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DEFINITION AND EPIDEMIOLOGY OF OVERACTIVE BLADDER

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ABSTRACT

The Standardisation Subcommittee of the International Continence Society (ICS) now recognizes overactive bladder (OAB) as a "symptom syndrome suggestive of lower urinary tract dysfunction." It is specifically defined as "urgency, with or without urge incontinence, usually with frequency and nocturia." The ICS definition was not formulated until January 2001 and was not formally approved until September 2001. Therefore, collection and discussion of the epidemiologic characteristics of OAB are somewhat hampered by the different definitions of this condition used by different investigators. Most communications that appeared before 2000 more often described characteristics of incontinence rather than OAB, and the estimates of OAB prevalence within those studies varied significantly. Until recently, little definite epidemiologic information was available on the prevalence and comorbidities of OAB. An important challenge in treating OAB is to increase awareness of this significant problem worldwide and to impress on other specialists and primary care physicians the importance of identifying this clinical problem and managing it in a way that will maximize quality-of-life improvement while minimizing morbidity. UROLOGY **60** (Suppl 5A): 7–12, 2002.
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Overactive bladder (OAB) is now classified as a symptom syndrome suggestive of lower urinary tract dysfunction by the International Continence Society (ICS).[1] A standardization subcommittee was formed because of increasing debate and discussion about various aspects of terminology and was announced at the ICS meeting in 1999. Sessions were held at the ICS annual meeting in August 2000 and at a 2-day committee meeting in London in January 2001. The latter resulted in a formalized approved draft, which was then presented to the ICS membership via the ICS Web site[2] and at the ICS meeting in September 2001. Minor changes were made at that point, and the document was formalized after an additional 2-month posting on the Web site. Specifically, OAB is now defined as denoting urgency with or without urge incontinence, usually with frequency and nocturia.

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In the document, OAB is referred to as the *overactive bladder syndrome*. Synonyms include *urge syndrome* and *urgency-frequency syndrome*. This particular section of the lexicon revision is introduced by the following quotation:

> Syndromes describe constellations, or varying combinations of symptoms, but cannot be used for precise diagnosis. The use of the word *syndrome* can only be justified if there is at least one other symptom in addition to the symptom used to describe the syndrome. In scientific communications the incidence of individual symptoms within the syndrome should be stated, in addition to the number of individuals with the syndrome. . . . The syndromes described are functional abnormalities for which a precise cause has not been defined. It is presumed that routine assessment (history taking, physical examination, and other appropriate investigations) has excluded obvious local pathologies, such as those that are infective, neoplastic, metabolic, or hormonal in nature.

The document adds that these symptom combinations are suggestive of detrusor overactivity (defined as urodynamically demonstrable involuntary bladder contractions) but can exist because of other forms of urethrovesical dysfunction. The document again restates that these terms can be used only if there is no proven infection or other obvious pathology. The document implies that

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OAB is an empirical diagnosis that can be used as the basis for initial management, after assessing the individual's lower urinary tract symptoms, physical findings, urinalysis, and other indicated investigations. The definitions and descriptions were meant to restate or update those presented in previous ICS Standardization of Terminology reports (see bibliography in the article by Abrams *et al.*[1]).

PAST DEFINITION

It is interesting that, although much argument was engendered by the use of the term *OAB*, this term was *never* actually defined or described by the ICS in any prior terminology reports. *Overactive detrusor function* (generally shortened to *overactive detrusor*) does appear,[1] and this term is defined as a condition characterized by involuntary detrusor contractions during the filling phase of cystometry, which may be spontaneous or provoked. Overactive detrusor function was then divided into detrusor hyperreflexia (caused by neurologic disease) and unstable detrusor (caused by a nonneurogenic cause), with the latter term used interchangeably with the term *idiopathic detrusor instability*. OAB was used interchangeably with overactive detrusor function and overactive detrusor, although it seems clear that this was never the intent of the ICS standardization and terminology committees.

