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## The Burden of Overactive Bladder on US Public Health

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### Abstract

Overactive bladder (OAB) is a highly prevalent symptom condition that affects millions of US men and women. Not only can the symptoms of OAB be very bothersome, but OAB can have significant detrimental effects on many aspects of individuals' lives, representing a particularly impactful health burden to quality of life and productivity. Estimates of the individual and societal costs for the management of OAB continue to rise, particularly as effective treatments remain elusive. As such, OAB represents a significant public health burden to the USA.

### Keywords

Overactive bladder; Public health; Epidemiology; Health economics

### Introduction

Overactive bladder (OAB) is a symptom syndrome defined by urinary urgency (i.e., the sudden compelling desire to pass urine that is difficult to defer), with or without urge urinary incontinence (UI), usually with frequency and nocturia [1]. As OAB is highly prevalent in the US population and accounts for considerable societal costs, it represents a significant public health burden to the USA. The aim of this review is to summarize the public health aspects of OAB in the USA related to: the epidemiology of OAB; the detrimental burden OAB places on individuals and society; treatment considerations that contribute to public health; healthcare utilization dedicated to OAB management; and finally, economic perspectives.

### Epidemiology of OAB

Epidemiologic research specific to OAB has only really been emphasized during the past decade. Historically, imprecise definitions of OAB have significantly hindered

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#### Compliance with Ethical Standards

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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epidemiologic studies; however, the codification of OAB by the International Continence Society [1] in 2002 represented a significant advancement for the field. Several studies have examined the US prevalence of OAB. One of the first US population-based studies to focus on OAB was the National Overactive Bladder Evaluation (NOBLE) study [2]. The NOBLE study was a nationwide, random sample, computer-assisted telephone survey with a nested case-control follow-up study of participants with OAB and controls. Selective sampling was used to generalize participants to the US population based on age, gender, and geographic region; 5204 participants completed the interview. Investigators defined OAB based on a composite definition incorporating the presence of urgency, frequency, and coping strategies, with and without urge UI. Based on this definition, NOBLE study investigators determined the national prevalence of OAB to be 16.5 %; 10.4 % of OAB without urge-UI and 6.1% of OAB with urge-UI. The prevalence of overall OAB was similar in women and men (16.9 vs. 16.0 %). However, while the prevalence of OAB with and without urge-UI was similar in women (9.3 and 7.6 %, respectively), men were more likely to have OAB without than with urge-UI (13.4 and 2.6 %, respectively).

The EpiLUTS study was a large, population-based, cross-sectional internet survey conducted in the UK, Sweden, and USA to evaluate the prevalence and symptom-specific bother of OAB and other lower urinary tract symptoms [3]. In the USA, 31,588 respondents completed the survey, making EpiLUTS one of the largest population-based epidemiologic study specifically focusing on OAB [3, 4]. Defined by the presence of urinary urgency at least “sometimes” and/or urge-UI, 43 % of female and 27 % of male respondents reported OAB. With a more restrictive definition of at least “often,” the prevalence of OAB was 33 % for women and 16 % for men.

Using methods similar to the EpiLUTS study, investigators for the OAB on Physical and Occupational Limitations (OAB-POLL) study recruited 10,000 US adults to complete internet survey information regarding OAB symptoms, demographic and clinical characteristics, and physical activity data in order to estimate the prevalence of OAB and LUTS and the effects of OAB on work productivity and physical functioning [5••]. The study selectively recruited subjects to reflect national demographics for age, gender, and race/ethnicity based on US Census data. The authors defined OAB similarly to the EpiLUTS study, as urgency at least “sometimes” and/or the presence of urge UI. Based on this definition, the overall prevalence of OAB in the total US population was 23.3 %, with women reporting OAB almost twice as frequently as men (30.0 vs. 16.4 %, respectively).

