

Economic Burden of Urgency Urinary Incontinence in the United States: A Systematic Review

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ABSTRACT

BACKGROUND: The International Continence Society (ICS) identifies several urinary incontinence (UI) subtypes: urgency urinary incontinence (UUI), stress UI (SUI), and mixed UI (MUI). UUI is a common symptom of overactive bladder (OAB) syndrome. Based on the current ICS definition of OAB, all patients with UUI have OAB, whereas not all patients with OAB have UUI. Because UUI is a chronic condition that is expected to increase in prevalence as the population of elderly individuals grows, it is important to understand its economic burden on society and patients and its cost components.

OBJECTIVE: To summarize the published English language medical literature on estimates of the economic burden of UUI in the United States from a societal and patient perspective, including direct costs (diagnosis, treatment, routine care [including incontinence pads], and UUI-associated comorbidities/complications); indirect costs (lost wages by patients and caregivers and lost work productivity due to absenteeism and presenteeism); and intangible costs (pain, suffering, and decreased health-related quality of life).

METHODS: A PubMed search of the literature for articles on the economic burden of UUI in the United States was conducted using the search terms (urgency urinary incontinence OR urge incontinence OR mixed incontinence OR overactive bladder) AND (burden OR cost OR economic) AND (United States), with limits for English language, publication from 1991 to 2011, humans, and adults (19+ years). Only primary articles of non-neurogenic UUI in the United States were retained.

RESULTS: Seven studies were identified that included data on the economic burden of UUI in the United States from a societal and patient perspective. Although estimates of the total economic burden of UUI include direct, indirect, and intangible costs, none of the 7 U.S. studies included all of these cost components. Furthermore, the costs of UUI often could not be fully extracted from the costs of OAB, which include patients with and without UUI, or the costs of other types of UI. The most recent cost analysis incorporated OAB with UUI prevalence rates and data on use of each cost component to calculate the total annual direct costs in 2007 for adults aged ≥ 25 years. The estimated total national cost of OAB with UUI in 2007 was \$65.9 billion, with projected costs of \$76.2 billion in 2015 and \$82.6 billion in 2020. This 2007 estimate was markedly higher than those reported in older studies. Direct costs are the main driver of the overall cost of UUI in the United States. Studies that assessed patient costs indicated that the personal costs of routine care items for UUI and MUI represent a meaningful contribution to the overall economic burden of these conditions. These substantial personal expenditures may explain why patients reported that they were willing to pay considerable amounts for a treatment that would reduce the frequency of their UUI episodes.

CONCLUSIONS: UUI in the United States is associated with a substantial economic burden from both a societal and patient perspective. Studies evaluating the impact of interventions that reduce the frequency of UUI episodes on the overall economic burden of UUI are warranted.

J Manag Care Pharm. 2014;20(2):130-40

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What is already known about this subject

- Urgency urinary incontinence (UUI) is a common chronic condition in men and women that increases in prevalence with increasing age and often remains undiagnosed and untreated.
- Estimates of the overall economic burden of UUI are dependent on the accuracy of prevalence data for UUI.

What this study adds

- A review of the literature indicates that detailed analyses of the total economic burden of UUI in the United States are limited and difficult to compare because of the different methodologies used.
- Overall, the available evidence demonstrates that UUI imposes a considerable economic burden on society and individual patients in the United States, with a substantial increase in societal costs projected to occur over the next several years with the aging of the population.
- Research on the impact of effective interventions on the economic burden of UUI is warranted.

The International Continence Society (ICS) identifies several urinary incontinence (UI) subtypes: urgency urinary incontinence (UUI), defined as the complaint of involuntary loss of urine associated with urgency; stress UI (SUI), defined as the complaint of involuntary loss of urine on effort or physical exertion or on sneezing or coughing; and mixed UI (MUI), defined as the complaint of involuntary loss of urine associated with urgency and with exertion, effort, sneezing, or coughing (i.e., UUI and SUI).^{1,2} UUI is a common symptom of overactive bladder (OAB) syndrome, defined by the ICS as urinary urgency, usually accompanied by frequency (typically defined in clinical trials as ≥ 8 micturitions per 24 hours) and nocturia (defined by the ICS as ≥ 1 micturition interrupting sleep), with or without UUI, in the absence of urinary tract infection or other obvious pathology.^{1,2} UUI is a highly bothersome symptom that affects many aspects of a patient's health-related quality of life (HRQL).³⁻⁶ UUI is also a driver of health care-seeking behavior, although approximately 3 of 4 individuals with UUI do not receive treatment.⁶ Based on the current ICS definition of OAB, all patients with UUI have OAB, whereas not all patients with OAB have UUI.

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TABLE 1 Studies of the Prevalence of UUI in the United States

