improved lever-activated brakes designed to facilitate safe transfers. An innovative foot-lift was invented to facilitate washing of feet. Larger hand rims were designed to aid in propulsion in wet environments. To prevent pressure ulcers, a chair frame and padding combination was designed to facilitate a seating position that optimally distributes body weight to prevent the development of pressure ulcers in the sacral and ischial areas. To address the common risk of heel ulcers, footrests, featuring edgeless, rounded heel cups, were designed. A new tubular chair frame, a new seat and smaller wheels were designed to enhance caregiver access and ensure proper chair positioning over the toilet.
Both a self-propelled chair and an assisted-care chair were designed and engineered. However, only the self-propelled chair prototypes were tested and clinically evaluated at the time of publication.
The authors first collaborated with Milwaukee-based Ortho-Kinetics [OKI] during the development stages of the advanced commode-shower chair. However, OKI decided not to commercialize this chair when it was completed. The chair was then presented to Invacare, Active Aid and Everest & Jennings, Everest & Jennings decided to manufacture and market the chair.

User Involvement: Safety and performance criteria for the chairs were established through evaluations done by the patients and their caregivers.
Patients and caregivers completed questionnaires addressing issues of their interaction with the new commode-shower chair. Primary Clinical Evaluation involved using one questionnaire for the patients and one questionnaire for the caregivers. The questions were related to the features of the chair relative to bowel care and showering, issues of seating, and transfer safety to and from the chair.
The prototypes underwent long term clinical evaluation at the Milwaukee and Tampa VA Medical Centers. Secondary Clinical Evaluation of the prototypes involved focus groups with patients and caregivers.

References:
Malassigne P M, Nelson A L Amerson T L, Binard J, Saltzstein R (1993) Design of a new bowel care chair for spinal cord injury: a pilot study Spinal Cord Injury Nurs 10(3): 84-90.
Nelson A L, Malassigne P M, Amerson T L, Binard J, Saltzstein R (1993) Descriptive study of bowel care practices and equipment in spinal cord injury Spinal Cord Injury Nurs 10(2): 65-67.

Mulholland S J, Packer T L, Laschinger S J, Lysack J T, Wyss U P & Balaram S (2000) Evaluating a new mobility device: feedback from women with disabilities in India Disability and Rehabilitation 22(3): 111-22 (#1643)

Model Components: Extended family and community member involvement in medical device development

Users: Women with bilateral lower extremity disabilities living in Gujarat, India

User Issues:
Women in India typically perform activities of daily living both inside and outside the house with common physical barriers such as slopes, mud, rocks and steps. Wheelchairs do not cope well in this type of terrain.
Most of the activities that these women need to perform are either on or close to the ground with the floor being used as the working surface. These activities include washing pots and clothes, and cooking.
The women in the study were unable to walk in a fully upright position, however they had functional upper extremity strength, range of motion and co-ordination, and they were able to sit independently of supports.

Device Design:
The design team comprised members from the technology group of the International Centre for the Advancement of Community Based Rehabilitation [ICACBR], Queens University Canada and the National Institute of Design [NID] India. The team included occupational therapists, physiotherapists, engineers, product designers and ergonomists from both countries.
The basis for this study was the need to develop appropriate technology that provides the optimal balance between the individual's needs, therapeutic and medical concerns e.g. body positioning and pressure relief, and technical and engineering constraints e.g. durability of materials versus weight and cost.
The first scale model, the GAD11, was designed and produced by an engineer in Canada. This was then used in a focus group with four of the participants being of Indian descent and offered insights into cultural and rehabilitation perspectives. This allowed for modifications to be made to the design including the placement of the driving wheels below the shoulders and changing the colour from bright to neutral or natural. The new design was the GAD12 which was then evaluated by the users.
Some of the women's preferences often opposed what would typically be recommended in a rehabilitation setting. For example, they preferred to sit cross legged rather than in the traditional up-right position, requiring a significantly wider sitting area and higher backrests compared to the sleek and narrow designs often recommended. The family dwellings comprised reasonably sized rooms and doorways. In this context a larger mobility device may be appropriate.
For a device to be appropriate it is essential that local materials and resources be used so that the device can be maintained and repaired within the users' community. For this reason the GAD12 was kept simple with respect to availability and accessibility to affordable parts and individuals with the skills to produce and/or repair it.

