0022-5347/05/1733-0933/0
THE JOURNAL OF UROLOGY®

Vol. 173, 933–937, March 2005
Printed in U.S.A.
DOI: 10.1097/01.ju.0000152365.43125.3b

Outcomes/Epidemiology/Socioeconomics

UROLOGIC DISEASES IN AMERICA PROJECT: ANALYTICAL METHODS AND PRINCIPAL FINDINGS

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ABSTRACT

Purpose: The burden of urological diseases on the American public is immense in human and financial terms but it has been under studied. We undertook a project, Urologic Diseases in America, to quantify the burden of urological diseases on the American public.

Materials and Methods: We identified public and private data sources that contain population based data on resource utilization by patients with benign and malignant urological conditions. Sources included the Centers for Medicare and Medicaid Services, National Center for Health Statistics, Medical Expenditure Panel Survey, National Health and Nutrition Examination Survey, Department of Veterans Affairs, National Association of Children's Hospitals and Related Institutions, and private data sets maintained by MarketScan Health and Productivity Management (MarketScan, Chichester, United Kingdom), Ingenix (Ingenix, Salt Lake City, Utah) and Center for Health Care Policy and Evaluation. Using diagnosis and procedure codes we described trends in the utilization of urological services.

Results: In 2000 urinary tract infections accounted for more than 6.8 million office visits and 1.3 million emergency room visits, and 245,000 hospitalizations in women with an annual cost of more than $2.4 billion. Urinary tract infections accounted for more than 1.4 million office visits, 424,000 emergency room visits and 121,000 hospitalizations in men with an annual cost of more than $1 billion. Benign prostatic hyperplasia was the primary diagnosis in more than 4.4 million office visits, 117,000 emergency room visits and 105,000 hospitalizations, accounting for $1.1 billion in expenditures that year. Urolithiasis was the primary diagnosis for almost 2 million office visits, more than 600,000 emergency room visits, and more than 177,000 hospitalizations, totaling more than $2 billion in annual expenditures. Urinary incontinence in women was the primary cause for more than 1.1 million office visits in 2000 and $452 million in aggregate primary cause for more than 1.1 million office visits in 2000 and $452 million in aggregate annual expenditures. Other manuscripts in this series present further detail for specific urologic conditions.

Conclusions: Recent trends in epidemiology, practice patterns, resource utilization and costs for urological diseases have broad implications for quality of health care, access to care and the equitable allocation of scarce resources for clinical care and research.

KEY WORDS: urologic diseases, healthcare common procedure system, diagnosis

The burden of urological diseases on the American public is immense in human and financial terms, and until now it has remained largely unquantified. Urological diseases encompass a wide scope of illnesses that can occur at any point in the course of human development. Acute and self-limited or chronic and debilitating, they may affect quality and quantity of life, and may be financially insignificant or catastrophic. Physician practice patterns for treating patients with urological conditions have evolved substantially during recent years.

Accurate information on the epidemiology and impact of urological diseases is critical to the equitable allocation of scarce resources at the national, state and local levels. In conjunction with findings from clinical studies and basic research an epidemiological approach offers insights on the

Submitted for publication September 8, 2004.
Study received University of California-Los Angeles and RAND institutional review board approval.
Supported by the National Institute of Diabetes and Digestive and Kidney Diseases.
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† Financial interest and/or other relationship with Abbott, Sanofi-Synthelabo, TAP and Amgen.

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prevalence, etiology and impact of urological conditions. This information can provide the basis for planning health care services and intervention programs.[1]

However, reliable and valid health services data about urological diseases have been scattered and inconsistent. Despite the capabilities of the information age there is no national surveillance system describing prevalence and incidence across all urological diseases. Instead, various government and nongovernment agencies in the United States maintain a patchwork of population based studies, observational cohorts, national interview surveys, reviews of physician practice patterns, hospital system databases, cancer registries, state health department health information systems, and federal, state and private insurance claims based datasets that can provide useful health statistics. These information sources contain a wealth of epidemiological and health services information about health care costs, access and quality as well as trends in the diagnosis and management of urological diseases. However, these sources have remained largely untapped.