Study	Sample	Survey (Response Rate)	UUI Definition/Questions	UUI Prevalence
Coyne et al. 2012; Coyne et al. 2011 (EpiLUTS Survey) ^{3,15}	20,000 adults (9,416 men; 10,584 women) aged ≥ 40 years	Population-based, cross-sectional, Internet survey in 2007-2008 (60%)	2002 ICS 1. During past 4 weeks, did you leak urine in connection with sudden need to rush to urinate? <i>Response:</i> yes/no 2. During past 4 weeks, how often have you leaked urine in connection with a sudden need to rush to urinate? <i>Response:</i> <once a month/a few times a month/a few times a week/daily/many times a day UUI=(1) yes and (2) at least a few times a month	<i>By gender:</i> 14.2% for men; 30.8% for women Of subjects with OAB symptoms (prevalence: men 27.2%, women 43.1%), 52.3% of men and 71.5% of women reported UUI.
Dooley et al. 2008 (NHANES) ⁷	4,229 white, black, and Mexican-American community-dwelling women aged ≥ 20 years	NHANES 2001-2004 representative-sample, interview survey	During the past 12 months have you leaked or lost control of even a small amount of urine with an urge or pressure to urinate and you could not get to the toilet fast enough? UUI=UUI only MUI=UUI and SUI	<i>Women:</i> UUI only 7.9%; MUI 17.0% <i>By age:</i> UUI: 4.6% for 20-39 years; 8.7% for 40-59 years; 11.7% for ≥ 60 years MUI: 7.7% for 20-39 years; 18.6% for 40-59 years; 28.7% for ≥ 60 years <i>By race:</i> UUI: 7.5% for whites; 11.0% for blacks; 7.5% for Mexican-Americans (white women significantly lower OR for UUI than black women after adjusting for age, BMI, live births, diabetes) MUI: 17.8% for whites; 14.3% for blacks; 13.2% for Mexican-Americans
Diokno et al. 2007 (NFO Survey) ⁸	21,590 male heads of household aged ≥ 18 years matched to 2000 U.S. Census for age, geographic region, income, household size	Cross-sectional mail survey in 2001 (67%)	UUI=yes to ≥ 1 of 2 questions on leakage or loss of urine because of an urge to urinate with no advanced warning during last 30 days; MUI=reported ≥ 1 UUI and ≥ 1 SUI symptom	<i>Men:</i> 4.3% of men aged ≥ 18 years reported UUI; 1.8% reported MUI <i>By age:</i> UUI and MUI prevalence rates increase with age in men (UUI: ~30% and 57%; MUI: ~15% and 22% for 18-35 years and > 75 years)
Thom et al. 2006 (RRISK) ⁹	2,109 women aged 40-69 years as of 1999 with goal of ~20% black, ~20% Hispanic, ~20% Asian-American, ~40% white	Population-based cohort study with self-report questionnaires and interviews	≥ 1 episode in last 12 months (with a physical sense of urgency), by < monthly, monthly, weekly, or daily frequency UUI=UUI only or MUI with the majority of episodes being urge (rather than stress)	<i>Women:</i> 9.7% (UUI only and MUI predominantly UUI ≥ weekly, adjusted for age) <i>By race:</i> UUI only (≥ weekly): 4.8% for whites; 7.6% for blacks; 5.8% for Hispanics; 3.0% for Asian-Americans ($P < 0.03$) MUI (predominantly urge; ≥ weekly): 4.0% for whites; 6.0% for blacks; 4.2% for Hispanics; 4.4% for Asian-Americans (not significant) MUI (equal urge and stress; ≥ weekly): 3.3% for whites; 1.9% for blacks; 5.3% for Hispanics; 3.2% for Asian-Americans (not significant) UUI only or MUI with the majority of episodes being urge (≥ weekly): OR similar in black, Hispanic, and Asian-American women vs. white women after adjusting for age, parity, hysterectomy, estrogen use, BMI, menopausal status, diabetes
Jackson et al. 2004 (Health, Aging, and Body Composition Study) ¹⁰	1,558 white and black, community-dwelling, well-functioning women aged 70-79 years with UI question data	Cross-sectional analysis of longitudinal cohort study with enrollment in 1997-1998	In the past 12 months: when does your leakage of urine usually occur? <i>Response (UUI):</i> when you have the urge to urinate and can't get to the bathroom quick enough.	<i>Women:</i> 8.9% (UUI ≥ weekly; 138 of 1,558 women) <i>Multivariate analyses:</i> significantly higher adjusted ORs for white race (OR=3.1), current estrogen use (OR=1.7), arthritis (OR=1.7), diabetes treated with insulin (OR=3.5), depressive symptoms (OR=2.7), and decreased lower extremity physical performance (OR=1.6) for women with UUI ≥ weekly vs. those with no UI

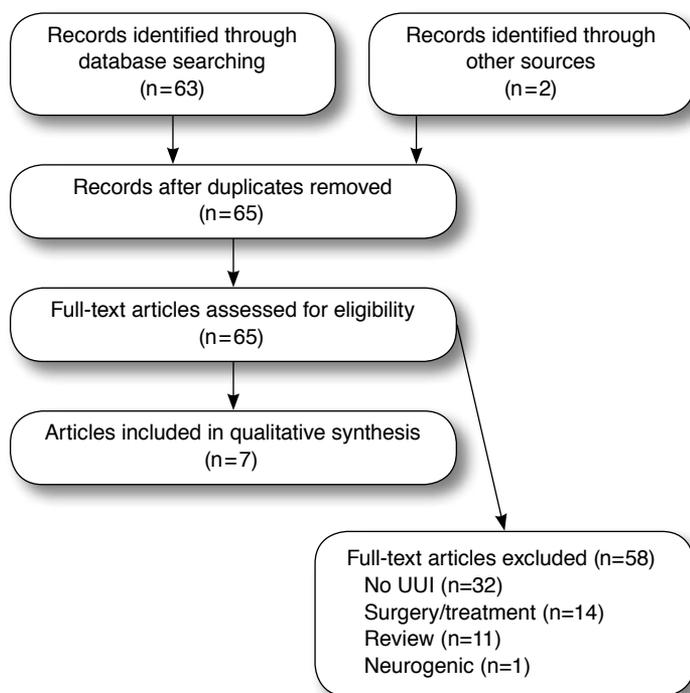
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TABLE 1 Studies of the Prevalence of UII in the United States (*continued*)

