

## CLINICAL REVIEW

# The PBRN Initiative: Transforming New Technologies to Improve Patient Care

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**Abstract:** *The NIDCR-supported Practice-based Research Network initiative presents dentistry with an unprecedented opportunity by providing a pathway for modifying and advancing the profession. It encourages practitioner participation in the transfer of science into practice for the improvement of patient care. PBRNs vary in infrastructure and design, and sustaining themselves in the long term may involve clinical trial validation by regulatory agencies. This paper discusses the PBRN concept in general and uses the New York University College of Dentistry's Practitioners Engaged in Applied Research and Learning (PEARL) Network as a model to improve patient outcomes. The PEARL Network is structured to ensure generalizability of results, data integrity, and to provide an infrastructure in which scientists can address clinical practitioner research interests. PEARL evaluates new technologies, conducts comparative effectiveness research, participates in multidisciplinary clinical studies, helps evaluate alternative models of healthcare, educates and trains future clinical faculty for academic positions, expands continuing education to include "benchmarking"*

*as a form of continuous feedback to practitioners, adds value to dental schools' educational programs, and collaborates with the oral health care and pharmaceutical industries and medical PBRNs to advance the dental profession and further the integration of dental research and practice into contemporary healthcare (NCT00867997, NCT01268605).*

**Key Words:** *Practice-based Research Network, good clinical practice, clinical studies, patient-reported outcomes, Comparative Effectiveness Research (CER), Evidence-based Dentistry (EBD).*

## Introduction

There are currently about 150 U.S. medical Practice-based Research Networks (PBRNs) listed by the Agency for Healthcare Research and Quality (AHRQ), three of which represent dentistry (AHRQ, 2011). PBRNs were the first real attempt to lessen the translational gap—the lag between technological discovery and clinical application (Hart *et al.*, 2004). AHRQ has developed a three-stage framework for transferring patient safety research into practice (Nieva

*et al.*, 2005). However, as new drugs and treatment regimens become increasingly sophisticated and expensive, the gap appears to be widening. Medicine and dentistry must accelerate the incorporation of advances into clinical applications directed at patient care. PBRNs provide an infrastructure designed to answer clinician-related questions generated from the community at large, in which practitioners can participate in clinical studies, assessing conventional and new technologies. Although no consensus definition of a PBRN presently exists, the PEARL Network (Practitioners Engaged in Applied Research and Learning) defines a PBRN as follows: a collaboration between an academic health science center(s) and community practitioners for conducting primarily clinical studies of mutual interest to benefit/enhance patient care and delivery, systems assessment, quality assurance, and other factors affecting health care policy. Health care cost research is generally beyond the mandate of PBRNs (Robbins, 1998; Kamerow, 2011).

First conceived over 100 years ago in England, PBRNs took root in the United States in the 1970s (Lanier, 2005; Green and Hickner, 2006). PBRNs are an important instrument of change, driven

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primarily by the recent health care reform legislation. AHRQ has been the main funding source for the medical PBRNs, study by study, and a supporter of their continued development. Further interest has been generated with the American Recovery and Reinvestment Act of 2009, of which patient-centered outcomes research is a centerpiece, and the development of the Patient-centered Outcomes Research Institute (PCORI) (American Recovery and Reinvestment Act, 2009; Clancy and Collins, 2010; Health Care and Reconciliation Act, 2010; Helfand *et al.*, 2011; Kamerow, 2011; Manchikanti *et al.*, 2011). Medical PBRNs were designed to bring together community physicians to conduct studies of interest and relevance to everyday clinical practice (Lanier, 2005); many conduct surveys to assess practitioner practice patterns. Comparative effectiveness research studies (CER) are directed at comparing treatment outcomes and are the clinical focus of PBRNs. They have addressed clinical issues regarding the treatment of acute otitis media (Froom *et al.*, 2001) and the management and outcomes of care of febrile infants (Pantell *et al.*, 2004). Though PBRNs are described by AHRQ as “group[s] of ambulatory practices devoted principally to the primary care of patients, and affiliated in their mission to investigate questions related to community-based practice and to improve the quality of primary care,” the concept is still evolving to include improved patient care, change in practice patterns, continuing professional education, and clinician access to underserved areas. Some have suggested “Health Improvement Network” as a new definition for the PBRNs (Williams and Rhyne, 2011).