Other studies have examined the prevalence of OAB based primarily on definitions of urge-UI, rather than on non-UI symptoms. One of the most representative studies in the USA is the National Health and Nutrition Examination Survey (NHANES). NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the USA [6]. The survey combines interviews and physical examinations from a nationally representative sample of the US population. Participants are asked several questions specifically related to urinary incontinence. According to whether a women experienced any incontinence in the previous 12 months, 7.9% of US women report urge-UI and 17 % mixed-UI [7].

Recently, the prevalence of OAB was systematically reviewed as part of an Agency for Healthcare Research and Quality (AHRQ)-sponsored comparative effectiveness report on treatment of OAB women [8]. Based on data from 15 studies specifically providing information about OAB in women in the USA, approximately 15.1 % of US women report OAB and 11.0 % report OAB with urge urinary incontinence (UUI).

Collectively, these data demonstrate that OAB affects a significant proportion of the US population and thus represents a significant public health burden by numbers alone. Compounding this is the fact that OAB seems to effect select groups of individuals more frequently than others. Multiple studies have consistently demonstrated that the prevalence of OAB increases with increasing age, with peak rates in the elderly [2–4, 5••]. The prevalence of OAB also varies by race/ethnicity for both men and women. Based on data from the EpiLUTS study, the prevalence of OAB is 33.3 % in African-American (AA) men, 28.0 % in Hispanic men, 27.0 % in Asian men, and 26.3 % in White men. OAB was reported by 45.9 % of AA, 43.4 % of White, 42.0 % of Hispanic, and 26.6 % of Asian women [9]. Data from the OAB-POLL study on racial prevalence are slightly different, even though methods were similar [5••]: OAB prevalence was higher for AA (20.2 %) men than Hispanic (18.1 %) or white men (14.6 %); and for women, OAB was prevalent in 32.6 % of AA, 29.0 % of Hispanic, and 29.4 % white women. NHANES data on UI supports that AA women report the highest prevalence of urge-UI (11.0 %) over white and Mexican-American women (7.5 and 7.5 %, respectively) [7].

## Health Burden of OAB on Individuals

Individuals with OAB report significant impairment to overall quality of life [10]. In an online survey of US women with symptoms of OAB [11], 39 % reported that OAB interfered with daily activities, including 12% for whom their symptoms caused them to stay at home; 38 % reported decreased physical activities because of OAB, while 34 % attributed weight gain because of an inability to exercise. Women with OAB were also significantly more likely than those without OAB to report disturbed sleep, decreased self-esteem, decreased sexuality, and feelings of overall declining health. Findings from the NOBLE study also demonstrated significant effects of OAB on health-related quality of life as measured by validate surveys (i.e., SF-36), with greater effects attributable to the presence of urge-UI than OAB without UI [2]. Investigators from the EpiLUTS study similarly reported significant detrimental effects of OAB on health-related quality of life, primarily for participants with bothersome OAB [4]. Interestingly, in this study, bother was most highly correlated with urinary urgency; urge UI and nocturia were less correlated.

Many authors have described the associations between psychological conditions and OAB, which further compound the health burden OAB invests in affected individuals. Kinsey et al. recently systematically reviewed the psychological impact of OAB [12]. In this analysis, results from 32 papers reveal that the most widely studied associations are depression and anxiety. However, their results also suggest that OAB significantly affects self-esteem, sexuality, and relationships. Personal embarrassment and shame are common themes as well. Overall, individuals with concomitant incontinence (OAB and urge-UI) reported more difficulties than those without UI. Vrijens et al. specifically reviewed 43 articles examining

depression and anxiety in individuals with OAB [13], with moderate evidence supporting these associations.

Recent studies have also focused on other aspects of health on which OAB may be a particular burden. The recent OAB-POLL study specifically examined the effects of OAB symptoms on physical activity [14]. As described above, investigators recruited 10,000 US adults to complete survey information regarding OAB symptoms, demographic and clinical characteristics, and physical activity data. For both men and women, individuals with OAB were significantly less likely to report moderate and vigorous physical activity in their leisure time. Furthermore, those with OAB were less likely to satisfy current national recommendations on physical activity issued by the US Department of Health and Human Services and US 2010 Healthy People objectives. For men, only 60.9 % of those with OAB met physical activity guidelines (compared to 67.5 % without OAB,  $p < .001$ ) and 46.1 % met 2010 Healthy People objectives (compared to 54.3 % without OAB,  $p < .001$ ). For women, 50.1 % of those with OAB met physical activity guidelines (vs. 58.1 % of those without OAB,  $p < .0001$ ) and 34.7 % met 2010 Healthy People initiatives (vs. 45.2 % of those without OAB,  $p < .0001$ ).