User Involvement:
Data from the women was collected in sessions lasting approximately 1.5 hours, during which the GAD12 was introduced, tested for a short period of time and then a feedback interview was conducted using the 'feedback interview tool'. Verbal instructions were given on how to turn the device on and off, transfer, propel forwards, backwards, and to turn. A 'hand-over-hand' teaching technique was used when necessary, whereby the primary investigator physically guided the participant's arms and body through the appropriate movements. The women tested the device in their homes for approximately 20 minutes before the interview.
The feedback interview tool was developed for the study based on available literature, information gathered during a discussion group in Canada, and results from the mobility needs assessment done in India (Mulholland et al 1998), input from engineers and designers in Canada and India, and clinical (occupational therapy) experience. The final feedback interview tool was peer-reviewed by a Canadian occupational therapist with experience in international development and appropriate assistive technology. A local university educated woman translated the interviews.
The resulting tool consisted of three sections:
Section One consisted of 31 closed-ended questions soliciting feedback specifically on aspects of the device design. The questions were predominantly closed-ended, with three questions asking the women to rate manoeuvrability, overall appearance and comfort, on a five point scale from very poor to very good.
The main purpose of Section Two was to determine the participant's perception of the usefulness and potential function of the GAD12. Each of the women were asked to pretend to 'go through the day from the time you get up until the time you go to bed to see where and what you think you would use the GAD12 for'. The investigator verbally guided the women through their activities of daily living and asked probing questions to clarify and provide detail when necessary.
Section Three photo-documented the woman sitting on the device in positions of comfort, propulsion, work (whereby various tasks were simulated) and whilst transporting objects.
Although the women were the primary focus of the study, their family, extended family, and community members participated in the interview in a spontaneous manner (in keeping with local customs). The authors expected this approach to capitalise on the experience of others e.g. those who are familiar with equipment maintenance or repair. It was also hoped to initiate wider interest in the project by nurturing support from the community for further field testing and to eliminate fears or suspicions by facilitating an open forum for sharing information.
The overall response for the GAD12 was positive and the feedback interview was successful in providing information to guide further development of the device. The small sample size and lack of consensus in some of the feedback indicates the need for further research and prototype testing.

Reference:
Mulholland S J, Packer T L, Laschinger S J, Olney S J, Panchal V (1998) The mobility needs of women with physical disabilities in India: a functional perspective Journal of Disability and Rehabilitation 20:168-178.

PART A APPENDIX F: GLOSSARY OF HEALTHCARE RELATED TOOLS

The following tools were encountered in the papers reviewed and are therefore defined with the original sources cited, in addition to the studies where they were used.

American Knee Society score (AKS) (Insall et al 1989) consists of two parts. The first part, the Knee Score's which considers pain, stability and range of motion as the main parameters, with deductions for flexion contractures, extension lag and malalignment. A maximum of 100 points will be obtained by a well-aligned knee with no pain, 125 degrees of motion and negligible anteroposterior or mediolateral instability. The second part, the Function Score, utilises walking distance and stair climbing as the main parameters, with deduction for the use of a walking aid. The maximum Function Score is 100, given to an individual who is able to walk an unlimited distance and can ascend and descend stairs normally. A patient categorisation system is included in the AKS to identify patients whose function may be undermined by factors other than the knee in question. The AKS is designed so that the Knee Score is independent of these factors, while the Function Score can decline with multiple joint arthrosis and generalised debility (used by Liow et al 2000, #220).

Arthritis Impact-Measurement Scales (Meenan et al 1980) are a validated self-administered health-status questionnaire designed for use by patients who have rheumatoid arthritis. It contains questions relating to pain, function, dexterity, and psychosocial status, but it is not specifically for evaluation of the hip (used by Johanson et al 1992, #1163).

Barthel Index (BI) (Mahoney & Barthel 1965) also known as Barthel's Activities of Daily Living Index measures the patient's performance in 10 activities of daily living (ADL). These items can be divided into groups. One is related to self-care (feeding, grooming, bathing, dressing, bowel and bladder care, and toilet use) and the other to mobility (ambulation, transfers, and stair climbing). The maximum score is 100, indicating that the patient is fully independent in physical functioning. However, the BI is limited by a pronounced ceiling effect, as it evaluates only basic ADL functions (used by Carod-Artal et al 2002, #642).