### PBRN Initiative in Dentistry

Dentistry has been on the periphery of health care policy, including the new health care reform acts (American Recovery and Reinvestment Act, 2009; Health Care and Education Reconciliation Act, 2010). In 2005, the National Institute of Dental and Craniofacial Research (NIDCR) funded three dental PBRNs as an experiment to initiate change in dentistry: PEARL at New York University (NYU); the

Dental Practice-based Research Network (DPBRN) at the University of Alabama; and the University of Washington–Oregon Health Sciences School of Dentistry collaboration, Northwest Practice-based REsearch Collaborative in Evidence-based DENTistry (Northwest PRECEDENT) (Practitioners Engaged in Applied Research and Learning, 2011; Dental Practice-based Research Network, 2011; Northwest Practice-based REsearch Collaborative in Evidence-based DENTistry, 2011). The three PBRN models became an “experiment within an experiment”. PEARL was designed as a unifying entity, bringing dentistry together with other health care disciplines to improve patient care. PBRNs may differ in design, content, practitioner engagement, infrastructure, IRB oversight, health care disciplines involved, and degree of data integrity. One of the key differences between the original concept of a PBRN and that mandated by the NIDCR is found in its metric of “generalizability”. The NIDCR-funded PBRNs were designed to implement change in the way dentistry is practiced. How this was to be implemented resides in the types of studies conducted, infrastructure, confidence in the data collected, and the oversight and efficient dissemination of clinical findings. The final RFA called for each PBRN to conduct 16 surveys and/or studies. Some two years into the program, recognizing that surveys are not a basis for change, the NIDCR requested that the PBRNs conduct a randomized controlled clinical study and other designs of clinical research. The infrastructure allowed practicing dentists to be part of a constituency that supports dental research—historically, limited to a small percentage of academic dentists and scientists. Basic research that remains in the laboratory, unable to be translated into clinical practice, does not contribute to improved patient care. Ultimately, the NIDCR’s vision includes dentists participating in pharmacogenetic studies (Tabak, 2010).

### The Role of the Practitioner

The PBRN initiative acknowledges that providers play a significant role in

generating data that can be translated into meaningful information to improve patient care.

The dental PBRNs were unique in their funding commitment and for the length of the granting period: seven years. The initial objective was to build a network of dental practitioners, engage them in surveys and standard-of-care studies, and keep them engaged through annual meetings, newsletters, study-related meetings, monthly teleconference calls, and monitoring visits to assess study progress. Funding reimburses dentists for their time spent participating in clinical studies; it does not subsidize patient care. Patients routinely visit the dental office, and any patient presenting with a clinical situation that fits a study’s clinical criteria is eligible for recruitment into that study. Funding covers the time the practitioner/staff spends on informed consent and on recording and transmitting data as well as follow-up visits.

Dentists must be able to diagnose disease and to prescribe medications, conduct diagnostic tests, and combine skill and information into effective treatments. Such communication is far from standard among dentists—a disparate group, relatively isolated in their (70% solo) practices (ADA Survey Center, 2007), whose primary means of advancement is attending continuing education courses or accepting other practitioners’ anecdotal evidence for initiating change. PBRNs are thus critical venues for dentists to learn newer and advanced treatments and techniques in a guided, university-based environment that allows for education through their peers, participation in study protocols, and an information dissemination process that ensures some quality control and practitioner feedback for best practice outcomes (Stephens *et al.*, 2011). Practitioners’ willingness to change, according to the Transformation Theory, may depend upon the network’s ability to establish credibility and trust (Matthew-Maich *et al.*, 2010)—objectives requiring a long-term commitment. These attributes may facilitate new technologies such as salivary diagnostics (Baum *et al.*, 2011; Giannobile *et al.*, 2011).