We undertook a project, Urologic Diseases in America, to quantify the burden of urological diseases on the American public. At the behest of the American Foundation for Urologic Disease and the American Urological Association as well as the scientific community in urological health services research the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) funded this endeavor and provided guidance and supervision in selecting the clinical conditions, data sets and analytic approaches. Herein we describe the analytic methods and survey the principal findings of the project. More detailed presentations of the results may be found in a series of articles to be published in *The Journal of Urology*® in the coming months. Additional details on the analytical methodology and technical programming are provided in the compendium.[2]

METHODS

Clinical conditions. We stratified the scope of urological practice into 12 discrete clinical areas for analysis. Limited resources allowed us to address only common urological diagnoses. The Appendix lists the topics selected for inclusion in Urologic Diseases in America, of which the first 4 were covered in an interim compendium available on line at no charge at http://www.niddk.nih.gov/fund/divisions/kuh/udadoc.pdf. The final compendium, which will be available in 2006, will include all 12 conditions.

Data sets. We identified a large number of public and private data sources, and compared their specific characteristics, uses, benefits and limitations based on criteria that included 1) availability of information of the data collection process, eg the unit of observation and reliability of the data, 2) issues related to study design, eg the target population and whether incidence or prevalence data were available, 3) analytical information, eg whether adjustment for sample design characteristics such as clustering was necessary, 4) the robustness of the data set relative to others available to assess the same clinical condition and 5) the estimated time required to procure and analyze the data set. Ultimately with approval from the NIDDK we selected 3 complementary groups of data sets (table 1) that allowed us to paint a broad picture of the burden of urological diseases in America.

The first group described the Medicare program experience with urological conditions. The data sets were derived from the Centers for Medicare and Medicaid Services (CMS) administrative records as a complete or a 5% sample (weighted to represent the national Medicare population). These samples have adequate power to detect significant racial and ethnic differences in the use of procedures and tests.[3] These data sets include the Medicare inpatient sample, the Medicare carrier file (previously referred to as the Physician/Part B file) and the hospital outpatient file. The Medicare denominator file supplied data on all Medicare beneficiaries enrolled in the years analyzed.

The second group included 5 other nationally representative data sets that allowed the computation of national estimates of resource utilization, costs and for some conditions prevalence. Data on inpatient utilization measures were obtained from the Healthcare Cost and Utilization Project (HCUP)-Nationwide Inpatient Sample performed by the Agency for Healthcare Research and Quality. Data on physician office, hospital outpatient and emergency room (ER) utilization measures were obtained from 2 surveys done by

TABLE 1. *Data sets analyzed for Urologic Diseases in America*

Database	Group	Purpose
Group 1:		
CMS-Medicare Provider Analysis + Review	Medicare	Records of hospital inpt services for Medicare beneficiaries
CMS-Carrier file	Medicare	Claims submitted by noninstitutional providers for Medicare beneficiaries
CMS-Outpt file	Medicare	Claims submitted by institutional outpt providers for Medicare beneficiaries
CMS-Denominator file	Medicare	Demographic + enrollment information on Medicare beneficiaries
Group 2:		
HCUP-Nationwide Inpt Sample	Disease burden national estimate	National sample of inpt stays + hospitalizations
NAMCS	Disease burden national estimate	National sample of ambulatory care use
NHAMCS-Outpt + ER components	Disease burden national estimate	National sample of ambulatory care services in hospital emergency + outpt departments
MEPS	Disease burden national estimate	National sample of health care use, expenditures + payment sources
NHANES	Disease burden national estimate	National survey to ascertain disease and risk factor prevalence, biometric data
Group 3:		
NNHS	Target populations	National sample of nursing homes, providers of care + their residents
VA-OPC files	Target populations	Veterans + outpt services use
MarketScan Health + Productivity Management database	Disease cost	Fortune 500 company inpt and outpt medical claims providing productivity and pharmacy data for employees and their dependents
Ingenix database	Disease cost	Medical claims database providing use + cost data on 75 large employers
NACHRI	Target populations	Pediatric inpt stays at member hospitals only
CHCPE	Target populations	Private health insurance claims experience for urological conditions

