

# Burden and Treatment of Bladder Symptoms in US Adults

L Brubaker<sup>1</sup>, M Reed<sup>2</sup>, J Tierce<sup>3</sup>, Z Jumadilova<sup>4</sup>, T Bavendam<sup>4</sup>, J Benner<sup>3</sup>  
 1 Loyola University Medical Center, 2 Vedanta Research, 3 ValueMedics Research, LLC, 4 Pfizer Inc.

## 1 Introduction

Overactive bladder (OAB) is defined as urinary urgency, with or without urgency urinary incontinence, usually with frequency and nocturia [1]. No metabolic or pathologic factors definitively explain the symptoms of OAB [3].

The National Overactive Bladder Evaluation (NOBLE) reported the overall prevalence of OAB to be 16.9% in women and 16.0% in men [4] which is approximately 33.3 million adults in the US population [5].

Among the female respondents in NOBLE, 7.6% had OAB without and 9.3%

had OAB with incontinence. Among male respondents, 2.6% had OAB without and 13.6% had OAB with incontinence[4].

Subject-perceived bother due to bladder symptoms and patterns of care for OAB have not been studied in a representative national sample.

## 2 Objectives

To describe the individual-perceived burden and treatment patterns for bothersome bladder symptoms, independent of diagnosis, by identifying:

- The demographic characteristics of sufferers
- The degree to which OAB is untreated and under-treated
- Initial treatment patterns, including medical consultations and prescription medication usage

## 3 Methods

### Subjects:

- In January 2005, a bladder symptom survey was mailed to a representative US sample of 260,000 adults 18 years and older.
- The sample was drawn from the 600,000 household National Family Opinion (NFO) panel which is constructed to match the 2003 US Census on key demographics (age and gender of household head, household size, income, population density and census region).

### Survey instrument:

- The survey included the Overactive Bladder-Validated 8 (OAB-V8), a self-administered questionnaire developed to identify patients who are bothered by OAB symptoms.[2]

OAB-V8 is a short, 8-item questionnaire that asks about how bothered one is by 4 OAB symptoms: urinary frequency, urgency, nocturia, and urge incontinence. Patients respond on a 6-point Likert scale ranging from 0 (not at all) to 5 (a very great deal). Men receive 2 additional baseline points to adjust for having a lower OAB threshold.

- Subjects were considered to have a probable history of OAB if their total score was  $\geq 8$ .

### Non-responder survey:

- A telephone survey individuals (n=1,004) who did not return the written survey was conducted to quantify non response bias.

### Analytic methods:

- Grossly incomplete surveys (n=49) and those missing age and sex (n=519) were excluded from the response rate calculation and all analyses.
- Descriptive statistics and cross-tabulations were conducted to assess the population-level degree of bother due to bladder symptoms, consulting behavior, and medication use, by age and gender.

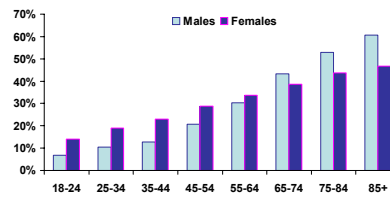
## 4 Results

- A total of 162,906 surveys were returned (63% response rate).
- Table 1 provides the sample characteristics and response rates by gender and age. The study sample approximated the 2003 US Census, with some under representation of men and younger age groups of both sexes.
- Women accounted for 55.1% of the survey sample; 21.6% of all responders were 65 years or older.
- OAB-V8 symptom bother scores  $\geq 8$  were reported by 26.6% of the total sample (23.7% of men; 28.9% of women) and increased with age (Figure 1).