Scientific diligence and application to patient care will be pivotal for the future of dentistry. Changing the dental paradigm from a procedural, interventional approach to a more science-based, preventive approach built on biological principles will fulfill the intellectual definition of a “doctor of dentistry” (Curro *et al.*, 2011). The promulgation of a new caries classification system and biologically preserving the pulp before it is removed are but two current examples of such a shift. Dentists are highly educated but underutilized health care professionals. They take medical histories, spending more time with a patient than do their physician counterparts; yet there is no forum for collaboration and transformation of this information. The advent of electronic health records means that dental practitioners will inevitably be part of a larger system of healthcare, inclusive of patients’ health histories through the “electronic medical home” (Office of the National Coordinator for Health Information Technology, 2011). PBRNs foster familiarity for such data exchange. The PBRN initiative also provides an infrastructure for dentists to participate in drug utilization and safety studies, acting as change agents for signal detection for new drug releases and in pharmacovigilance studies. Fig. 1 illustrates how PEARL builds on practitioner experience to conduct more demanding clinical studies. The infrastructure can support large, longitudinal, and standard-of-care studies, which can provide clinical solutions to optimize oral health treatment and prevention paradigms (Hujuel *et al.*, 1997).

### PBRN Goals

The PEARL Network was designed to provide dentistry with a vision for the future and the opportunity to participate in many aspects of the changing health care model. PEARL is in the process of forming a dental PBRN clinical network consortium that incorporates both Northwest PRECEDENT and the CROWN Networks: the more practitioners engaged, the more feasible the process of information dissemination and change (Community Research for Oral Wellness Network, 2007; Northwest Practice-based

REsearch Collaborative in Evidence-based DENTistry, 2011).

PEARL includes a registry of over 519 dentists termed ‘practitioner–investigators’ (P-Is) with 364 credentialed, of whom 311 are trained to participate in the network (see Fig. 1), and 30 community centers, and includes physicians. Representing over 35 states, PEARL is a national network supported by a Data Coordinating Center, The EMMES Corporation (Rockville, MD, USA). Credentialing is based on a number of parameters for IRB risk mitigation and regulatory compliance.

Northwest Practice-based REsearch Collaborative in Evidence-based DENTistry (Northwest PRECEDENT) is a collaboration of investigators at the University of Washington in Seattle, Washington, and the Oregon Health & Science University of Portland, Oregon. The network is supported by a Data Coordinating Center at the University of Washington and Axio Research in Seattle. Presently there are 358 practitioners, of whom 216 are trained and participating in the network. This network distinguishes itself by having some 20 dentists working in community clinics, and dental specialties representing pediatrics and orthodontics. The network covers 25 states and has survey participants in 10 countries. Credentialing is based on review of limitations of practice by State Boards of Dentistry.

The Dental Practice-based Research Network (DPBRN) is a collaboration of investigators at the University of Alabama at Birmingham. DPBRN is comprised of dental offices in the United States and Scandinavia.

The Community Research for Oral Wellness Network (CROWN), based at Case Western Reserve University (Cleveland, OH, USA), began in 1998 as the Direct Observation Study of Prevention in Dental Practice (DOS), the basis for an NIDCR-funded grant. As CROWN, it resides in 18 Ohio counties and includes 160 dental practices. The network provides information based on observational studies. Credentialing of practitioners is based on dentists being licensed by the State Board of Dentistry.

**Figure. 1**

PEARL study categorization depending upon level of practitioner clinical study experience (Tier). Experienced Practitioner-Investigators both credentialed and trained.

<b>Research Trained Investigators</b>
Beyond The Scope of a PBRN
<ul style="list-style-type: none"> <li>Phase I Trial Development-First in Man</li> <li>Phase II Trial Development-Dose Ranging</li> </ul>
<b>Experienced (Tier I) PBRN Practitioner-Investigators</b>
Standard of Care-Randomized Clinical Studies using FDA / ADA Approved Products
Phase III Trial Development Randomized Clinical Trial
<b>Trained (Tier II) PBRN Practitioner-Investigators</b>
Standard of Care Studies
Comparative Effectiveness Research(CER) -Prospective
Comparative Effectiveness Research(CER) -Retrospective
Standard of Care-Phase IV Trial Development -Randomized Clinical Trial -Pharmacovigilance
<b>Credentialed (Tier III) PBRN Practitioner-Investigators</b>
Surveys

## Materials & Methods

### Infrastructure

PEARL was designed to have both academic and pharmaceutical industry characteristics, and exceeds the original RFA objectives. Modeled after a pharmaceutical clinical unit but functioning within an academic institution, PEARL has the flexibility to be interdisciplinary—and includes a medical component, in anticipation of conducting oral health studies with medical consequences (Payne *et al.*, 2011).