Thus, overactive detrusor function and the terms that, correctly or incorrectly, have been used as substitutes (overactive detrusor, detrusor overactivity, and OAB) are all originally urodynamic-based terms and, strictly speaking, describe abnormalities of detrusor function during filling cystometry. Thus, a urodynamic study was required to make a definitive diagnosis. Abrams and Wein[3,4] and others recognized the difficulty of using a frequently used term that could be defined only on the basis of a relatively complicated study. They feel that many patients could be treated initially with reversible conservative therapy after a minimal evaluation, and primary care physicians could and should become more involved in the initial management of such patients. They further supported the view that the OAB, a very patient- and physician-friendly term, is capable of being used as a diagnosis based on symptoms and was sufficient for the initiation of management in many cases. They proposed preserving detrusor overactivity or overactive detrusor as a urodynamic-based definition that describes a particular type of detrusor dysfunction during filling cystometry. Spirited discussions on terminology occurred after Abrams and Wein[3] chaired a consensus conference entitled "The Overactive Bladder: From Basic Science to Clinical Management." Further correspondence on this subject followed,[5] finally resulting in the formalization of OAB as a recognized symptom complex.

Artibani,[6] Wein,[7] and others have pointed out some of the problems in using only a urodynamic-based definition for OAB: (1) cystometry is an invasive test that requires administration and evaluation by skilled and trained specialists; (2) because of the high worldwide prevalence of OAB, it is neither necessary nor economically feasible for all patients to be evaluated initially by specialists using cystometry; (3) the sensitivity in detecting involuntary detrusor contractions in patients with OAB symptoms varies with the type of study done, with up to 60% to 80% of patients who are "negative" on routine supine cystometry demonstrating involuntary bladder contractions on either provocative cystometry or ambulatory urodynamics; (4) >60% of healthy volunteers show involuntary detrusor contractions during ambulatory urodynamics; and (5) most traces on cystometry that show low compliance change into phasic involuntary detrusor contractions when long-term ambulatory monitoring is performed.

These considerations and others prompted the ICS Standardisation Subcommittee to change other items in the ICS lexicon (Table I). Detrusor hyperreflexia and detrusor instability were eliminated in favor of *neurogenic detrusor overactivity* and *idiopathic detrusor overactivity*. These former 2 terms had both been used generically before the first ICS report in 1976. The most recent subcommittee thought that because there was no real logic or intuitive meaning to these terms, they should be abandoned in favor of others that were more descriptive and readily understood. Additionally, as most experienced clinicians have come to recognize, the extent of neurologic examination and investigation varies in clinical and research practice, and it is likely that the proportion of patients in the neurogenic versus the idiopathic overactivity group would increase if a more complete neurologic assessment were performed. *Motor urgency* and *sensory urgency* have been completely eliminated, and no terms have replaced them.

EPIDEMIOLOGY: PREVALENCE

Little definite epidemiologic information was available on the prevalence of OAB until very recently. Nearly all epidemiologic studies in this area have focused on urinary incontinence. The prevailing method for estimating the prevalence of OAB seems to have been to take the prevalence of urinary urge incontinence (including mixed incontinence) and multiply by 3, estimating that approximately 33% of patients with OAB had urinary urge incontinence. The remaining patients did not, complaining only of urgency, generally with frequency and nocturia.[8,9] The median prevalence of incontinence in women has been reported as vary-

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TABLE I. ***International Continence Society terms***

Eliminated Term	Replacement Term
Detrusor hyperreflexia	Neurogenic detrusor overactivity
Detrusor instability	Idiopathic detrusor overactivity
Motor urgency	None
Sensory urgency	None
Motor urge incontinence	Detrusor overactivity incontinence with urgency
Reflex incontinence	Detrusor overactivity incontinence without sensation

TABLE II. ***Prevalence of overactive bladder symptoms in the study by Milsom*** **et al.**[9]

Symptom	Prevalence (%)
Frequency alone	4.5
Urgency alone	1.5
Urge incontinence alone	1
Frequency and urgency	7
Urgency and incontinence	4.5
Frequency, urgency, and incontinence	3.5

ing from 14% to 40.5% (using the ICS definition, it is 23.5%); in men, it varied from 4.6% to 15%. In women, urge and mixed incontinence accounted for a median relative share of 51% of cases, whereas in men, the combined total was 92%.[8]