Table 1. Survey Distribution and Response Rates

	Survey Response Rate (%) (n=260,000)	U.S. Population Distribution (%)	Returned Sample Distribution (%) (n=162,906)	Delta (columns 3 and 4)
<b>Males (yrs)</b>				
18-24	37.6	6.5	4.0	-2.5
25-34	43.5	9.2	6.4	-2.7
35-44	53.1	10.2	8.7	-1.5
45-54	63.4	9.2	9.5	0.1
55-64	73.8	8.2	12.2	1.0
65+	81.5	6.8	9.2	2.4
<b>Females (yrs)</b>				
18-24	42.1	6.5	4.3	-2.3
25-34	54.0	9.2	7.9	-1.3
35-44	64.1	10.5	10.4	-0.1
45-54	76.5	9.7	11.6	1.9
55-64	80.7	6.7	9.1	2.4
65+	80.5	9.3	12.4	3.1
<b>Total</b>	<b>62.7</b>	<b>100.0</b>	<b>100.0</b>	<b>---</b>

Figure 1. Percentage of Subjects with OAB-V8 Score  $\geq 8$



- OAB-V8 scores  $\geq 8$  were more common in women than in men up to age 65; the trend reversed at older ages.
- OAB-V8 symptom bother scores  $\geq 8$  by age and gender were similar between the written survey responders and those non-responders interviewed by phone.
- Of the OAB-V8 symptoms, "Waking up to urinate" was most frequent with 14.7% of subjects reporting a "very great deal," "great deal," or "quite a bit" of bother, followed by "nighttime urination" (11.1% of subjects).
- Table 2 shows the percentage of subjects that reported "a little bit" or greater bothersomeness for individual OAB-V8 questions.

Table 2. Subjects That Reported "A Little Bit" or Greater Bothersomeness

	Frequent daytime urination (%)	Overactive bladder/urgency (%)	Nocturnal urination (%)	Accidental loss of urine (%)	Nighttime urination (%)	Waking up to urinate (%)	Overactive bladder/urgency with desire to urinate (%)	Other OAB symptoms (%)
<b>Males 18-24</b>	17.6	9.5	7.5	4.6	14.9	27.6	6.4	6.5
25-34	21.3	12.6	9.8	6.8	18.7	37.3	9.1	6.5
35-44	22.7	14.3	10.8	8.5	26.2	44.7	9.8	6.5
45-54	31.3	21.9	17.4	13.8	39.8	57.6	16.4	9.3
55-64	40.2	30.5	25.1	20.6	48.1	69.4	28.4	12.9
65-74	52.6	42.2	37.1	32.1	62.2	77.2	34.7	17.1
75-84	63.3	52.3	45.3	42.1	76.0	82.1	45.3	21.2
85+	70.9	59.2	53.8	53.1	80.5	85.9	53.1	26.1
<b>Total males</b>	<b>33.8</b>	<b>24.8</b>	<b>20.2</b>	<b>16.7</b>	<b>40.5</b>	<b>55.5</b>	<b>19.1</b>	<b>13.2</b>
<b>Females 18-24</b>	33.6	22.1	19.4	19.0	24.4	44.4	15.7	10.4
25-34	37.6	26.9	23.7	32.0	31.7	57.2	18.9	13.6
35-44	40.4	29.0	27.9	42.7	38.0	60.7	22.8	20.0
45-54	45.5	33.6	33.6	50.0	48.1	69.4	28.4	20.4
55-64	50.4	37.2	37.9	52.7	58.9	72.8	32.6	24.5
65-74	54.7	40.8	42.5	54.2	67.8	77.8	37.7	24.5
75-84	60.0	45.4	47.6	58.2	77.3	81.4	45.5	28.9
85+	65.8	50.8	53.8	62.6	84.7	83.0	54.0	32.7
<b>Total females</b>	<b>45.9</b>	<b>33.4</b>	<b>33.2</b>	<b>45.4</b>	<b>48.9</b>	<b>66.1</b>	<b>28.6</b>	<b>16.5</b>
<b>Total respondents</b>	<b>40.5</b>	<b>29.3</b>	<b>27.4</b>	<b>32.5</b>	<b>46.1</b>	<b>61.3</b>	<b>24.3</b>	<b>20.5</b>