Study	Sample	Survey (Response Rate)	UII Definition/Questions	UII Prevalence
Stewart et al. 2003 (NOBLE Program) ⁵	5,204 adults aged ≥ 18 years (2,469 men; 2,735 women)	Population-based, cross-sectional, telephone survey in 2000-2001 (68%)	1. ≥ 4 urgency episodes in the last 4 weeks 2. Either ≥ 8 micturitions/day or use of a coping strategy 3. ≥ 3 episodes of urinary leakage in the past 4 weeks not due exclusively to SUI	Overall: 6.1% (2.6% for men; 9.3% for women; did not vary by race) for adults aged ≥ 18 years By age: significantly steeper age-related increase in women vs. men (e.g., 19.1% for women aged 65-74 years vs. 8.2% for men aged 65-74 years)
Espino et al. 2003 (Hispanic EPESE) ¹¹	1,589 Mexican-American women aged ≥ 65 years	Community-based, in-home interview in 1993-1994	Do you have a feeling of needing to urinate before you lose your urine?	Women: UII 5.0%; MUI 6.3%
Sze et al. 2002 ¹²	2,370 (932 white, 799 black, and 639 Hispanic) women aged 15-94 years from gynecology clinics	Clinic-based survey in 2000-2001	Do you lose urine less than 5 minutes after you feel the urge to urinate more than once per week?	Women: UII: 16% for whites; 19% for blacks; 16% for Hispanics (<i>P</i> =0.214) MUI: 15% for whites; 14% for blacks; 9% for Hispanics (<i>P</i> <0.001) By race: Nulliparous Hispanic women aged <30 years were significantly more likely to have UII or MUI than black or white women (<i>P</i> =0.002); multiparous black women aged 30-50 years were significantly more likely to have UII than Hispanic or white women (<i>P</i> =0.008); multiparous black or white women aged 30-50 years were significantly more likely to have UII or MUI than Hispanic women (<i>P</i> =0.011)
Brown et al. 2000 (SOF) ¹³	6,049 community-dwelling white women aged 72-99 years from population-based listings at 4 clinical centers who provided UI information and 1 follow-up on falls	Longitudinal survey in 1994-1996	1. During the last 12 months, have you ever leaked or lost control of your urine? If yes: 2. How often does this leakage of urine usually occur: daily, ≥ 1 times per week but not every day, ≥ 1 times per month but not every week, <once per month? 3. Under what circumstances does your leakage of urine usually occur: when I cough/sneeze/laugh/lift/stand up/exercise, etc. (SUI); when I have the urge to urinate and can't get to the toilet fast enough (UII); when I am sleeping/napping/dozing (other) UII=(1) yes and (2) ≥ weekly and (3) UII	Elderly women: 24.7% of women aged 72-99 years reported UII; 11.7% reported MUI
Nygaard et al. 1996 (Iowa 65+ Rural Health Study of EPESE) ¹⁴	2,025 women aged ≥ 65 years	6-year, longitudinal, community-based survey in 1981-1982 (baseline)	How often do you have difficulty holding your urine until you can get to the toilet? Response: never, hardly ever, some of the time, most of the time, all of the time UII= ≥ some of the time	Elderly women: 36.3% at baseline (increased with increasing age; <i>P</i> =0.017)

BMI=body mass index; EPESE=Establishment of Populations for Epidemiology Studies of the Elderly; EpiLUTS=Epidemiology of Lower Urinary Tract Symptoms; Health ABC=Health, Aging, and Body Composition; ICS=International Continence Society; MUI=mixed urinary incontinence; NFO=National Family Opinion; NHANES=National Health and Nutrition Examination Survey; NOBLE=National Overactive Bladder Evaluation; OAB=overactive bladder; OR=odds ratio; RRISK=Reproductive Risks of Incontinence Study at Kaiser; SOF=Study of Osteoporotic Fractures; SUI=stress urinary incontinence; UI=urinary incontinence; UII=urgency urinary incontinence.

FIGURE 1 PRISMA Flow Diagram of Article Identification, Inclusion, and Exclusion



PRISMA = Preferred Reporting Items for Systematic Review and Meta-Analysis;
 UUI = urgency urinary incontinence.

UUI-specific prevalence data can be difficult to locate in the medical literature because they are often embedded within OAB or overall UI prevalence data. To date, the prevalence of UUI among adults in the United States has been estimated in 10 studies conducted from 1981 to 2007 (Table 1).^{3,5,7-15} The overall prevalence of UUI (both UUI alone and MUI [i.e., UUI and SUI]) ranged from 2.6%⁵ to 14.2%³ in U.S. men and from 8.9%¹⁰ to 36.3%¹⁴ in U.S. women in these studies. The variability in data from these studies results at least in part from differences in UUI definitions (e.g., frequency, severity); the question and response formats used (e.g., yes/no vs. Likert scale responses); the characteristics of the populations studied (e.g., age, gender); and survey administration (e.g., face-to-face interview, mail survey, telephone survey, internet survey). Of the 10 UUI prevalence studies conducted in the United States, only 3 studies surveyed men,^{3,5,8} and only 4 studies reported UUI prevalence according to age. The data indicate that the prevalence of UUI increases with increasing age in men^{5,8} and women.^{5,7,14} As the population of older individuals increases, both in number and proportion, the estimated percentage of adults in the United States affected by UUI alone has been projected to increase by 11.1% from 2008 to 2013 and by 22.5% from 2008 to 2018, and the percentage of adults in the United

States affected by both UUI and SUI (i.e., MUI) has been projected to increase by 11.6% in 2013 and by 23.6% in 2018.¹⁶

Although variability exists in published prevalence rates, the overall evidence indicates that UUI is a common and chronic condition that affects millions of U.S. adults, and the number of affected individuals is expected to increase with the continued aging of the population. Because UUI is a prevalent condition, it is important to understand its economic burden to society and the individual patient and to identify the components contributing to this burden. A complete and up-to-date estimate of the economic burden of UUI is crucial to the proper allocation of health care resources.

The total economic burden of UUI includes 3 categories of expenditures: direct costs (diagnosis, treatment, routine care [including incontinence pads], and UUI-associated comorbidities/complications); indirect costs (lost wages by patients and caregivers and lost work productivity due to absenteeism and presenteeism); and intangible costs (pain, suffering, and decreased HRQL).¹⁷ Intangible costs are difficult to assess but can be estimated using quality-adjusted life years or the willingness-to-pay method. The purpose of this review is to summarize the published medical literature on estimates of the economic burden of UUI on society and patients in the United States.