The PEARL Network is anchored in academia and representative of a broad base of stakeholders, including

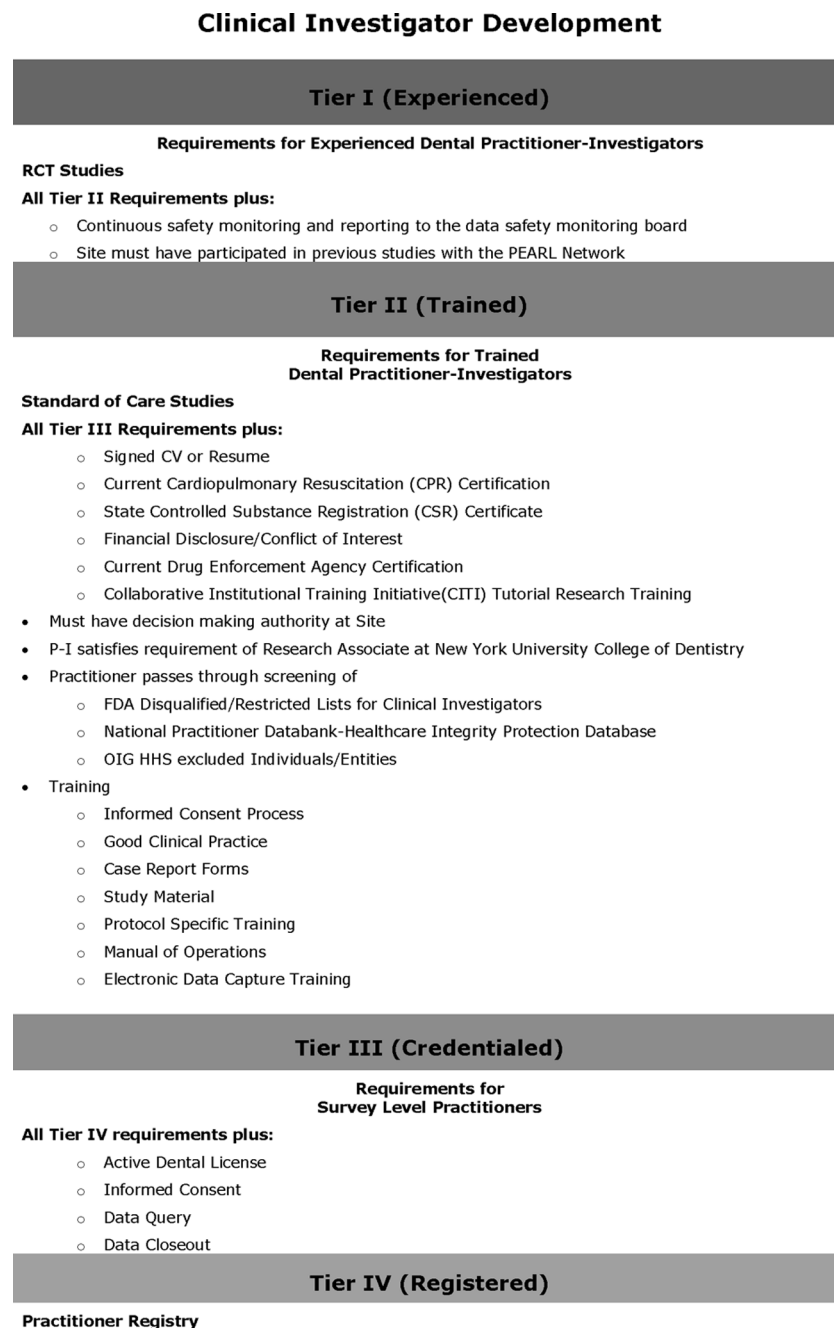
community clinics, professional associations, and third-party payers such as MetLife and Delta Dental. PEARL has a number of participating community clinics nationwide, from California, to Boston, to San Antonio. [PEARL, at formation, incorporated the extant Orthodontic PBRN of the University of Texas at San Antonio Dental School Health Science Center (Deahl *et al.*, 2007).] Representatives from a number of dental societies (*e.g.*, Hispanic Dental Association, National Dental Association) also collaborate with the PEARL Network.