Bristol Score (Mackinnon et al 1988) is an assessment system using for assessing outcomes in patients post-knee arthroplasty. The clinical rating system is based on pain, movement, fixed flexion contracture or extension lag, maximum varus/valgus deformity, mobility, walking stairs, chair and giving way (used by Bach et al 2001, #117).

Canadian Occupational Performance Measure (COMP) (Law et al 1990 & 1997) is a standardised, client centred outcome measure that uses a semi-structured interview format with a structured scoring method to detect changes in self-perception of

occupational performance over time. Consumers are asked to prioritise (1=highest priority to 10=lowest priority) the importance of each reported task or activity into three categories: 1) self-care – personal care, functional mobility and community management; 2) productivity – paid/unpaid work, household management, and play/school; 3) leisure – quiet recreation, active recreation, and socialisation (used by Mills et al 2002, #1497).

Cantril's Life Satisfaction Ladder (Cantril 1965) provides an overall rating of life evaluation in which patients choose 1 rung of a 10 rung ladder (scored 1-10) to represent their evaluation of their life from "best possible" to "worst possible" (used by Salmon et al 2001, #725).

Care Provider Burden Scale (Zarit et al 1986) utilised as a measure of the time spent by the care provider in caring for the person and the perceived stress and burden related to providing care (used by Nochajski et al 1996, #320).

Center for Epidemiologic Studies Depression Scale (CESD) (Radloff & Locke 1986) utilised to measure depression. Individuals are asked to rate the frequency with which each of twenty events was experienced during the previous week (used by Mann et al 1995, #22).

Chalder et al Fatigue Scale (Chalder et al 1993) designed to detect and quantify symptoms of clinical fatigue. Individuals respond to questions about mental and physical fatigue on a 4 point Likert scale ranging from "better than usual" to "much worse than usual" which are summed to provide a single score (used by Salmon et al 2001, #725).

Consumer Assessments Assistive Technology Used Instrument (CAATU) (Mann et al 1994) provides a count of the number of devices and number of persons using specific categories of devices. Devices are grouped for persons with: 1) physical disabilities, 2) hearing impairments, 3) visual impairments, 4) tactile impairments and 5) cognitive impairments. Individuals are asked what devices they have in an open ended format. They are asked if they use the device and if they are satisfied with it. For any devices they do not use or are not satisfied with an open ended question seeks an explanation for non-use or dissatisfaction (used by Mann et al 1995, #22).

Environment Survey (Mann et al 1994) is utilised as a measure of the problems the person has within the home environment. Using open ended questions the interviewer asks the subject to describe problems experienced in the home environment. Following the interview the interviewer walks through the house and notes any problems that were not indicated by the individual (used by Nochajski et al 1996, #320).

EuroQol 5D (EQ-5D) (Brooks 1996) is a patient based generic questionnaire for assessing quality of life, identifying 243 possible health states. It is based on 5 questions about mobility, self-care, usual activity, pain/discomfort and anxiety/depression. There are 3 possible levels of response for each item. Each state carries a utility value, which is calculated using time trade-offs. Perfect health and death have utility values of one and

zero, respectively, and states worse than death (<0) are possible (used by Dawson et al 2001, #144; Tidermark et al 2003, #535)

Ferrans & Powers' Quality of Life Index, Cardiac III, parts I & II (QLI) (Ferrans & Powers 1985) measures patient satisfaction within 4 domains of the life situation, with the importance placed on these domains by the participants. There are 38 statements in each domain: health-functioning, socio-economic, psychological-spiritual and family. Statements are rated on a 6 point Likert scale, ranging from very satisfied to very dissatisfied for the satisfaction items and from very important to very unimportant for the importance items (used by Bolse et al 2002, #1355).

Frenchay Activities Index (FAI) (Holbrook & Shilbeck 1983) is a self-report assessment tool originally developed to gather information on the pre-morbid life style of individuals who have had a stroke and record changes in the frequency of engagement in independent activities of daily living (IADL) tasks after stroke. And, it has been validated by factor analysis in stroke patients. The assessment, however, does not exclusively examine IADL tasks; leisure and vocational activities are also included. The FAI rates the frequency with which respondents perform 15 activities, each rated from one to four points (e.g. gardening, washing dishes). These activities have been content-validated for application to the stroke population. They are measured as a total score ranging from 15-60 points, or divided into three sub-scales (domestic activities, work/pleasure and social activities) (used by Carod-Artal et al 2002, #642).