the National Center for Health Statistics, namely the National Ambulatory Medical Care Survey (NAMCS), and the outpatient and emergency department components of the National Hospital Ambulatory Medical Care Survey (NHAMCS). We supplemented our analyses with the household component of the Medical Expenditure Panel Survey (MEPS), a population based survey that allowed us to create nationally representative estimates of expenditures. Finally, we examined data from the population based National Health and Nutrition Examination Survey (NHANES) to estimate nationally representative disease prevalence for urinary incontinence and urinary tract infection.

The third group of data sets targeted an array of unique populations not completely captured in the databases described, including children, the elderly, veterans and 2 populations that allow us to combine data to perform a cost analysis, that is the privately insured and the employed populations. Sources included the National Nursing Home Survey (NNHS) and the Veterans Health Administration (VA) Outpatient Clinic (OPC) data set. The urology subset of the MarketScan Health and Productivity Management database provided unique information on indirect costs (eg work absences associated with medical services for urological conditions). Data from the Ingenix claims data set were used to model costs of care. To enhance the analysis of the burden of urological illnesses on the pediatric population we also examined data from the National Association of Children's Hospitals and Related Institutions (NACHRI), and private claims data from the Center for Health Care Policy and Evaluation (CHCPE).

Collectively these data sets allowed us to construct a comprehensive evaluation of all primary service utilization categories, namely 1) inpatient stays, 2) physician office visits, 3) hospital outpatient visits, 4) ER visits and 5) ambulatory surgery center visits. The data also enabled us to derive estimates of disease prevalence for some conditions.

Analytical approach. For each condition we developed a set of codes from the National Center for Health Statistics International Classification of Diseases, 9th revision (ICD-9), the American Medical Association Current Procedural Terminology and the Healthcare Common Procedure Coding System to define relevant diagnoses, diagnostic procedures and therapeutic interventions. We applied these codes to analytical files from each data set. We stratified results into major demographic groups, usually by age, gender, race/ethnicity, geographic region, rural/urban and insurance status. When relevant, we age adjusted the final tables. For certain economic analyses we constructed multivariate models. We received guidance on our analytical approach from an External Consultation and Advisory Committee appointed by the NIDDK.

For Medicare data after linking the files we used dates and scrambled personal identifiers from facility records in the inpatient and outpatient files to ascertain the number of visits to hospitals, emergency rooms, hospital outpatient departments and ambulatory surgery centers. We next linked identifiers and dates of service for these visits to the matching line items listing payment for services recorded in the carrier file. We developed an algorithm to assign the remaining carrier file line items and outpatient file records to the appropriate place of service. Utilization of physician office visits was determined by examining line items in the carrier file for appropriate place of service and physician evaluation and management billing codes. We used this approach to calculate average payments for each condition by place of service. Average cost per service unit was calculated by dividing this total by the number of disease related visits to that place of service. Hospitalization or facility visit was used as the unit of analysis for the number of claims for each type of service. Rates were standardized to the Medicare population for that year. CIs were calculated using standard methods for proportions.[4]

For the other nationally representative data sets, we first identified visits for specific urological conditions. Analytical files for outpatient visits included records of visits with a relevant diagnosis code listed as *any* of the reasons for the visit. We produced tables reflecting service use when the relevant codes were listed as the *primary* reason or as *any* of the reasons for the visit. Analytical files for inpatient stays included only records for which a relevant diagnosis code was listed as the *primary* diagnosis during the hospitalization. Analyses were done at the visit level or the stay level depending on the database. MEPS was used to calculate payments for all services and derive nationally representative estimates of outpatient prescription drug use.