PEARL is designed to support the “generalizability of the data”. This has an impact on how the network conducts its studies and how it is organized; it also distinguishes a PBRN focused on surveys from one conducting clinical studies to initiate change. But how can a clinical network take naïve clinicians with no training in clinical research, have them conduct a study, and expect enough confidence in the data that it will be “generalizable” to the profession? “Generalizability” suggests some level of confidence to ensure robustness of the findings to the community at large.

To address generalizability, PEARL was designed to follow the principles of Good Clinical Practice (GCP) for investigator training and clinical operations. GCP creates an audit trail of the data to ensure a level of confidence in clinical study findings (International Conference on Harmonisation, 1996). The entire clinical process is supported with standard operating procedures (SOPs) and oversight from certified Clinical Research Associates (CRAs). The GCP process extends to the official closeout of a study, including final monitoring visit, queries resolution, and database lock that ensures the completeness of the archived study. PEARL, the first GCP PBRN in the United States, has developed an organizational structure at each dental practitioner’s site. In addition to the Practitioner-Investigator (PI), an essential member of the study team is the Practice Research Coordinator (PRC), the key person through whom PEARL CRAs maintain liaison *via* monthly teleconference calls and whenever there is a study-related issue. The

**Figure 2.**

Practitioner-Investigator process of clinical development from point of entry (registry) to an experienced investigator (Tier 1).



dental practice unit also includes a dental hygienist, dental assistant, and an office manager—a configuration PEARL has found to be optimal for the conduct of office-based studies but one that understandably limits practitioner recruitment. However, PEARL has created a schema for determining a practitioner’s

appropriate participation level (Fig. 2), to capture the input of as many practitioners as possible and include those who may want to participate only in surveys. PEARL’s surveys assess practitioner interest in a given study and/or the feasibility of a study in terms of patients, logistics, and dental practice ergonomics;

they are usually, but not always, followed by a study. Recruitment strategies are designed to attract practitioners who understand the long-term benefits of a PBRN, since it costs time and money to replace and train P-Is. High practitioner turnover can stall clinical study progress. Motivated practitioners are screened by PEARL, based on criteria from various agencies (FDA, OIG, state Boards of Dentistry), to ensure data integrity (see Fig. 2). Though the size of any network is limited by the cost of supporting it, each dental PBRN was mandated to have 100 active practitioners—a number postulated by the medical PBRNs, although traditionally each of their studies includes few practitioners (National Institutes of Health, 2003). As noted, 311 of PEARL's 364 credentialed practitioners are trained P-Is, having fulfilled the requirements of Tier II participation (Fig. 2).

The official IRB of record for the PEARL Network is the NYU School of Medicine. PEARL is structurally obligated to advise its IRB of the risk potential of its studies, ensure patient safety, and maintain a level of quality assurance for the practitioners and their staff through education and training, thereby maintaining protocol compliance and adherence to GCP. Each PEARL practitioner engaged in a study is appointed as an NYUCD Research Associate, to be under the IRB 'umbrella'. PEARL terms its undertakings as clinical *studies*, not clinical *trials* (a term reserved for the drug development pipeline; see Fig. 1). This mitigates the risk potential for the IRB, so network studies are mainly deemed low-risk and "standard-of-care".

### Information Dissemination and Education in Evidence-based Dentistry (EBD)

Information dissemination is a mandated core of the PBRN concept. Practitioners are more likely to accept change if they generate the data in EBD. The audience for the clinical results is the practitioners, and it is sometimes a challenge to target a journal that is in concert with the needs of academicians for promotion. PEARL balances the needs

of the practitioners while maintaining academic credibility. Study information is disseminated through annual meetings, publications, newsletters, social media, and online learning. Practitioners have been encouraged to learn the process of presenting clinical results.

The PEARL Network views its educational component as paramount in sustaining the PBRN concept. The centerpiece of this component is practitioner "benchmarking": Practitioners participating in a study receive from PEARL a report measuring their performance anonymously against that of their study peers. This feedback is unique for each dental practitioner and informs him/her regarding how he/she may improve delivery of care and/or treatment outcomes. The PEARL Network envisions educating dentists in clinical research as a means of generating potential clinical faculty to fill the vacancies in U.S. dental schools. An educational value from a PBRN is a real-time dental curriculum revised as clinical study results become available, closing the gap between academics and practitioners. In time, the PBRN concept may offer dental schools additional pathways for dental education, and at NYU, PEARL has been projected to the undergraduate program (Curro *et al.*, 2011). Students can be benchmarked with PBRN practitioners, and this pathway may be an alternative to clinical board examinations. Additionally, PEARL has been contacted by specialty organizations to assist in programs where residents participate in clinical studies to satisfy part of the clinical research requirements.