Functional Assessment System (FAS) (Oberg et al 1994) was specially designed to diagnose the functional and social incapacity of an individual. FAS consists of 20 variables reflecting major lower extremity function, and the items are divided into 5 subgroups: hip impairment (range of motion measured by goniometer) knee impairment (range of motion measured by goniometer) physical disability (performance tests), social disability, and pain. The scale can be used for pre-operative and post-operative evaluation, for individual goal-setting, follow-up and for planning and design of specific training programmes (used by Nilsdotter 2001, #686; Oberg & Oberg 1996, #1869).

Functional Independence Measure (FIM) (Hamilton et al 1987) is an 18 item, 7-level scale, which assesses severity of disability in six areas: self-care, sphincter control, mobility, locomotion indoors, communication and social cognition. The conceptual basis of the FIM is the burden of care required for a disabled individual to perform a selected minimum of basic life activities safely and effectively (used by Andren & Grimby 2000, #782; Stickel et al 2002, #664; Nochajski et al 1996, #320).

Glasgow Benefit Inventory (GBI) (Robinson et al 1996) is an 18 item patient-orientated questionnaire designed initially to consist of 18 post-intervention questions. It provides a measure of patient benefit (change in health status) otorhinolaryngological procedures. The GBI allows a comparison of benefit across different interventions. It is designed to measure change in health status, where health status is defined as the general

perception of well-being. This includes total psychological, social as well as physical well-being (used by Dutt et all 2002, #611).

Harris Hip Score (HSS) (Harris 1969) condition-specific score for measurement of hip function. The clinical rating system is based on pain, range of movement, absence of deformity, gait and performance of activities including climbing stairs, use of public transport, putting on shoes and socks, and sitting (used by Ritter et al 2004, #401).

Harold Wood Stanmore Mobility Scale (Hanspal et al 1991) measures achieved mobility using a range of scores from 1 (cosmetic use of limb only) to 6 (normal gait over all types of terrain) (used by Fisher & Hanspal 1998, #60).

Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith 1983) is a 14-item scale developed to provide a brief measure of anxiety and depression, and detect clinical cases and the severity of anxiety and depression, without contamination of scores by reports of physical symptomatology. Each item is scored from 0 to 3 and total scores range from 0 to 21 for both subscales. Higher scores indicate greater anxiety and depression (used by Berry & Kennedy 2003, #5; Fisher & Hanspal 1998, #60).

Hospital for Special Surgery Hip Scale (Salvati & Wilson 1973) measures pain, walking ability, motion/muscle power, and independence in daily activities. The overall score has a range of 0-40, with the higher scores indicating better status (used by Mancuso et al 2003, #52)

Hungerford Score (Hungerford et al 1982) is an assessment system using for assessing outcomes in patients post-knee arthroplasty. The clinical rating system is based on pain, flexion contracture, stability, varus or valgus deformity and quadriceps strength (used by Bach et al 2001, #117).

Knee Society Score (KSS) (Install et al 1989) condition-specific score for measurement of knee function. The clinical rating system is based on pain, range of movement and stability with a measurement of function including walking and climbing stairs, maximum total score of 100 (used by van Essen et al 1998, #210).

The Life Space Questionnaire (LQS) (Stavley et al 1999) adapted from the 1985 version, is a self-administered instrument consisting of 9 questions that measures movement patterns over 3 days. The limitation to a 3 day time span is suggested to establish a consistent pattern of daily activities without permitting unusual circumstances to influence their routine. Each question establishes movement in a life-space zone ranging from one's dwelling to travel outside of a region of the country in which one lives. Each question has a yes/no answer and uses a points system for easy interpretation of scores. In 1999 test-retest reliability was found to be 80% overall, with questions 1-5, and 8 and 9 having 90% agreement, and questions 6 and 7 having between 70-73% (used by Parker et al 2001, #2155).

London Handicap Scale (Harwood et al 1994) comprises a disability classification questionnaire with six sections or dimensions: mobility, independence, occupation, orientation, social integration, and economic self-sufficiency, with a matrix of scale weights relating to responses on each dimension. Each dimension has six hierarchically arranged descriptions of what the subject does or does not do, each respondent being asked to choose which one applies. The scale weights were derived from valuations of disadvantage (utility measurements) made by a representative population and combine to give and overall interval-level score. A score of 100 implies no disadvantage, whilst a score of 0 represents maximum disadvantage (used by Harwood & Ebrahim 2000; #231; Harwood & Ebrahim 2002; #628).