A Population-Based Prevalence Study

Milsom *et al.*[10] reported on a study performed by the Svenska Institutet for Opinionsundersokingar (SIFO)/Gallup Network in France, Germany, Italy, Spain, Sweden, and the United Kingdom. This study used a telephone questionnaire involving a 2-stage screening procedure, which first identified individuals with bladder control problems and then characterized the nature of the urinary condition. The first step specifically excluded individuals whose only complaint was urinary tract infection. Symptoms attributable to OAB were identified by positive response to specific questions on frequency, urgency, and urge incontinence. Frequency caused by OAB was arbitrarily defined as >8 micturitions in 24 hours. For nocturia, the working definition was having to get up ≥2 times a night to urinate. Respondents could have >1 OAB symptom, but they were classified only once as having OAB. Positive responses that were suggestive only of stress incontinence, prostatic obstruction, or the occurrence of urinary tract infection resulted in exclusion from further investigation. Respondents who were ≥40 years of age with OAB only or mixed symptoms were included.

The interviewed population totaled 16,776 subjects. Approximately 19% of all respondents reported current bladder symptoms, but, overall, 16.6% of total respondents, 15.6% of men, and 17.4% of women reported symptoms suggestive of OAB. Responses by country varied somewhat, without explanation. The prevalence of OAB of men and women in Spain was 20% and 24%, respectively, whereas the prevalence in France was 11% and 13%, respectively. In all, 79% of these patients had had their symptoms for ≥1 year, and 49% had had them for >3 years. Of those subjects with bladder symptoms, frequency was the most commonly reported symptom (85%), followed by urgency (54%) and urge incontinence (36%). The presence of individual symptoms occurring alone was small, as was the prevalence of respondents with all symptoms of OAB (Table II). The prevalence of OAB and of all 3 symptoms increased with advancing age. This trend was apparent in both men and women. For men and women, respectively, prevalence percentages were as follows: 3.4% and 8.7% for those 40 to 44 years old, 9.8% and 11.9% for those 50 to 54 years old, 18.9% and 16.9% for those 60 to 64 years, 22.3% and 22.1% for those 70 to 74 years, and 41.9% and 31.3% for those ≥75 years of age.

The National Overactive Bladder Evaluation Program

Stewart *et al.*[11] have been conducting the National Overactive Bladder Evaluation (NOBLE) Program to provide a clinically valid research definition of OAB, to establish estimates of its overall prevalence and the individual burden of illness,

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and to explore differences between OAB populations (i.e., those who are incontinent and those who are dry). A computer-assisted telephone interview was developed to estimate variation and prevalence of OAB by demographic and other factors. This was assessed for reliability and clinical validity. Clinical validity was assessed by comparison with a clinician's diagnosis. The sensitivity and specificity of the computer-assisted telephone interview for OAB were 61% and 91%, respectively. The validated US national telephone survey involved 5204 adults ≥18 years of age who were representative of the noninstitutionalized US population with respect to sex, age, and geographic region. *OAB dry* was defined as ≥4 episodes of urgency in the previous 4 weeks with either frequency >8 more times per day or the use of ≥1 coping behaviors to control bladder function. *OAB wet* included the same criteria as OAB dry with, in addition, ≥3 episodes of urinary incontinence in the past 4 weeks that were clearly not episodes of stress incontinence. The overall prevalence of OAB was reported as 16.9% in women and 16.2% in men, increasing with age. The overall prevalence of OAB dry and OAB wet in women was 7.6% and 9.3%, respectively, whereas in men it was 13.6% and 2.6%, respectively. In the United States, these figures would translate to 33.3 million adults with OAB, 12.2 million of whom had incontinence and 21.2 million of whom did not. Interestingly, prevalence by age increased by approximately the same slope in both men and women. The prevalence of OAB dry seemed to level off in men at about the age of 60 years and in women at about the age of 50 years. The prevalence of OAB wet was quite low in men (3%) until the age of about 60 years, and this number increased to approximately 8% at the age of ≥65 years, whereas for women, the prevalence increased from approximately 12% at the age of 60 years to approximately 20% at the age of ≥65 years.