The clinical philosophy of the PEARL Network is to design studies that are of interest to the practitioners, are clinically relevant, and have the potential to change practice patterns and improve patient care. Studies are also designed to evaluate the capability and robustness of the Network, and to balance science with clinical relevance and the logistics of conducting the study in the practice. All studies conducted undergo review by Network practitioners through an Executive Committee and are approved by a formal process *via* a Protocol

Review Committee, where the NIDCR is non-voting. PEARL studies are designed to be patient-centered and to include patient-reported outcomes (PROs) as described in the 2009 FDA Guidance for Industry document entitled "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims" (Food and Drug Administration, 2009). The studies also adhere to the recent guidelines stated by the Patient-centered Outcomes Research Institute (PCORI) (Health Care and Reconciliation Act, 2010). Additionally, the broader perspective of PROs is reflected in PEARL studies which include oral-health-related quality of life (OHRQoL) findings related to specific protocols (Sischo and Broder, 2011).

### Results

The PEARL clinical dataset portfolio is comprised of a variety of studies to demonstrate its capability to interact with different organizational needs. The studies described in the Appendix Table show the attention to detail, duration, and depth in an effort to maximize the patient visit and collect as much information as possible. PBRN studies balance control *vs.* risk with office logistics. As study risk increases, so does the control of the study for patient safety and IRB compliance.

The study design behind the PEARL portfolio and key study findings (Table) begin with a survey designated by the white highlight, followed by a clinical study with a light yellow highlight and/or a randomized controlled study in a dark yellow highlight. PEARL studies include one on post-operative hypersensitivity in occlusal restorations (PRL0602), with a finding that 62% of dentin caries were classified as inactive (Lehmann *et al.*, 2010). The findings led to PEARL's second CER randomized controlled study (PRL1013), assessing the need for a dental liner prior to placement of a resin-based composite filling. To support the decision process in treatment planning regarding whether to perform root canals and/or extract the tooth and place an implant, PEARL conducted two parallel