Methods

A search of the literature on the economic burden of UUI in the United States was conducted using PubMed on March 17, 2012, and updated September 7, 2012, based on the recommendations in the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) statement.¹⁸ The following search terms were used to identify relevant articles: (urgency urinary incontinence OR urge incontinence OR mixed incontinence OR overactive bladder) AND (burden OR cost OR economic) AND (United States), with limits for English language, publication from 1991 to 2011 (electronic or print), humans, and adults (19+ years). Criteria for inclusion or exclusion of retrieved articles were determined a priori; article review was conducted independently by 3 reviewers. Articles reporting data on direct costs (diagnosis, treatment, routine care [including incontinence pads], and UUI-associated comorbidities/complications); indirect costs (lost wages by patients and caregivers and lost work productivity due to absenteeism and presenteeism); and/or intangible costs (pain, suffering, and decreased HRQL) were included if they provided costs specifically for adults with UUI only or MUI or adults with OAB with UUI. Articles were excluded if they were (a) non-U.S. studies; (b) reviews or comments; (c) primarily assessing neurogenic UUI, UUI diagnosis, UUI treatment/management outcomes, pregnancy-associated UUI, surgery-associated or surgically treated UI, or questionnaire validity; (d) duplicate articles; or (e) updated in a more recent article. References cited in the retained articles were

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TABLE 2 Studies Reporting Economic Burden of UUI in the United States

Study	Sample	Analysis Perspective/ Design	Cost Components	Model and Data Used in Cost Assessments	Reported Costs (USD Year)	Adjusted Costs (USD 2012) ^a
National Studies						
Ganz et al. 2010 ²⁰	All subjects aged ≥25 years with OAB (urgency with UUI) from community and institutions	Societal/prospective	<i>Direct costs:</i> physician visits, diagnostic laboratory tests, anticholinergic medications, OTC medications, physical therapy, surgical procedures, ER visits, UTI treatment, falls/fractures costs, OAB-related depression costs, OAB-related nursing home costs, costs of pantliners, pads, diapers, latex gloves, bedside toilet, skin protection <i>Indirect costs:</i> lost work productivity of patient	Cost-of-illness, prevalence-based model, with costs based on administrative data, using NOBLE study age- and gender-specific prevalence data for OAB with UUI, U.S. Census Bureau data, usage data, and NOBLE study work productivity data; U.S. Census population projections were used to project the costs to 2015 and 2020 <i>Limitations:</i> intangible costs not included	<i>Overall costs (USD 2007):</i> Annual per capita: \$1,925 Total annual: \$65.9 billion <i>Direct costs (USD 2007):</i> Annual per capita: \$1,499 Total annual: \$51.4 billion <i>Indirect costs (USD 2007):</i> Annual per capita: \$426 Total annual: \$14.6 billion <i>Projected costs:</i> Annual per capita: \$1,944 in 2015; \$1,969 in 2020 Total annual: \$76.2 billion in 2015; \$82.6 billion in 2020	<i>Overall costs:</i> Annual per capita: \$2,132 Total annual: \$73.0 billion <i>Direct costs:</i> Annual per capita: \$1,660 Total annual: \$56.9 billion <i>Indirect costs:</i> Annual per capita: \$472 Total annual: \$16.2 billion
Hu et al. 2004 ²¹	Adults aged ≥18 years with UI and/or OAB from community and institutions	Health care professionals and policy makers/prospective	<i>Direct costs for UUI and MUI (community):</i> pharmacologic treatment costs <i>Direct costs for UUI and MUI (institution):</i> diagnostic, pharmacologic treatment, routine care, and consequence costs (skin, UTIs, falls/fractures)	Incremental cost-of-illness, prevalence-based model, with costs based on administrative data, using pooled daily UI prevalence data (men 5%; women 12%) and NOBLE OAB prevalence data, study treatment data, consequence probabilities, cost estimates <i>Limitations:</i> only direct costs reported for UUI and MUI; intangible costs not included; only pharmacologic treatment costs reported by type of UI for community-based adults	<i>Direct costs for UUI and MUI (community; USD 2000):</i> Annual cost UUI and MUI treatment: \$210 million <i>Direct costs for UUI and MUI (institution; USD 2000):</i> Total annual: \$3.5 billion (diagnosis \$16.0 million; pharmacologic treatment \$3.7 million; routine care \$3.4 billion; consequence \$78.9 million)	<i>Direct costs for UUI and MUI (community):</i> Annual cost UUI and MUI treatment: \$280 million <i>Direct costs for UUI and MUI (institution):</i> Total annual: \$4.7 billion (diagnosis \$21.3 million; pharmacologic treatment \$4.9 million; routine care \$4.5 billion; consequence \$105.2 million)
Hu et al. 2003 ²³	Adults with OAB with UUI in a nursing home	Societal/prospective	<i>Direct costs:</i> diagnostic costs, treatment costs, routine care costs, and consequence costs (skin, UTIs, bone fractures)	Cost-of-illness, prevalence-based model, with costs based on administrative data, using method of aggregating individual-level data pertaining to the average cost of treatment or supply use, multiplied by the average amount of health care use	<i>Direct costs of OAB+UUI (institution; USD 2000):</i> Total annual: \$2.85 billion Routine care: \$2.77 billion Other: \$0.08 billion Annual per capita: \$5,635	<i>Direct costs of OAB+UUI (institution):</i> Total annual: \$3.80 billion Routine care: \$3.69 billion Other: \$0.11 billion Annual per capita: \$7,513
Wilson et al. 2001 ²⁴	Adults of all age groups from community and institutions	Societal/prospective	<i>Direct costs:</i> routine care, diagnostic evaluation, treatment (surgical, behavioral, pharmacologic), consequences (skin, UTIs, falls), nursing home admission	Prevalence-based model, with costs based on administrative data, using UI prevalence data from published studies, U.S. Census Bureau data, diagnosis and treatment algorithms, and mean Medicare reimbursement data <i>Limitations:</i> assumptions regarding those residing in community vs. institution and type of UI in community; indirect and intangible costs not included; only pharmacologic treatment cost reported by type of UI	<i>Total treatment (USD 1995):</i> \$1.3 billion (SUI 82%; MUI 12%; UUI 4%)	<i>Total treatment:</i> \$2.0 billion