EPIDEMIOLOGY: QUALITY OF LIFE AND COMORBIDITIES

In the study by Milsom *et al.*,[10] 65% of men and 67% of women with OAB reported that their symptoms had an effect on daily living, and 60% of those with symptoms found them bothersome enough to consult a medical practitioner. Frequency and urgency alone (59%) were almost as common as urge incontinence (66%) as reasons for seeking help. Of those who sought medical care, only 27% were receiving medication for symptoms at the time of the interview. Of those who were not taking medication, 27% had previously tried pharmacologic treatment, which failed. Of those who were not taking medication and who had never tried drugs, 54% reported they were likely to discuss the problem with a physician again and 46% were not. Of those who had tried drugs but in whom the drugs had failed, 65% reported they were likely to discuss the problem with a physician again and 35% were not.

Liberman *et al.*[12] assessed the impact of symptoms of OAB on the quality of life in a community-based US sample population. The survey was conducted in 2 phases: (1) a cross-sectional household telephone survey was performed among an age-stratified sample of 4896 adults; and (2) a follow-up questionnaire was mailed to a subset of these respondents to assess their health-related quality of life (HRQOL). The Medical Outcomes Study Short-Form (SF)-20 was used. This measures HRQOL during the past month in 6 domains: physical functioning, role functioning, social functioning, mental health, health perception, and bodily pain. Both groups, OAB wet and OAB dry, had significantly lower crude HRQOL scores than the control groups in every domain. This was true also after adjustment for confounders. Statistically significant differences were observed in 5 of the 6 domains for the total OAB group, all 6 domains for the OAB wet group, and 3 of 6 domains for the OAB dry group. In the OAB dry group, after adjustment for confounders, individuals with symptoms of both frequency and urgency scored statistically significantly lower than did the controls in all 6 HRQOL domains. There were numerical differences for the frequency-only and urgency-only subgroups, but these did not reach statistical significance. Individuals reporting ≥11 micturitions per day did have statistically significant lower domain-specific scores than those of controls in the areas of physical functioning, mental health, and bodily pain. The HRQOL scores for individuals with 9 to 10 micturitions per day were not significantly different from those of controls.

In a study by Stewart *et al.*,[11] illness impact was assessed by completed self-administered questionnaires on quality of life, depression status, and sleep quality. Quality of life was assessed with the 36-Item Short-Form (SF-36) Health Survey, a standardized generic instrument that measures HRQOL in the previous month in 8 domains (physical functioning, role functioning, social functioning, mental health, vitality, health perception, emotional role, and bodily pain). Depression status was assessed by the Center for Epidemiologic Studies Depression Scale, which is a self-reported scale developed to identify depression-related symptoms. Sleep quality was assessed by the Medical Outcomes Sleep Scale, a 12-item questionnaire that measures sleep disturbance, insomnia, sleep quality and duration, and restfulness. After adjusting for differences in comorbid illnesses and other demographic factors, both men and women with OAB wet and OAB dry had clinically and significantly lower quality-of-life subscores,

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more depression-related symptoms, and a poorer quality of sleep.

Kobelt[13] reported that the results of the assessment of HRQOL with the SF-36 in a Swedish population with established urge or mixed incontinence indicated that this cohort scored significantly lower in all domains than did the general Swedish population, matched for age and sex distribution. In addition, she reported that these results were, to some extent, confirmed using data from a clinical trial in the United States and Canada in which 2 treatments for urinary incontinence were compared with placebo. The SF-36 scores of the trial population at baseline were significantly lower than those of the healthy, age-matched population in 6 of 8 domains. In 3 of these (social functioning, role limitations caused by emotional problems, and mental health), the scores were significantly correlated with micturitions and leaks at baseline, whereas the correlations with scores in the domains of vitality and general health were of borderline significance. Using some of the same data, Abrams *et al.*[14] reported that patients with OAB were found to have a lower quality of life in the social and functional domains of the SF-36 than did patients with diabetes. They pointed out that many patients with OAB tend to stop pursuing enjoyable social and physical activities, living with the condition in silence because they are too embarrassed to talk about their condition or are unaware that it can be treated. They list the most common reactions to the urinary incontinence component of OAB as embarrassment, frustration, anxiety, annoyance, depression, and fear of odor. Abrams *et al.*[1] also enumerate the elaborate behaviors (coping mechanisms) that many patients develop, which are aimed at hiding and managing such urine loss. They also cite the results of Kelleher *et al.*[15] who used the King's Health Questionnaire, a survey originally developed to evaluate quality of life in women with urinary incontinence. Using this survey, women with OAB and incontinence were reported to have significantly greater quality-of-life impairment compared with women with stress incontinence and normal urodynamic function. These last few reports emphasize a difficulty in assessing impairment of quality of life in patients with OAB: most of these surveys have been performed in patients with OAB wet, which must be acknowledged, because quality-of-life impairment in this group is most likely greater than in the OAB dry group. More recent studies have begun to overcome the deficit in data on quality of life as it applies to the total OAB population and its subdivisions of OAB wet and OAB dry.