**Table**

## Summary of Key Study Findings

Study	Key Findings	Publication(s)
<b>PRL0501</b> Deep Caries Treatment Survey	Approximately 20% of network dentists favor partial caries removal techniques and that deep caries treatment outcome studies are warranted, given the various treatments employed.	<i>Gen Dent</i> 2007; May-June: 197-203 PMID, PMCID, NIHMSID 17511360, PMC-
<b>PRL0602</b> Post-operative Hypersensitivity in Occlusal Restorations	In a study of shallow dentin caries lesions, 62% of dentin caries were classified as inactive. No relationship was found between dental materials/techniques and post-operative hypersensitivity or quality of life.	<i>J Dent Res</i> 2008; 87 (A): 1086 <i>J Dent Res</i> 2009; 88 (A): 0171 <i>J Dent Res</i> 2011; 90 (A): 148 <i>JADA</i> 143 (4): 377-385 <i>J Dent Res</i> 2010, 89 (A): 1507
<b>PRL0603</b> <b>CONDOR</b> Trans-PBRN Case Control Study of Osteonecrosis of the Jaw	Both IV and oral bisphosphonate use were strongly associated with ONJ. Duration of treatment > 2 yrs; suppuration and dental extractions were independent risk factors for ONJ.	<i>J Dent Res</i> 2010. 90 (2): 439-444. PMID: 21317246 <i>JADA</i> 143 (4): 377-385
<b>PRL0604</b> Complete vs. Partial Removal of Caries: a Comparison Study of Treatment Outcomes. 1. Community Centers 2. Private Practices	Active dentin caries was related to the likelihood of leaving caries but not to preparation depth. Dentin caries was left in a larger portion of teeth than anticipated (15%).	Study in progress: <i>J Dent Res</i> 2012, 91 (A): 7 <i>J Dent Res</i> 2011, 90 (A): 427 <i>J Dent Res</i> 2010, 89 (B): 2086
<b>PRL0705</b> Outcomes for Endodontic Treatment and Restoration of Teeth in Dental Practice	Results suggest that the root canal therapy failure rate (root canal therapy plus restoration) in general practice is higher than previously reported (28%).	<i>J Dent Res</i> 2008; 87 (A): 0212 <i>J Dent Res</i> 2010, 89 (B): 2084 <i>J Dent Res</i> 2011, 90 (A): 432 <i>JADA</i> 143 (5): in press. <i>JADA</i> 143 (7): in press.
<b>PRL0706</b> Analgesic Use and Effectiveness	Analysis of data suggests that there can be improvement in patient communication when analgesic medication is prescribed and/or recommended and in adherence to pharmacokinetic principles when analgesic medication is prescribed.	<i>J Dent Res</i> 2010, 89 (B): 2084 <i>J Dent Res</i> 2011, 90 (A): 2375 <i>J Dent Res</i> 2009; 88 (A): 0278
<b>PRL0707</b> Non-carious Cervical Lesion Treatment Outcomes: Randomized Clinical Study	Dentin-bonding agent followed by sealant and resin-based composite restoration significantly lowered baseline air sensitivity.	Baseline findings: <i>J Dent Res</i> 2011, 90 (A): 149
<b>PRL0808</b> Case Study of Diagnosis, Treatment, and Maintenance/ Recall of Periodontal Patients by General Dentists	General practitioners demonstrated variation in periodontal terminology affecting diagnosis, possibly due to the lack of consistency in periodontal definitions.	<i>J Dent Res</i> 2011, 90 (A): 429
<b>PRL0809</b> <b>CONDOR</b> Impact of Dental Practice-based Research Networks on Patient Care, a Trans-PBRN Study	Dental PBRNs may offer information on characteristics associated with faster translation of research results into practice.	

(continued)

Table (continued)

Study	Key Findings	Publication(s)
<b>PRL0910</b> <b>CONDOR</b> Advancing Care Management for TMJD Pain: Planning for a Clinical Trial	It is feasible to conduct a RCT in the PBRNs to assess the effectiveness of self-care, splint therapy, and/or medications for the initial management of painful TMJD.	
<b>PRL0911</b> Screening and Interventions for Tobacco, Alcohol, and Other Drug Use in Dental Settings: Survey to Assess Provider Practices and Interest	Dentists recognize the importance of screening for substance use, but lack clinical training and systems that facilitate intervention. (Dental/Medical)	College for Problems of Drug Dependency (CPDD) 73rd Annual Meeting, Hollywood, Florida, June 2011. Clinical Translational Research and Education (ACRT/AFMR/SCTS Joint Annual Meeting), Washington, DC, June 2011. NIDA Clinical Trials Network Steering Committee Meeting, Bethesda, MD, September 2011.
<b>PRL1012</b> Outcomes for Single-unit Implant Placement and Restoration in General Dental Practice	Interim study findings to date. Parallel study to PRL0705 to determine implant placement outcomes, including failure rate.	<i>J Dent Res</i> 2012, 91 (A): 172 Study in progress.
<b>PRL1013</b> Resin-based Composite Restoration Post-operative Hypersensitivity: Randomized Comparative Effectiveness Research Study	Practitioner and patient assessment of post operative hypersensitivity with liner vs. no liner.	Study in progress.
<b>PRL1014</b> Assessment of Oral Pain by Dentists & Physicians	Comparison of analgesic (NSAID and opioids) use by physicians and dentists. (Dental/Medical)	AHRQ 2011 Data analysis.
<b>PRL 1115</b> Caries Classification System	Practitioner assessment of new caries classification system to assist in patient care.	Data analysis.

studies: PRL0705 to assess endodontic outcomes and PRL1012 to assess implant outcomes. Responding to concerns raised, at a 2008 joint NIDA–NIDCR meeting, about the overprescribing of opioids by dentists, PEARL launched an analgesic study (PRL0706) to assess how dentists evaluate pain after a procedure with a one-week post-procedural patient follow-up. Interim findings suggested that issues exist in patient communication and in the dentists' understanding of pharmacokinetic principles (Hudson *et al.*, 2011). PEARL's first office-based, standard-of-care, randomized controlled CER study (PRL0707) was a six-month study with a total of four visits comparing three forms of dental treatment for hypersensitivity. This is the longest

dental hypersensitivity study conducted beyond the label claim of two months. PEARL conducted the first randomized periodontal case study presentation (PRL0808), with findings supporting the literature reviews in suggesting an issue with periodontal terminology (Rosen *et al.*, 2011).