For NHANES the frequency of individual yes answers and answers regarding the intensity of symptoms was tabulated by gender, age and other demographic variables. Using formulas provided by National Center for Health Statistics raw counts were weighted to give nationally representative estimates of disease prevalence if 1) the unweighted counts equaled at least 30 and 2) the estimates had a relative standard error of less than 30%. When insufficient data were available, subgroups (eg age categories) were combined to create adequate unweighted counts. In some instances unweighted corresponding counts for conditions in NHAMCS Outpatient and NAMCS were combined to provide reliable estimates of overall outpatient service use. HCUP cell sizes were always large enough to produce reliable estimates (30 or greater) without combining or regrouping of stratification variables. To create an estimate of the burden of outpatient visits for urological conditions in relation to the total burden of illness represented by outpatient visits national estimates of visits for urological conditions within various subpopulations were divided by national estimates of the total number of outpatient visits for the demographic groups of interest. This number was multiplied by 100 to generate a percent. National annual inpatient and outpatient visit rates were calculated using the United States Census noninstitutionalized civilian population estimates corresponding to demographic and visit characteristic groupings for each survey year used.

NACHRI staff created an analytical file containing all inpatient discharges reported at member institutions for which a relevant urological code appeared as the primary diagnosis for admission. Mean values and counts for these variables were compared with those provided by NACHRI to ensure data integrity after importation. One-way ANOVA was used to generate CIs for the frequency and mean of desired variables.

For the NNHS the analytical approach followed that used for the other nationally representative data sets except urolithiasis, sexually transmitted diseases and pediatric conditions were excluded due to small sample sizes.

VA OPC event files were used to identify all unique cases of each urological condition in 1999 through 2001. Prevalence estimates were then created by first (or *primary*) diagnosis and by *all* diagnosis codes. Prevalence rates are presented in total, and by select demographic characteristics and geographic features as unique cases per 100,000 population of veteran users served by the VA in each year studied. The unit of analysis is the patient. A patient who had more than 1 qualifying diagnosis code was counted as a single case. Similarly a patient with 1 or more qualifying diagnosis codes at more than 1 VA health care facility was counted only once. VA data represent the population of all adult veteran users of VA health care services during the years under study. Therefore, CIs are not included for the calculated rates. Denominator data were obtained on all adult veteran outpatient users and then refined based on age, gender or other restrictions of Urologic Diseases in America conditions to generate

unadjusted prevalence rates for the number of cases per 100,000 population.

For CHCPE data records were linked using common fields, such as member and physician identifiers and dates of service. The enrollment file includes date of birth, gender and dates of enrollment and disenrollment. The physician and facility files contain unique identifiers, services performed, diagnosis codes, place of service, billed amounts and payments, and the insurance plan under which the service falls. Diagnoses are coded using ICD-9-CM codes and procedures are coded using ICD-9-CM procedure codes or Current Procedural Terminology-4 procedure codes. Claims from out of network facilities are included. Analyses were done on members of 15 commercial and Medicaid health plans located in 4 regions (Midwest, Northeast, South and West) of the United States. Data on commercial and Medicaid health plan members were reported separately because these populations tend to differ in socioeconomic status.

Calculating costs. We measured direct resource costs with attention to having appropriate measures of utilization and unit cost. Medical expenditures were estimated by assigning prices to a comprehensive list of utilization and services. For the nonMedicare population average prices of a hospitalization, an ER admission, a hospital outpatient visit and a physician office visit were imputed based on average payments reported in MEPS. In cases for which MEPS lacked adequate statistical power to estimate reliably prices for specific services average payments from a large administrative database of private employers or Medicare claims were imputed. Average prices for outpatient prescription drugs were based on published compilations from First Data Bank[5] and *RedBook*.[6] Medicare claims were used to impute average annual growth rates in expenditures during this period. These rates were then applied to prices derived from MEPS. All expenditures for medical and pharmacy services are reported in nominal dollars. National surveys and claims based databases were relied on for deriving estimates of medical service utilization by the nonMedicare population, for which the data source depends on the type of service provided (table 2). Medicare claims were used to estimate utilization and average reimbursements for the Medicare population. Medicare does not provide full coverage for all services. Moreover, because beneficiaries pay deductibles and co-insurance expenses that are not included in the Medicare claims, we followed CMS recommendations to inflate Part A payments by 8% and Part B payments by 38%.[7]