Brown *et al.*[16] provide an overview of the impact of OAB on other problems now known to coexist with this condition. They report that urinary incontinence is independently associated with falls and fractures among community-dwelling, elderly women in that women with weekly urge incontinence have a 26% greater risk of sustaining a fall and a 34% increased risk of fracture after adjusting for other causes. More frequent incontinence was associated with increased risk, and women with daily urge incontinence had increased risks of 35% and 45% of sustaining falls and fractures, respectively. These investigators believe that because previous studies have demonstrated that urge incontinence has been associated with frequency/urgency and nocturia, OAB symptom, and not just urge incontinence, has the potential to increase the risk of falls and fractures among elderly women. They cite previous studies as identifying urinary tract infections and skin infections as factors that increase the cost of OAB and cite recent analyses that suggest a potential reduction in health care costs for patients receiving treatment for OAB. After the diagnosis of OAB, the number of services received for urinary tract infections and skin infections decreased 40% and 60%, respectively, and was associated with potential cost savings in a small sampling from the 1996 to 1997 California Medicaid program. Regarding depression, Brown *et al.*[16] cite data that suggest a strong association between depression and urge incontinence in a survey that used a Beck Depression Inventory. They cite the prevalence of depression as 60% in those with idiopathic urge incontinence, as 42% in patients with mixed incontinence, and as only 14% in patients with stress incontinence. Finally, although it seems intuitive that OAB would be associated with sleep disturbances, they caution that the extent to which OAB alone contributes to sleep disturbances remains unclear, because many individuals, particularly elderly individuals, report sleep problems that are unrelated to the nocturia component of OAB.

ASSOCIATED COSTS

In this area, as in many others, analyses of the economic implications of OAB, separate from incontinence, are essentially nonexistent. Wagner and Hu[17] reported the total costs of urinary incontinence in the United States in 1995 to be $26,292,400,000. Of these, direct costs accounted for $25.6 billion and indirect costs for $700 million. It is imperative that a similar analysis be performed for patients with OAB, including those with OAB wet and OAB dry. Only by quantification of the total economic burden of OAB will the importance of the disease in society be established. Hu and Wagner[18] believe that it is likely that the economic burden of OAB is significantly greater than that of urinary incontinence.

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CONCLUSION

OAB is a highly prevalent disorder that affects the lives of millions of people worldwide. The importance of OAB as a term has been recognized by the ICS, which now incorporates this term in its lexicon as a symptom syndrome. Prevalence of OAB, as distinct from urinary incontinence, is now the subject of some well-performed surveys, and, through these, we are beginning to be able to characterize the disorder in terms of various demographic features. Data on the effects on quality of life and the economic burden of OAB are still relatively scarce, and information on the effects of various treatments on these parameters is essentially nonexistent. All of these factors will become increasingly important as we try to increase awareness of this significant problem worldwide and try to impress on other specialists and primary care physicians the importance of identifying this clinical problem and managing it in a way that will maximize quality-of-life improvement while minimizing morbidity.