OAB also appears to have significant detrimental effects on occupation and work productivity as assessed by the OAB-POLL study [15]. Survey respondents completed validated instruments measuring the contribution of health conditions to work productivity and impairment. Almost uniformly men and women with OAB noted significantly increased impairment to all aspects of occupation compared to those without OAB, including factors such as work time missed and impairment while working due to urinary symptoms. Unemployment was higher for those with OAB than without (men: 43.6 vs. 24.2 %,  $p < .0001$ ; women: 54.1 vs. 41.4 %,  $p < .0001$ ) and remained significant when controlled for multiple variables in men (OR 1.48; 95 % CI, 1.2–1.8), but not women (OR 1.12; 95 % CI, 0.95–1.32).

Comparing similar variables related to work productivity, Tang et al. examined results of a survey of male and female patients with OAB that had had at least some exposure to anticholinergic medications [16]. The authors report that patients with OAB and urge-UI generally had greater work productivity impairment than those with OAB but no UI. Even after adjusting for demographic and clinical co-variables, individuals with OAB and UI were impaired during work 9.21 % more of the time and experienced overall work impairment 10.5 % more of the time than those without UI.

Administrative disability claims also demonstrate effects of OAB on occupational performance. In a study comparing disability claims in individuals with OAB and controls, those with OAB were found to have 2–3 more work loss days due to medically related absenteeism (RR 1.2,  $p < .01$ ) and due to disability (RR 1.7,  $p < .01$ ) than those without OAB [17]. Interestingly, about 14 % of individuals with OAB went on disability compared to 11 % of non-OAB controls over a 2.5-year observation period. Those with OAB had significantly shorter times (6 months sooner) to disability than those without OAB.

## Management and Treatment Considerations on OAB Health Burden

An important public health consideration of OAB relates to the gap between the presence of symptoms and seeking and receiving treatment for symptoms. This difference represents the so-called iceberg phenomenon [18], whereby relatively few individuals in the population who have OAB seek care and even fewer receive care. In fact, individuals with symptoms of OAB often delay seeking treatment or even discussing their symptoms with healthcare providers. In one study, women who had discussed OAB symptoms with a provider had waited on average 3.1 years after the onset of symptoms [11]. For those who had never discussed OAB symptoms, 84% did not think the problem was important enough, 71 % were not asked about OAB by a healthcare provider, and 69 % thought OAB symptoms were just something to live with. Even among those who had discussed their symptoms with a provider, 64% thought OAB was something they had to live with and 32% were not aware that anything could be done about it. Overall, only 44 % of women surveyed reported being asked about OAB symptoms by their provider.

Increased symptom severity or bother appears to be a driving force for patients to seek treatment. According to data from the EpiLUTS study in the USA, both men and women with bothersome OAB were more likely to have sought treatment from a healthcare professional than those either without bother (men: 35 vs. 19 %,  $p < .001$ ; women: 27 vs. 13 %,  $p < .001$ ) or without OAB (men: 35 vs. 4 %,  $p < .001$ ; women: 27 vs. 4 %,  $p < .001$ ) [4].

Similarly, both men and women with bothersome OAB from the EPIC study reported initiating a conversation about their symptoms with a healthcare provider (52 vs. 22 % of those without bother,  $p < 0.05$ ) [19]. In addition, those who did initiate a conversation were more likely to be older than 50 years (OR 1.5; 95 % CI, 1.2–2.0), complain of UI (OR 1.5; 95 % CI, 1.1–2.0), report duration of OAB symptoms of more than 4 years (OR 1.9; 95% CI, 1.5–2.5), and have had a doctor visit in the previous 6 months for any reason (OR 2.8; 95% CI, 2.0–3.9). Men were more likely than women to initiate a conversation about their symptoms (OR 1.6; 95 % CI, 1.2–2.2).