- Less than half (45.7%) of subjects with bother scores  $\geq 8$  had discussed their symptoms with a health care provider. The consultation rate was similar for men and women (Table 3). Survey responders with scores  $\geq 8$  who had discussed their symptoms with a medical provider were more likely to have received prescription medication and more likely to be currently using the medication.
- Of those with symptom bother scores  $\geq 8$ , only 8.1% have been diagnosed with OAB (Table 3). Also, only 8.1% were on treatment at the time of the survey, 22.5% had ever used a prescription medication for their bladder symptoms and 13.5% had used medication for their symptoms in the past 12 months.
- The rates of treatment with prescription OAB medications in the past 4 weeks for subjects who had discussed their symptoms with a health care provider are reported by age and sex in Figure 2.
- The rate of OAB diagnosis was twice as high (16.1%) in subjects who had discussed their symptoms with a healthcare provider.

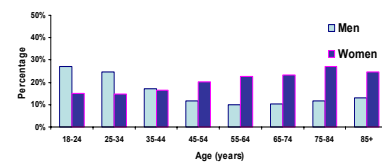
## 5 Discussion

- Many symptomatic OAB patients do not discuss their symptoms with medical professionals, despite the increased public awareness of the condition or treatment opportunities.
- A substantial proportion of the US adult population experiences some degree of bother due to bladder symptoms in the domains of nocturia, frequency, urgency, and/or urgency urinary incontinence. The burden of bothersome symptoms increased with age.
- A relatively small proportion of individuals with symptom scores indicative of probable OAB have received treatment with medication, and only a minority are currently on treatment.
- The panel data under-represent very high and low income households and ethnic minorities. But the high response rate (63%) and the ability to determine the lack of non-response bias outweigh these limitations.

Table 3. Rate of consulting for symptoms and diagnosis in subjects with positive screens for OAB

	Rate of consulting for symptoms among subjects OAB positive screens (N=43,283)	OAB diagnosis rates among positive screens
<b>Males 18-24</b>	19.9%	4.9%
25-34	21.8%	5.1%
35-44	23.8%	5.9%
45-54	32.8%	7.0%
55-64	43.7%	7.7%
65-74	58.3%	8.5%
75-84	63.7%	8.7%
85+	62.2%	8.5%
<b>Total Males</b>	<b>45.2%</b>	<b>6.8%</b>
<b>Females 18-24</b>	27.9%	6.0%
25-34	27.9%	6.9%
35-44	35.1%	6.1%
45-54	43.9%	10.4%
55-64	62.0%	11.6%
65-74	64.2%	12.0%
75-84	67.3%	11.6%
85+	67.1%	14.9%
<b>Total Females</b>	<b>49.0%</b>	<b>8.1%</b>
<b>Total Respondents</b>	<b>45.7%</b>	<b>8.1%</b>

Figure 2. Current OAB Rx by Age and Gender Among Those with OAB-V8 scores  $\geq 8$  who have Consulted with a Medical Provider (N=19,761)



## 6 Conclusions

- The burden of bothersome overactive bladder symptoms in the US adult population is substantial, yet only a small proportion of affected individuals consult with health care providers or receive treatment with prescription medications.
- Clinicians may need to be more proactive in initiating conversations about this very common condition and available treatments.
- More research is needed to understand why this apparent treatment gap exists and identify ways to reduce the burden of treatable bladder symptoms in US adults.

## 7 References

1. The standardisation of terminology in lower urinary tract function: report from the standardisation subcommittee of the International Continence Society. Urology. 2003;61:37-49.
2. Coyne KS et al. Validation of an overactive bladder awareness tool for use in a primary care setting. Advances in Therapy [in press].
3. Scott Sereis. The Wet Patient: Understanding Patients With Overactive Bladder and Incontinence. Curr Med Res Opin. 20(6):791-801, 2004.
4. Stewart WF, Van Rooyen JB, Cundiff GW, et al. Prevalence and burden of overactive bladder in the United States. World J Urol. 2003;20:327-36.
5. Wein AJ, Rovner ES. Definition and epidemiology of overactive bladder. Urology 2002;60(Suppl 5A):7-12.