For indirect costs we used the MarketScan Health and Productivity Management database to derive the average work loss associated with each condition. These data are collected through employer payroll systems and they include detailed information on when employees are out of work, the number of hours missed and the reasons for absences. Reasons for absence include sickness, disability, vacation and other types of leave. Absence data are linked to eligibility files and medical claims to estimate the hours of work loss associated with each condition.

Limitations. Our analytical approach had several inherent limitations. We found that for many urological conditions population based data sets contained limited information on true prevalence. Many conditions were not studied in prevalence surveys or they were studied in limited fashion. To buttress our analysis we turned to published estimates of prevalence and incidence drawn from specific population based studies focusing on various urological conditions. For *de novo* analyses we relied heavily on data sets that use administrative coding systems such as the ICD-9 CM to identify disease burden. Reliance on such administrative codes can result in the underestimation or overestimation of utilization depending on the sensitivity and specificity of the disease code in question.

Quality assurance. We implemented a systematic 5-step approach to ensure the accuracy and consistency of the results generated from these analyses. 1) For the first level of review required confirmation that the base populations used for each database were appropriate for each condition (eg the population at risk for benign prostatic hyperplasia included only males 40 years and older, whereas the 2 sexes are at risk for sexually transmitted diseases). Total frequencies were examined to ensure that there was no double counting of cases. 2) Individual frequencies were evaluated within patient subgroups to ensure appropriate counts. Inconsistent frequencies were flagged for review. For example, the incidence of a particular condition should not be more or less common among divorced than married persons and this inconsistency might be identified for further review. 3) Rates were compared with time for unusual secular trends and rates that appeared out of range were flagged for further review. This step was complemented by a comprehensive literature review using the relevant disease search terms to provide comparisons with published estimates. With input from chapter authors our clinical experts adjucated whether discrepancies signaled analysis errors. During this step CI calculations were reviewed to ensure that they were within the appropriate range for all reported rates. 4) A mean annual payment summary table was produced to compare payments across years and services. Any payments that appeared out of range were flagged for further evaluation. In many cases small sample size explained a wide variation. 5) Summary base population tables were generated for all conditions and years to ensure that the sum of subpopulations equaled the base population for a given year and the correct base populations were used for each year.

Interpretation of findings. After completing initial data analyses and constructing draft tables to present information on trends in incidence, prevalence, practice patterns, resource utilization and costs we convened writing committees of academic physicians with experience in health services research and detailed clinical knowledge of each condition. At these meetings we also provided detailed literature reviews that included all published, population based epidemiological and economic studies in the urological conditions of interest. Writing committee members provided expert feedback and subsequent input on the execution of additional analyses and refinement of the previous ones. After completing a final set of tables and figures we asked the writing committee members to provide insight, elaboration and interpretation, that is to draw qualitative meaning from the quantitative findings. The essays that they submitted on each clinical topic were subjected to 3 rounds of formal peer review before inclusion in the compendium. The chapter authors then distilled their work for submission to *The Journal of Urology®*. Although the principal findings have been summarized for *The Journal of Urology®*, readers are encouraged to examine the full compendium for the myriad results, both annotated and unnoted. Interested readers could explore any of these findings in more detailed, multivariate analyses.

This study received approval from the institutional review boards at University of California-Los Angeles and RAND, and it was compliant with the Health Insurance Portability and Accountability Act.