Matching Person and Technology (MPT) was first presented 1989 (Scherer 1998). The model addresses three primary areas to assess: determination of the milieu/environment factors influencing use; identification of the consumer's needs and preferences; and description of the functions and features of the most desirable and appropriate technology. It is a practical and research tool which identifies barriers to AT use for a particular individual's strengths and participatory needs, preferences and temperament. This information is balanced with the characteristics of the environment in which the technology will be used along with the features and functions of the technology itself (used by Scherer & Cushman 2002, # 663).

Millon Multiaxial Inventory-II (MCMI-II) (Millon 1985) is a 175-item test that assesses 13 personality disorders (DMS-III-R Axis II disorders) and 9 clinical syndromes (DSM-III-R Axis I disorders) in adult patients in outpatient, inpatient, chemical dependency, and other treatment settings (used by Ta et al 2002, #561).

Mini Mental State Exam (Folstein et al 1975) is utilised to measure mental status and cognitive functioning (used by Nochajski et al 1996, #320; Mann et al 1995, #22).

Minnesota Multiphasic Personality Inventory (MMPI) (Derogatis et al 1976) is an objective verbal inventory designed as a personality test for the assessment of psychopathology consisting of 550 statements, 16 of which are repeated (used by Ta et al 2002, #561).

Modified Merle d'Aubigne & Postel (Charnley 1972) a functional hip grading assessment, which assesses pain, function and passive range of motion of the hip on a 6 point scale (used by Joshi et al 2002, #617).

Mishel Uncertainty in Illness Scale – community version (MUIS-C) (Mishel 1981) consists of 23 items assessing uncertainty in illness. Statements are rated on 5 point Likert scales, ranging from agree strongly to disagree strongly (used by Bolse et al 2002, #1355).

Modified Musculoskeletal Tumor Society Score (MSTS) (Enneking et al 1993) accounts for pain, function, emotional acceptance, supports, walking and gait. Each

parameter is graded 0, 1, 3 or 5 with intermediate values of 2 or 4 based on the examiner's judgement, when performance falls between the specific values. The maximum score is 30 points (used by Cottias et al 2001, #689).

Needs Assessment Checklist (NAC) (Kennedy & Hamilton 1999) is a rehabilitation outcome measure, specifically developed for patients with spinal cord injury (SCI). It consists of 199 behavioural indicators, assessing patient achievement in 9 core areas of rehabilitation in order to provide each individual with the skills they require to maintain their health and quality of life after sustaining a SCI. These areas are: activities of daily living, skin management, bladder management, bowel management, mobility, wheelchair and equipment, community preparation, discharge coordination, and psychological issues. The NAC was developed to incorporate individual perceptions and each individual rates his/her own level of independence for each task/item by means of an interview, lasting approximately 1 hour. Each item receives a score from 0 to 3 (0=completely dependent, 2=moderately dependent, 3=completely independent or not applicable). Item scores for each subscale are totalled and a 'percentage achieved' score is derived, reflecting the individual's level of independence in each rehabilitation area. Thus, for each NAC subscale total scores range between 0-100% with higher NAC scores indicating greater levels of independence (used by Berry & Kennedy 2003, #5).

(Nottingham) Extended Activities of Daily Living scale (Nouri & Lincoln 1987) has 22 items scored on the basis of requiring help in performing the described activity. It gives scores on four subscales: mobility, domestic, leisure, and kitchen, and a total score. The scoring range is 0-22, with higher scores representing better function (used by Harwood & Ebrahim 2000; #231; Harwood & Ebrahim 2002, #628).

Nottingham Health Profile (NHP) (Hunt et al 1981) is a health related quality of life score and consists of 2 parts. The first contains 38 questions requiring yes or no answers dealing with 6 aspects of health namely pain, energy, sleep, mobility, emotional reaction and social isolation. The items are weighted and each yields a value of between 0 and 100 with the worst state being 100. The second part has 7 sections answered yes or no which reflect the frequency of problems with occupation, housework, social life, family life, sexual function, hobbies and holidays (used by Alonso et al 2000, #219).