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TABLE 2 Studies Reporting Economic Burden of UUI in the United States (continued)

Study	Sample	Analysis Perspective/ Design	Cost Components	Model and Data Used in Cost Assessments	Reported Costs (USD Year)	Adjusted Costs (USD 2012) ^a
Patient-Based Studies						
Subak et al. 2007 (RRISK) ²⁷	Population-based study conducted from 1999 to 2003 of 528 community-dwelling women aged 40-69 years with ≥ weekly UUI, MUI, or SUI	Patient/prospective	<i>Direct costs:</i> routine care (pads, diapers, laundry, dry cleaning, other)	Direct costs of routine care of UI were calculated using actual prevalence data, actual resource use, and mean national unit costs <i>Limitations:</i> Other direct costs, indirect costs, and intangible costs not included	<i>Direct costs of routine care (USD 2005):</i> Mean cost/wk: \$6.35 for MUI; \$6.02 for UUI; \$3.91 for SUI Mean annual cost: \$330 for MUI; \$313 for UUI; \$204 for SUI Among women with UI-related cost in multivariate analysis: Routine care cost was 42% higher for MUI vs. SUI (P=0.05)	<i>Direct costs of routine care:</i> Mean cost/wk: \$7.47 for MUI; \$7.08 for UUI; \$4.60 for SUI Mean annual cost: \$388 for MUI; \$368 for UUI; \$240 for SUI
Subak et al. 2006 (DAISy) ²⁸	Cross-sectional survey of 293 community-dwelling women aged ≥40 years with ≥3 UI episodes/wk; seeking treatment; not treated in prior 3 months conducted in 2005 at 5 sites	Patient/prospective	<i>Direct costs:</i> routine care (pads, diapers, toilet paper, paper towels, laundry, dry cleaning) <i>Intangible costs:</i> WTP for improvement in incontinence episode frequency	Direct costs of routine care of UI were calculated using actual resource use and national resource cost data; patient-reported WTP for UI improvement were assessed by UI type, with proportion of patients WTP plotted according to cost and stratified by percent improvement expected <i>Limitations:</i> Other direct costs and indirect costs not included; only assessed untreated women seeking treatment; WTP can be sensitive to survey methodology and statistical analyses used	<i>Direct costs of routine care (USD 2005):</i> Median cost/wk: \$6.57 for UUI; \$3.96 for MUI; \$2.31 for SUI In multivariate analysis: Cost ratio (95% CI) vs. SUI: 1.7 (1.3-2.1) for UUI (P<0.001); 1.5 (1.0-2.1) for MUI (P=0.05) <i>Intangible costs (USD 2005):</i> Women WTP mean of \$28/month (\$336/year) for 25% improvement, \$39/month (\$468/year) for 50% improvement, \$49/month (\$588/year) for 75% improvement, \$70/month (\$840/year) for 100% improvement in UI frequency (P<0.001); WTP not significantly associated with UI subtype	<i>Direct costs of routine care:</i> Median cost/wk: \$7.72 for UUI; \$4.66 for MUI; \$2.72 for SUI <i>Intangible costs:</i> Women WTP mean of \$33/month (\$395/year) for 25% improvement, \$46/month (\$550/year) for 50% improvement, \$58/month (\$691/year) for 75% improvement, \$82/month (\$988/year) for 100% improvement in UI frequency (P<0.001)
O'Connor et al. 1998 ²⁹	257 non-randomly selected patients with UUI or MUI who completed a self-administered mail survey in 1997	Patient/prospective	<i>Intangible costs:</i> WTP for reduction in micturitions and urine leakages	Contingent valuation method, with relation between hypothetical costs and proportion of patients agreeing to purchase at given costs generating a demand curve <i>Limitations:</i> nonrandom sample; WTP can be sensitive to survey methodology and statistical analyses used	<i>Intangible costs (USD 1997):</i> For a 25% reduction in UUI/MUI symptoms, 70% of respondents willing to pay \$10/month and 4% willing to pay \$400/month. For a 50% reduction in UUI/MUI symptoms, 95% of respondents willing to pay \$10/month and 13% willing to pay \$400/month. Median willingness to pay was \$27/month for 25% reduction and \$76 for 50% reduction in symptoms.	<i>Intangible costs:</i> For a 25% reduction in UUI/MUI symptoms, 70% of respondents willing to pay \$14/month and 4% willing to pay \$572/month. For a 50% reduction in UUI/MUI symptoms, 95% of respondents willing to pay \$14/month and 13% willing to pay \$572/month. Median willingness to pay was \$39/month for 25% reduction and \$109 for 50% reduction in symptoms.

^aAdjusted costs for 2012 were calculated using Consumer Price Index inflation calculator from U.S. Department of Labor, Bureau of Labor Statistics.¹⁹

CI=confidence interval; DAISy=Diagnostic Aspects of Incontinence Study; ER=emergency room; MUI=mixed urinary incontinence; NOBLE=National Overactive Bladder Evaluation; OAB=overactive bladder; OTC=over the counter; RRISK=Reproductive Risks of Incontinence Study at Kaiser; SUI=stress urinary incontinence; UI=urinary incontinence; USD=U.S. dollars; UTI=urinary tract infection; UUI=urgency urinary incontinence; wk=week; WTP=willingness to pay.

reviewed for additional articles. It was planned a priori that the 3 reviewers would discuss any inclusion/exclusion discrepancies; no such discrepancies occurred. Overall, of 63 articles retrieved by the PubMed search and 2 articles that were cited references in the retrieved articles, 7 peer-reviewed articles that included U.S. cost data for UII were retained (Figure 1). Data were qualitatively summarized. Cost data reported in the retained articles were adjusted to 2012 U.S. dollars (USD) using the Consumer Price Index inflation calculator from the U.S. Department of Labor, Bureau of Labor Statistics.¹⁹