TABLE 2. *Primary data source for medical care use in nonMedicare population*

Service Type	Primary Data Source
Hospital inpt	HCUP
Hospital outpt	NHAMCS
ER	NHAMCS
Physician office	NAMCS
Outpt prescription drugs	MEPS
Nursing home	NNHS

TABLE 3. *Burden of urological diseases in America in 2000*

	No. NAMCS Office Based Physician + NHAMCS Hospital Outpt Clinic Visits		No. NHAMCS ER Visits	No. Hospital Stays	Total NAMCS, NHAMCS, HCUP + MEPS Expenditures ($ millions)
	Primary Diagnosis	Any Diagnosis			
Urolithiasis	1,996,907	2,682,290	614,647	177,496	2,067.4
Benign prostatic hyperplasia	4,418,425	7,797,781	117,413	105,185	1,099.5
Urinary incontinence:					
Female adult	1,159,877*	2,130,929	†	46,470	452.8
Male adult	†	†	†	1,332	10.3
Urinary tract infection:					
Female adult	6,860,160	8,966,738	1,311,359	245,879	2,474.0
Male adult	1,409,963	2,049,232	424,705	121,367	1,027.9

* Physician office visits only since counts not available for hospital outpatient clinics.
† Counts too low to produce reliable estimate.

TABLE 4. *Expenditures for Medicare beneficiaries with urological diseases in 1998**

	Medical Expenditures ($ million)			
	Inpt	Outpt	ER	Totals
Urolithiasis	518.9	296.1	19.4	834.4
Benign prostatic hyperplasia	315.0	441.2	19.8	776.0
Urinary incontinence:				
Female adult	110.1	123.7	0.6	234.4
Male adult	11.3	27.1	0.6	39.0
Urinary tract infection:				
Female adult	687.6	210.5	58.4	956.5
Male adult	376.4	81.4	22.4	480.2

* CMS.

RESULTS

In the coming months *The Journal of Urology*® will review and publish individual manuscripts submitted by the individuals who authored chapters for the *Urologic Diseases in America* compendium. These articles present thoughtful summaries and discussions of the data generated in this project. Furthermore, each chapter in the compendium concludes with specific recommendations for improving the available data sets to support more thorough descriptions of the impact of each condition. Table 3 recapitulates the most salient observations regarding outpatient visits, inpatient hospitalizations and costs for 2000, the most recent year of data analyzed for the interim compendium. Table 4 lists expenditures for Medicare beneficiaries with urological diseases in 1998.

DISCUSSION

By any measure the burden of urological disease on the American public is immense and it deserves further attention in terms of clinical investigation, epidemiological analysis and health services research.

We faced important challenges in our analytical endeavors. Foremost among them was the limited amount of data available on conditions in pediatric urology, particularly the lack of information on the costs of pharmaceutical and medical services. Much of the data that we analyzed was drawn from provider claims for medical services. Claims files are designed primarily to provide billing information, not detailed clinical information. Additional methodological limitations are presented in the compendium.

Accurately describing the burden of urological disease on the American public is one of the most important efforts that the NIDDK has ever undertaken. Documenting trends in epidemiology, practice patterns, resource utilization and costs for urological disease has broad implications for quality of health care, access to care and the equitable allocation of scarce resources in terms of medical services and research budgets. The Urologic Diseases in America project represents a major step toward accomplishing those goals.

APPENDIX: CONDITIONS ANALYZED IN UROLOGIC DISEASES IN AMERICA

- Urolithiasis
- Benign prostatic hyperplasia and lower urinary tract symptoms
- Urinary incontinence
  - Female
  - Male
  - Pediatric
- Urinary tract infection
  - Female
  - Male
  - Pediatric
  - Sexually transmitted diseases
- Prenatal hydronephrosis
  - Vesicoureteral reflux
  - Posterior urethral valves
  - Ureterocele
  - Ureteropelvic junction obstruction
- Male reproductive health
  - Erectile dysfunction
  - Peyronie's disease
  - Infertility
  - Undescended testis
- Urethral diseases
  - Hypospadias
  - Stricture
- Interstitial cystitis and chronic prostatitis
- Prostate cancer
- Bladder cancer
- Kidney cancer
- Testis cancer

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