Older Americans Resources and Service Center Instrument/Multidimensional Functional Assessment of Older Adults (OARS) (Fillenbaum 1988) includes physical health scales, instrument activities of daily living and a social resources scale (used by Mann et al 1995, #22; Nochajski et al 1996, #320).

Oral Health Impact Profile (OHIP) (Slade & Spencer 1994) is an oral-specific health status measure. It consists of 49 items organised in 7 subscales: functional limitation, physical discomfort/pain, psychological discomfort, physical disability, psychological disability, social disability and handicap, with responses being: never, hardly ever, occasionally, fairly often or very often. Each statement is weighted to allow the full impact

of that problem to be described. Summary scores are calculated in 2 ways: first, by summing the response scores (higher scores indicated poor oral health status) and second, by multiplying each statement and summarizing the scores within subscales (used by Allen et al 2001, #208).

Oxford Hip Score (OHS) (Dawson et al 1996) is a 12-item patient based questionnaire developed and validated specifically to assess function and pain after total hip arthroplasty (used by Dawson et al 2001, #144; O'Brien 2002, #31).

Oxford Knee Score (Dawson et al 1996) was developed specifically to assess the individual's perceptions of pain, mobility, and function in relation to problems of the knee (used by O'Brien 2002, #31).

Patient-Specific Index (Wright & Young 1997) is a standardised method that allows individuals who are scheduled for a total hip arthroplasty to indicate the type, severity and importance of their concerns, which can be aggregated in a single summary score. It also allows a surgeon to document an individual's concerns and expectations of surgery and thereby provides an opportunity for a surgeon to address any unrealistic expectations of an individual prior to surgery (used by Wright et al 2000, #57).

Profile of Mood States (POMS) (McNair et al 1992) – Each mood score for tension-anxiety, depression, fatigue and vigour are the sum of ratings of several mood adjectives on a 5 point intensity scale (used by Salmon et al 2001, #725).

Psychosocial Impact of Assistive Devices Scale (PIADS) (Day & Jutai 1996) is a 26-item self-report paper and pencil measure of the impact of rehabilitative technologies and assistive devices on the quality of life of their users. It captures, through 3 subscales, the concepts of competence, adaptability and self-esteem; all subsumed as fundamental dimensions under quality of life. The competence subscale is composed of 12 items related to perceived functional capability, independence, and performance. The adaptability subscale is composed of 6 items reflecting inclination or motivation to participate socially and take risks. The self-esteem subscale is composed of 8 items reflecting self-confidence, self-esteem, and emotional well-being. When administering the PIADS, respondents are asked to read al list of words or phrases that describe how using an assistive device may affect the person who wears or uses it. They then rate each item on a 7 point Likert scale ranging from -3 (maximum negative impact) to +3 (maximum positive impact) (used by Demers et al 2002, #2153; Stickel et al 2002, #664).

Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) (Demers et al, 2000) designed as an outcome measurement instrument to evaluate a person's satisfaction with a wide range of assistive technology (AT). It was intended as a clinical and research instrument. Although its experimental version consisted of 24 items, an item analysis subsequently resulted in a reduced 12-item scale. The instrument was developed in Canadian English and French. It was subsequently translated into Dutch (D-

QUEST), Swedish, Norwegian, Danish and Japanese. QUEST 1.0 (Demers et al 1996) was validated in areas related to wheelchair seating and positioning, mobility and home adaptations, and electronic aids to daily living (used by Demers et al 2002, #2153; Demers et al 2002, #572; Stickel et al; 2002, #664).

Quick Environmental Exposure and Sensitivity Inventory (QUESSI) (Miller & Prihoda 1999) designed to evaluate patients for the presence of symptoms that might be attributed to chemical exposures such as disseminated implant particles. It is a self-administered 50 item questionnaire that contains 4 core scales: symptom severity, chemical (inhalant) intolerance, other intolerance and life impact (used by Ta et al 2002, #561).

Recovery Inventory (Wolfer & Davis 1970) devised to measure recovery after major surgery. It provides a single score from the sum of individuals' ratings on a 6 point Likert scale from "very poor" to "excellent", on aspects of bodily function, including appetite, sleep, stomach and bowel condition and mobility (used by Salmon et al 2001, #725).