PEARL has also formed collaborations with the Wisconsin Research and Education Network (WREN) to assess and compare dentist and physician prescription patterns of analgesics and opioids and has presented the findings at the 2011 Annual AHRQ meeting (Reniker, 2011). Additionally, PEARL is in the process of participating in a study with the Children's Hospital of Harvard University with its Center for

Adolescent Substance Abuse Research (CeASAR) (study not listed) to determine the feasibility of using dental offices to evaluate an Internet-/Intranet-based Motivational Enhancement Therapy (iMET) program for adolescents that targets tobacco, alcohol, and drug use.

All three dental PBRNs have collaborated under the acronym CONDOR (Collaboration on Networked Dental and Oral Health Research) on a number of initiatives: surveys for the development of a future clinical TMJ study by practitioners; a Practice Impact Research Group (PIRG) that surveyed dentists on their acceptance of clinical results for change in practice patterns; and a 2006 case-control study of dental risk factors on osteonecrosis of the

law (Barasch *et al.*, 2011). PIRG is the designated group that will be monitoring change in dentist practice patterns as a result of the clinical studies. PIRG has completed practitioner baseline data assessment, and its first paper is currently under review. Information dissemination and the acceptance of that information or data as a basis for change in practice behavior will be a focus of the National PBRN. The ONJ study was the first time that the PBRNs were used to address a clinical situation that had national visibility and significant practice impact for dentistry (Barasch *et al.*, 2011).

## Discussion

The national discussion regarding the importance and value of patient care has resulted in significant health care legislation. A long-term consequence of this initiative for dentistry will be the electronic dental record as part of the patient's electronic health record or medical home. This eventually may alter the isolation of the traditional dental practitioner in private practice. The Institute of Medicine (IOM) has published the top 100 research questions to be addressed by CER, as a guide for evaluating best-practice patient treatment outcomes (Institute of Medicine, 2009). The report was followed by a recent IOM report reviewing dentistry and its relationship to healthcare in terms of delivery and prevention (Institute of Medicine, 2011). The PBRN initiative, to date the largest investment by the government in dentistry, if directed toward meaningful programs, can serve as a platform for change in almost every aspect of dentistry and may have as great an impact on the profession as the 1926 Gies Report on dental education (Donoff, 2006; DePaola, 2008). The PBRN can be a model for new strategies in education, incorporating dentistry into healthcare reform, and for scientific assessment for clinical outcomes.

The ultimate vision of PEARL is to affect change in clinical practice behavior and treatment based on clinical evidence as well as input from regulatory agencies such as the FDA. PEARL is planning to conduct a study, on the use of patient

opioid agreements, with a division of the FDA. Further, PEARL is structurally able to participate in dental studies with medical consequences (Payne *et al.*, 2011), Rx to OTC switches, and pharmaco-vigilance, drug safety, and Phase IV studies.

Fully utilizing the patient information that practitioners gather, and having a PBRN to help capture and relate that information for inclusion in the patient's medical home, is an opportunity to be seized upon by the profession. This is a chance to expand the domain of interests and responsibilities for dentists at a time when they may be challenged by mid-level providers—and do so in a venue that ensures confidence as its basis.

Thus, the PBRN initiative is an opportunity for dentistry in time, place, and direction. The *time* reflects the changes occurring in health care and the emergence of the electronic health record; the *place* is what a network like PEARL has to offer, the design of its infrastructure, and its support from NYU; and the *direction* from a PBRN based on a level of confidence to support data integrity for generalizability of its clinical results.

The PBRN initiative offers the profession the chance to build a research constituency beyond the academic scientists the profession currently has. This constituency can also provide a resource of trained and credentialed practitioners with the clinical knowledge base to fill the vacancies currently existing in many of the nation's dental schools. The PBRN initiative can be a platform for change that offers the profession a chance to collaborate across healthcare disciplines by providing an infrastructure that can effect change from dental education to practice.

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