An important aspect to consider about the public health burden of OAB is that it remains difficult to treat effectively. Pharmacotherapy is generally efficacious based on individual clinical trials; however, in aggregate, the mainstay of pharmacotherapy, anticholinergic medications, is only modestly superior to placebo [20]. In a recent comparative effectiveness review of anticholinergic agents for OAB, meta-analyses of data from 50 randomized controlled trials estimated that daily agents reduced urge incontinence by 1.73 episodes per day (95 % CI 1.37–2.09) and voids by 2.06 per day (95 % CI 1.66–2.46). By comparison, placebo reduced daily incontinence episodes by 1.06 (95 % CI 0.7–1.42) and voids by 1.2 (95 % CI 0.72–1.67). Similar findings were reported for achieving continence in women with urge incontinence: about 20 % of cases of continence were attributable to anticholinergic pharmacologic agents [21].

Furthermore, persistence or compliance with pharmacotherapy remains a significant barrier to effectively managing OAB. Data from a large, US representative prescription claims database of 103,000 individuals with OAB suggest that 92 % of patients with OAB failed

initial treatment with anticholinergic medication within 2 years [22]. Most (82 %) discontinued therapy altogether and within the first 6 months after initial prescription. Only 5.8 % switched therapy to a different agent.

Sexton et al. performed a recent systematic review specifically examining adherence to anticholinergic agents [23]. According to their results, up to 31 % of participants in 12-week clinical trials discontinue therapy; in longer observational studies, this can be as high as 72 %, with higher discontinuation rates seen with longer follow-up. Often discontinuation resulted from intolerance of adverse effects. Based on studies examining medical claims data, including prescription claims, 43 to 83 % of patients discontinue medication with the first 30 days after initial prescription and over half do not refill their initial prescription.

Among participants in the BACH study, OAB medication use was very limited in those who reported OAB [24]. Overall, only 1.7 % of the female population reported the use of OAB medications; in men, this was less than 1 %. As might be expected, OAB medication use was highest for men (1.3 %) and women (5.8 %) with moderate/severe OAB symptoms; for those with UI, 0.7 % of men and 7.9 % of women with moderate/severe symptoms reported using medications.

In the 5-year follow-up BACH study [25], the prevalence of medication use for lower urinary tract symptoms (including, but not limited to, OAB medication) remained very low: overall only 2.5 % reported taking medication at baseline and follow-up; 4.2 % reported medication use during follow-up visit only. Men were more likely to be on medications than women, and individuals with moderate to severe lower urinary tract symptoms (defined by a score of 8 on the AUA symptom index) were more likely to be on medications than those without symptoms (19.6 vs. 5.4 %).

Primary reasons for discontinuing OAB medications are often unmet treatment expectations (46 %) and side effects (21 %); cost appears to be an important consideration as well (17 %) [26]. In recognition of these barriers to medication persistence, recent guidelines on the diagnosis and management of OAB published by the American Urological Association (AUA) and the Society for Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) specifically recommend addressing and managing adverse events before abandoning medical therapy [27, 28••]. The guidelines also provide approaches to managing patients with inadequate treatment responses, in order to avoid discontinuation.

## US Healthcare Resource Utilization for OAB

Information on US healthcare resource utilization is overall lacking for OAB. Most health services research studies using claims-based data sources have focused on urinary incontinence generally, rather than on OAB specifically. In one of the only studies to examine healthcare utilization for OAB, Ju et al., using data from the 2009 US National Ambulatory Medical Care Survey, estimated that US women made 8.1 million ambulatory visits (i.e., 1.6 % of all ambulatory visits) that were associated with anticholinergic OAB medications [29]. This represents an annual rate of 68 visits per 1000 women. The majority of these women were white (70 %) and insured with Medicare (61 %).