Rosenberg Self Esteem Scale (Rosenberg 1965) is utilised to measure self-esteem. The scale contains 10 items that are answered on a four point scale from strongly agree to strongly disagree (used by Mann et al 1995, #22).

Scandinavian Neurological Stroke Scale (SSS) (Scandinavian Stroke Study Group 1985) evaluates level of consciousness, eye movement, power in arm, hand and leg, orientation, aphasia, facial paresis, and gait. The total score ranges from 0-58 (used by Carod-Artal et al 2002, #642).

Short From Health Survey (SF-12) (Ware et al 1996) is a 12 item, self-administered questionnaire that assesses symptoms, functioning and quality of life. It is an abbreviated version of the SF-36 (see below). The 12 items take about five minutes for the patient to complete and the questions can be administered to people who can't read. The SF12 generates two scores; a mental component score and a physical component score used by Whitehouse et al 2003, #32; Dunbar et al 2001, #203)

Short Form Health Survey (SF-36) (Ware et al 1993) otherwise known as the Medical Outcomes Study Short Form Health Survey is a general health status measure developed by the Medical Outcomes Study in the USA. It is a self-administered measure that contains 36 items, each having a yes/no response or a hierarchical scale of severity and measures 3 major health attributes (functional status, well being, and overall health). The SF-36 generates a profile of eight dimensions: energy/vitality, health perception, mental health, pain, physical function, role limitation due to physical problems, role limitation due to emotional problems and social activity based on patients' responses to questions about daily life. Each dimension is scored 0-100 (worse to best scale), with higher scores representing better function or fewer problems (used by Harwood & Ebrahim 2000, #231; Nilsdotter 2001, #686; Harwood & Ebrahim 2002, #628).

Sleep Quality Index (SQI) (Belza 1995) is a 6 item sleep survey that ranges from 0 to 18 with lower scores representing better sleep (used by Ta et al 2002, #561).

Spinal Cord Independence Measure (SCIM Version 2) (Catz et al 1997; Catz et al 2001) is a disability scale, specifically developed in order to assess the capacity of the individual with spinal cord injury to perform daily tasks. It consists of 18 items divided into three subscales: self-care (score range 0-20), respiration and sphincter management (score range 0-40), and Mobility (0-40). The total score ranges between 0 and 100 (used by Berry & Kennedy 2003, #5).

Sickness Impact Profile (SIP68) (de Bruin et al 1992) is a shortened version (68 items) from the original version of the Sickness Impact Profile containing 136 items. It is a generic measure used to evaluate the impact of disease on both physical and emotional functioning. Individuals are asked to respond to the items as they are on that day (used by Jedeloo et al 2002, #119).

Symptoms Checklist-90 (SCL-90) (Derogatis et al 1976) is a multidimensional self-report inventory widely used in psychiatric screening to measure psychological distress levels. It provides four normative scoring versions for both males and females. The norms have been established for psychiatric inpatients, psychiatric outpatients, non-patient adults, and non-patient adolescents (used by Ta et al 2002, #561).

Toronto Extremity Salvage Score (TESS) (Davis et al 1996) is a quality of life questionnaire developed for patients undergoing limb preservation surgery for tumours of the extremities. It is self-administered and evaluates physical disability based on a patient's perception of their function. Functional difficulty is rated on a 5 point scale from "not at all difficult" to "impossible to do" (used by Cottias et al 2001, #689).

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy et al 1988) is a disease-specific instrument. It is a self-administered instrument validated for osteoarthritis in the lower extremities. It consists of 24 items grouped into 3 subscales: pain (5 questions), stiffness (2 questions) and physical function (17 questions). This assessment is based on performing routine activities. Each item is scored on a 5-point Likert scale (used by Nilsdotter 2001, #686).

World Health Organization Quality of Life Questionnaire (short version, or WHOQOL: BREF) (WHOQOL Group, 1998) produces scores for four domains related to quality of life- physical health, psychological, social relationships, and environment. The instrument consists of 28 items rated on 5-point Likert scale. The WHOQOL: BREF has been shown to discriminate between ill and healthy respondents, with significant differences apparent on all domains. The WHOQOL Group (1998) envisaged the WHOQOL: BREF to be of use in studies that require a brief assessment of quality of life and to health professionals in the assessment and evaluation of treatment efficacy (used by Gallagher & MacLachlan 2000, #754).

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