Results

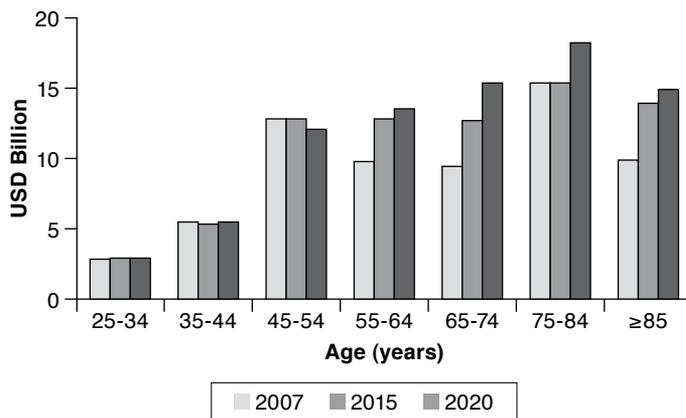
Seven national and patient-based studies that estimate the economic burden of UII in the United States are summarized in Table 2.

U.S. National Studies

The most recent prevalence-based model by Ganz et al. (2010) incorporated age- and sex-specific prevalence rates of OAB with UII, data on the use of various cost components, and work productivity data from the NOBLE study to calculate annual per capita and total U.S. costs (i.e., direct and indirect costs) for 2007 among community-dwelling and institutionalized adults aged ≥ 25 years. In addition, U.S. Census forecasts were used to project the costs for 2015 and 2020.²⁰ The average annual per capita cost (USD in 2007) of OAB with UII was estimated to be \$1,925 (\$1,433 direct medical costs, \$66 direct nonmedical costs, and \$426 indirect costs). After applying these costs to the total number of adults in the United States with OAB with UII, the total national cost was \$65.9 billion (\$49.1 billion direct medical costs, \$2.3 billion direct nonmedical costs, and \$14.6 billion indirect costs). The average annual per capita cost in 2015 and 2020 is projected to be \$1,944 and \$1,969, respectively. The total national cost is projected to be \$76.2 billion in 2015 and \$82.6 billion in 2020, with the highest costs incurred by patients aged 75-84 years (Figure 2).²⁰ These cost projections suggest that the total cost of OAB with UII will increase by 25% from 2007 to 2020 in the United States, largely because of the aging of the population, and will be driven by direct costs rather than indirect costs. As a result, these increasing costs will be borne primarily by patients and private health insurance enrollees.²⁰

In 2004, Hu et al.²¹ reported costs for OAB with UII in community-dwelling and institutionalized adults aged ≥ 18 years using an incremental cost-of-illness, prevalence-based model that was based on prevalence data for daily UI²² and NOBLE study⁵ prevalence data, treatment data, consequence probabilities, and cost estimates based on USD in 2000. Because it was often not possible to separate costs for UI and OAB due to data limitations (i.e., UI costs included the costs for patients with OAB and UII, and OAB costs included costs for UII), the annual cost for pharmacologic treatment in community-dwelling adults (\$210 million) and the total annual

FIGURE 2 Projected Total Annual National Costs Associated with Urgency or UII from 2007 to 2020 in the United States



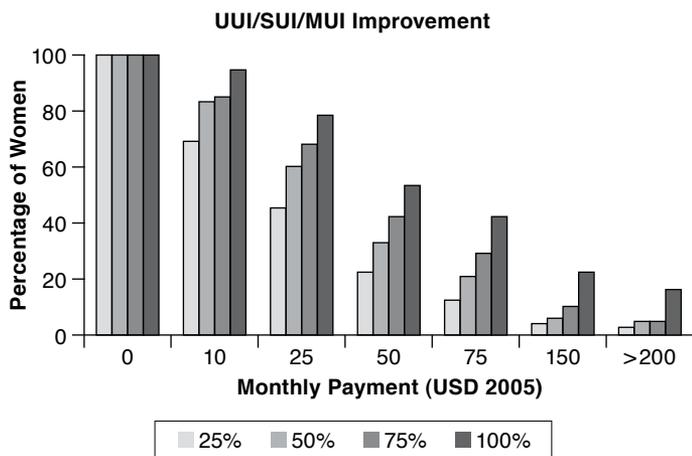
Adapted from Ganz et al., *Economic costs of overactive bladder in the United States*.²⁰

USD = U.S. dollars; UII = urgency urinary incontinence.

direct cost for institutionalized adults (\$3.5 billion) were the only UII-specific cost data reported.²¹ The cost of routine care, including absorbent pads, was \$3.4 billion, which represented the primary contributor to the total annual direct cost of UII and MUI.²¹ An annual direct cost for UII and MUI in institutionalized adults of \$2.9 billion (based on USD in 2000) was reported by Hu et al. in 2003 (Table 2).²³

A high annual direct cost of UI in the United States was also reported in an analysis using a prevalence-based model and diagnostic and treatment algorithms from published clinical practice guidelines, UI prevalence data from published studies, and Medicare reimbursement data.²⁴ The annual direct cost (USD in 1995) of UI was \$16.3 billion (\$12.4 billion for women, \$3.8 billion for men). Among women, the annual direct cost was \$8.6 billion for those in the community versus \$3.8 billion for those who were institutionalized. The annual direct cost was higher for women aged ≥ 65 years (\$7.6 billion) than for those aged < 65 years (\$3.6 billion). Overall, the largest direct cost category was routine care (\$11.3 billion; 70% of total direct costs), followed by nursing home admissions (\$2.4 billion), treatment (\$1.3 billion), complications (\$1.0 billion), and diagnosis/evaluations (\$0.2 billion). However, only the cost of treatment (behavioral, pharmacologic, and surgical) was analyzed according to UI subtype. For women, 85% of the total UI treatment cost was for SUI, 12% was for MUI, and 2% was for UII; for men, the corresponding percentages were 55%, 14%, and 22%.²⁴ Thus, the treatment costs for UII and MUI combined contribute less to overall UI treatment costs than the treatment cost for SUI.