Participants of the EpiLUTS survey study were asked about annual visits to healthcare professionals [4]. Both men and women with OAB reported more visits to healthcare professionals for any cause in the previous year, especially for those reporting bother with their symptoms. On average, men and women with OAB with bother reported twice as many annual visits to healthcare providers than those without OAB (men:  $6.1 \pm 7.1$  vs.  $2.9 \pm 4.3$ ,  $p < .001$ ; women:  $6.0 \pm 8.1$  vs.  $3.2 \pm 4.4$ ,  $p < .001$ ).

## Economic Impacts of OAB

From a patient's perspective, the brunt of costs associated with OAB tends to be for routine care, such as incontinence pads, diapers, and laundry, generally reflecting the burden of UI. Based on results from the Reproductive Risks for Incontinence Study at Kaiser (RRISK) study, which was a survey of women participating in Kaiser Permanente Medical Care Program in California, women with urge- or mixed-UI annually spent significantly more on routine care costs than those with stress-UI alone (\$313 and \$330 vs. \$204, respectively, 2005 US dollars) [30]. Similar results were reported from analyses of data from participants in the Diagnostic Aspects of Incontinence Study (DAISy), in which women with urge- and mixed-UI spent 50 % more on routine care costs than those with stress-UI alone [31].

Several studies have examined the total economic impact of OAB from a societal perspective. Ganz et al. modeled total societal costs, including direct (i.e., medical and non-medical costs) and indirect costs (i.e., lost productivity), and OAB prevalence to determine that the average US annual per capita costs of OAB in 2007 were \$1925 (\$1433 in direct medical, \$66 in direct nonmedical, and \$426 in indirect costs) [32]. Factoring in a prevalence of OAB of 34 million people in the USA resulted in estimates of total national costs of \$65.9 billion. Based on forecasted increases in US population, the projected national costs in 2015 and 2020 were \$76.2 billion and \$82.6 billion, respectively. Estimates of per capita costs were similar between men and women, although direct non-medical costs were generally higher for women than men, likely reflecting greater incontinence. Per capita costs also increased markedly for individuals aged 65 and older, from approximately \$1500 for those <65 to over \$6500 for those >85. Total national US costs peak at ages 45–54 (\$12.5 billion) and 75–84 (\$15.3 billion).

Onukwugha et al. used prevalence data from the EpiLUTS study as well as claims-based costs for direct medical care (OAB drug therapy, outpatient and inpatient services) and published costs for indirect societal costs to calculate OAB disease-specific US societal costs [33]. Based on an overall prevalence of urgency and/or urge incontinence of 18.6 % of the US population, the authors estimated disease-specific total US cost of OAB to be \$24.9 billion (in 2007 US dollars), including \$22.3 billion in direct costs. Women accounted for a significantly larger proportion of total costs than men (\$18.8 billion compared to \$6.1 billion). In this analysis, higher total costs were attributable to individuals less than 65 years old compared to older ones (\$19.4 billion vs. 7.9 billion). Sensitivity analyses suggest that total costs were most sensitive to variations in the average outpatient costs, cost of pads, and the cost of lost worker productivity, although variation in the prevalence of OAB is also a significant factor.

Previously, Hu et al. had calculated total US societal costs (in 2000 dollars) for individuals with OAB and urinary incontinence based on survey data from the NOBLE study and publically available cost estimates for healthcare services [34]. From their analyses, they reported that total US costs of OAB were \$267 million and of UI were \$801 million in US 2000 dollars. Costs for women were generally between 1.5 and 4 times higher than for men. From an earlier study by the same group, direct medical costs for OAB, including diagnostic, treatment, and consequences costs, were almost five times as high for women as men (\$6971 million vs. \$1356 million) and twice as high for those 65 years compared to younger [35].

## Conclusions

OAB represents a significant public health burden, as it affects one out of seven US women [8] and a similar proportion of men. While the personal burden and individual costs related to OAB are high, OAB also accounts for considerable total annual US societal costs and can be difficult to treat effectively. Despite increased attention and research on OAB, there appear to be many unmet needs to improve the overall public health burden as it relates to OAB.

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