FIGURE 3 Willingness to Pay for Improvement in Incontinence Frequency by Women in the United States with UII, SUI, or MUI



Adapted from Subak et al., The "costs" of urinary incontinence for women.²⁸ MUI=mixed urinary incontinence; SUI=stress urinary incontinence; USD=U.S. dollars; UII=urgency urinary incontinence.

U.S. Patient-Based Studies

The cost of routine care (e.g., pads, diapers, laundry, and dry cleaning) from the patient perspective accounts for the majority of direct nonmedical costs associated with UII in community dwellers.²⁴ Routine care costs, especially for community-dwelling adults, are often borne by the individual patient or family members because patients frequently do not discuss their symptoms with or seek treatment from health care providers.^{6,25,26} In a population-based study conducted from 1999 to 2003, 528 racially diverse, community-dwelling women aged 40-69 years (mean age, 57 years) with UII (UII alone or MUI with UII predominant), SUI (SUI alone or MUI with SUI predominant), or MUI (neither UII or SUI predominant) with ≥ 1 event per week were assessed as part of the Reproductive Risks for Incontinence Study at Kaiser (RRISK).²⁷ Annual out-of-pocket costs (in 2005 USD) for routine care (i.e., pads, diapers, laundry, dry cleaning, other) were notably higher for women with UII (\$313 per year) or MUI (\$330 per year) than for those with SUI (\$204 per year). In a multivariate analysis model that included women with UI-related costs, the cost of routine care was higher for MUI than for SUI ($P=0.05$). In addition to MUI, increased UI severity, African-American race, and increased body mass index were significant predictors of higher routine care costs.²⁷ The Diagnostic Aspects of Incontinence Study (DAISy), conducted in 2005 by Subak et al., estimated the out-of-pocket costs (USD 2005) for 293 women with UII (UII alone or MUI with UII predominant), SUI (SUI alone or MUI with SUI predominant), or MUI (neither UII

nor SUI predominant).²⁸ The results indicated that the most frequently used item was pads (74% of respondents; mean cost \$1.69 per week, range \$0.06-\$19.93 per week), but the most expensive items were diapers (5% of respondents; mean cost \$33.84 per week, range \$2.60-\$91.11 per week), dry cleaning (18% of respondents; mean cost \$17.29 per week, range \$4.82-\$67.34 per week), and laundry (57% of respondents; mean cost \$6.09 per week, range \$2.50-\$20.00 per week).²⁸

The value of intangible costs (in 2005 USD) was also estimated in DAISy using assessments of women's willingness to pay for a treatment that would decrease the frequency of their incontinence episodes by 25%, 50%, 75%, and 100%.²⁸ The 293 women (mean age, 56 years) reported that they were willing to pay a mean of \$28 per month (\$336 per year) for a 25% improvement, \$39 per month (\$468 per year) for a 50% improvement, \$49 per month (\$588 per year) for a 75% improvement, and \$70 per month (\$840 per year) for a 100% improvement in their UI frequency ($P<0.001$; Figure 3).²⁸ In a multivariate logistic regression model, the willingness to pay for a 50% and 100% improvement was not significantly associated with the subtype of UI.²⁸ In a study conducted by O'Connor et al. (1998), 332 nonrandomly selected members of the National Association for Incontinence (mean age, 65 years) with self-reported UII or MUI responded to a self-administered mail survey in 1997.²⁹ A total of 257 patients reported their willingness to pay for a treatment that would reduce their micturitions and urine leakage episodes. Patients reported that they were willing to pay a mean of \$87.74 per month for a 25% reduction and \$244.54 per month for a 50% reduction. For a 25% reduction in symptoms, 70% of respondents reported a willingness to pay \$10 each month, whereas 4% were willing to pay \$400 each month. For a 50% reduction in symptoms, 95% would be willing to pay \$10 monthly, and 13% would be willing to pay \$400 monthly.²⁹ As willingness to pay is a hypothetical assessment, the amounts that patients actually would pay are unknown.

The indirect cost of lost wages for patients with UII or their caregivers was not estimated in any of the patient-based studies.

Discussion

Current studies reporting the total national cost of UII in the United States are based on different analysis models, different populations, different cost components, and different prevalence estimates. However, the evidence consistently indicates that UII places a substantial economic burden on society. Because the prevalence of UII increases with age and the number of individuals aged ≥ 65 years will increase over the next decade, the prevalence rates of UII alone and MUI are also expected to increase.¹⁶ The most recent analysis of direct costs for OAB plus UII among adults aged ≥ 25 years estimated an annual national cost of \$82.6 billion in 2020.²⁰

The results of patient-based studies indicate that the personal costs of routine care items for patients with UII or

MUI in the United States represent a meaningful contribution to the overall economic burden of these conditions. Perhaps because of these personal expenditures, patients reported that they would be willing to pay substantial additional amounts for a treatment that would reduce the frequency of their UUI episodes. Of note, the cost of lost wages for patients and caregivers associated specifically with UUI was not estimated in any study.

Possible approaches to reducing the significant economic burden of UUI are worthy of discussion. Toward this end, an accurate understanding of the cost components and their relative contribution to the overall costs of UUI are crucial. Direct costs are the main driver of the overall cost of UUI in the United States, with the cost of routine care items (e.g., diapers, incontinence pads) borne largely by the patient accounting for the majority (70%) of direct costs, followed by the costs of nursing home stays (14%), treatment (9%), complications (6%), and diagnosis/evaluations (1%).²⁴ Similar results for the breakdown of the contributors to the direct costs of OAB (incontinence pads, 63%; physician visits, 20%; drugs, 10%; and complication treatment, 7%) in 5 European countries were reported by Reeves et al. (2006), with the direct costs for patients with UUI representing 70% of the direct costs of the overall OAB population.³⁰ Of note, the cost of treatment (behavioral, pharmacologic, and surgical) of UUI and MUI in the United States in 2001 was markedly less than that of SUI in both men and women.²⁴

The first-line pharmacologic treatment for OAB symptoms, including UUI, is antimuscarinic therapy. U.S. Food and Drug Administration (FDA)-approved antimuscarinics indicated for the treatment of OAB symptoms include darifenacin (Enablex), fesoterodine (Toviaz), oxybutynin (Ditropan; Oxytrol), solifenacin (Vesicare), tolterodine (Detrol), and trospium (Sanctura), with oxybutynin and tolterodine available as generic products. Oxybutynin (Oxytrol) was approved by the FDA in 2013 as an over-the-counter treatment for women with OAB symptoms. Other recently licensed drugs for the treatment of OAB symptoms include onabotulinumtoxinA (Botox), an acetylcholine release inhibitor and neuromuscular blocker, and mirabegron (Myrbetriq), a β_3 -adrenoceptor agonist.

Based on the relative contribution of the costs of incontinence pads and nursing home stays versus the cost of treatment, it has been suggested that effective treatment of UUI and its complications may lessen the direct costs and economic burden of UUI.^{24,27,28}

The results of other studies suggest that effective treatment of UUI may lead to a reduction in resource utilization and result in cost containment. A study of 441 adults aged ≥ 18 years with diagnosed OAB, including 76% reporting UUI, who were followed up from the U.S. National Health and Wellness Survey found that patient-reported treatment success with prescription medications for OAB was associated with significantly lower rates of health care resource consumption

(health care provider visits, $P=0.02$; incontinence pad use, $P<0.001$) and fewer complications (urinary tract infections, $P<0.013$; skin infections, $P=0.034$; falls, $P=0.017$) compared with unsuccessful management.³¹ In a cohort study of 43,367 subjects aged ≥ 18 years who had at least 1 OAB symptom (i.e., UUI, urinary frequency, nocturia, bladder dysfunction) or were taking an antimuscarinic medication, annual direct medical costs (medications and all other pharmacy claims); outpatient care costs (emergency department visits, physician visits, laboratory tests, all outpatient services); and inpatient hospitalization costs were estimated in 2007 USD and compared with 43,367 matched nonpharmacologically managed patients.³² As expected, patients treated with pharmacologic medication had significantly higher mean annual pharmacy costs (\$2,796) compared with nonpharmacologically managed patients (\$2,150; $P<0.001$). However, patients treated with pharmacologic medication had significantly lower annual OAB-related outpatient care costs (\$176 vs. \$277; $P<0.001$) and inpatient costs (\$47 vs. \$93; $P<0.001$) than nonpharmacologically managed patients.³² Finally, the results of a longitudinal cohort study of 275 patients aged ≥ 65 years with OAB symptoms, including UUI, and taking antimuscarinic medication indicated that increased antimuscarinic adherence was the most significant predictor of decreased annual costs for health care services in a managed care setting.³³

Overall, these results suggest that successful treatment can result in lower costs for health care services. Future research is needed to evaluate the impact of early diagnosis on the overall economic burden of UUI. In addition, controlled studies are needed to assess the impact of long-term treatment with drug therapy and behavioral modification on UUI costs. Finally, the effects of patient age and disease severity on national and patient costs of UUI need to be evaluated.

Limitations

There are several limitations of published articles that estimate the economic burden of UUI in the United States and, thus, of this review of those articles. First, the estimation of the economic burden of UUI is directly related to UUI prevalence data used in the cost analysis model; however, there is considerable variability in estimates of the prevalence of UUI, which is likely attributable to methodological differences among prevalence studies. As a result of the variability in UUI prevalence data, estimates of the economic burden of UUI also are highly variable. Second, few studies have estimated the economic burden of UUI in the United States without confounding from costs for OAB without UUI or other subtypes of UI. Third, cost estimates from different studies are not standardized to comparable U.S. dollar amounts. Because UUI is a large cost driver for patients with OAB, it is important to have accurate and up-to-date data on the costs that are attributable specifically to UUI. Recent studies of prevalence, which is a key component in many analysis models used for estimating economic

burden, provide data for UUI, MUI, and SUI, thereby allowing a distinction among the different subtypes of UI. Future economic analyses will need to incorporate this same approach to improve the accuracy and our understanding of the costs specific to UUI, as well as the other UI subtypes.

Conclusions

UUI is a chronic and age-related condition that imposes a substantial economic burden on society and individual patients in the United States. Estimates of the overall costs of UUI are highly dependent on the accuracy of prevalence data and the cost components included in the analysis model, making it difficult to ascertain the true cost of UUI based on the limited number of available studies. Controlled studies of the impact of effective interventions that reduce the frequency of UUI episodes on the economic burden of UUI are warranted.

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DISCLOSURES

Funding for this study was provided by Pfizer Inc.

Coyne is an employee of United Biosource Corporation who was a scientific consultant to Pfizer. Wein consults/advises for Astellas, Allergan, Endo, Medtronic, Theravida, Pfizer, Ferring, Opko, Ethicon, Uroplasty, and Merck. Nicholson has been a consultant to Pfizer in connection with developing economic models of the costs associated with diabetes, cardiovascular disease, smoking, and urinary incontinence and has received grant support from Pfizer, Merck, J&J, and AstraZeneca. Kvasz was an employee of Pfizer PIO at the time this study was conducted; Chen is currently employed by Pfizer China. Milsom is a scientific consultant for Pfizer Inc. and United Biosource Corporation; has been an investigator for Pfizer and Astellas and a lecturer for Pfizer, Astellas, Recordati, SCA and Novartis; and has received grant support from Pfizer and Astellas.

All authors contributed equally to study concept and design, data interpretation, and writing and revision of the manuscript. Kvasz, Chen, and Coyle were responsible for data collection.

ACKNOWLEDGMENTS

Medical writing and literature-searching assistance was provided by Patricia B. Leinen, PhD, and Colin P. Mitchell, PhD, of Complete Healthcare Communications, Inc., and were funded by Pfizer Inc.

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