REFERENCES

1. Abrams P, Cardozo L, Fall M, *et al:* The standardisation of terminology of lower urinary tract function: report from the Standardisation Subcommittee of the International Continence Society. Neurourol Urodyn **21:** 167–178, 2002.
2. International Continence Society. Available at: http://www.continet.org. Accessed.
3. Abrams P, and Wein AJ: The overactive bladder: from basic science to clinical management. Urology **50**(suppl 6): 1–3, 1997.
4. Abrams P, and Wein AJ: The overactive bladder and incontinence: definitions and a plea for discussion. Neurourol Urodyn **18:** 413–416, 1999.
5. Payne CK: Overactive bladder [letter and comment]. Urology **51:** 106, 1998.
6. Artibani W: Diagnosis and significance of idiopathic overactive bladder. Urology **50**(suppl 6): 25–32, 1997.
7. Wein AJ: Overactive bladder: defining the disease. Am J Managed Care **6**(suppl): S559–564, 2000.
8. Hampel C, Weinhold D, Benker N, *et al:* Definition of overactive bladder and epidemiology of urinary incontinence. Urology **50**(suppl 6): 4–14, 1997.
9. Milsom I, Stewart W, and Thuroff J: The prevalence of overactive bladder. Am J Managed Care **6**(suppl): S565–S573, 2000.
10. Milsom I, Abrams P, Cardozo L, *et al:* How widespread are the symptoms of an overactive bladder and how are they managed? A population-based prevalence study. BJU Intl **87:** 760–766, 2001.
11. Stewart W, Herzog R, Wein A, *et al:* Prevalence and impact of overactive bladder in the US: results from the NOBLE program. Presented at the International Continence Society, Seoul, Korea, September 2001.
12. Liberman JN, Hunt TL, Stewart WF, *et al:* Health related quality of life among adults with symptoms of overactive bladder: results from a US community-based survey. Urology **57:** 1044–1050, 2001.
13. Kobelt G: Economic considerations and outcome measurement in urge incontinence. Urology **50**(suppl 6): 100–107, 1997.
14. Abrams P, Kelleher CJ, Kerr LA, *et al:* Overactive bladder significantly affects quality of life. Am J Managed Care **6**(suppl): S580–S590, 2000.
15. Kelleher CJ, Cardozo LD, Khuller V, *et al:* A new questionnaire to assess the quality of life of urinary incontinent women. Br J Obstet Gynaecol **104:** 1374–1379, 1997.
16. Brown JS, McGhan WF, and Chokroverty SA: Comorbidities associated with overactive bladder. Am J Managed Care **6**(suppl): S574–S579, 2001.
17. Wagner TH, and Hu T: Economic costs of urinary incontinence in 1995. Urology **51:** 355–361, 1998.
18. Hu T, and Wagner TH: Economic considerations in overactive bladder. Am J Managed Care **6**(suppl): S591–S598, 2001.

DISCUSSION FOLLOWING DR. WEIN'S PRESENTATION

David R. Staskin, MD (New York, NY): A patient comes to you reporting the following: (1) I have had urinary frequency all of my life; (2) I have never had an accident; (3) I have never lost any urine, no matter how bad the frequency is (as opposed to the woman who says I have had frequency and urgency. Every once in a while, I can't make it to the toilet, and I leak urine).

Would you use an afferent drug with this patient because this is a sensory condition, rather than using an efferent drug because this is a motor condition?

Karl-Erik Andersson, MD, PhD (Lund, Sweden): We do not know how our drugs work, not even antimuscarinics. You cannot exclude the fact that antimuscarinics affect the sensory arm of the micturition reflex. Therefore, we are not really helped in our choice of drug by the basic physiology and pharmacology. The mechanism of action does not indicate whether the patient would respond to a certain drug better than to another drug. We have to determine that by clinical trials.

Dr. Staskin: However, if you had the perfect sensory drug, it would inhibit both categories. When is a specific diagnosis needed, and when is it not needed? I think that you do not need a specific diagnosis to begin to treat people as long as you are going to treat them with behavioral modification. It is a symptom syndrome. Instead of urgency with frequency and nocturia, it is overactive bladder.

Joseph G. Ouslander, MD (Atlanta, GA): I agree with what you said, given what we know now. It would make a difference if the definitional issues that you are talking about predicted response to specific treatments.

Alan J. Wein, MD (Philadelphia, PA): I think that people who have higher degrees of awareness, concern, and the ability to stop the involuntary detrusor contractions once they start do much better with behavioral therapies than those who are totally unaware. I think there are many different kinds of treatments that do better in some categories than others. If we do not continue to make these subtle distinctions, we will treat everybody the same way, and we will not make inroads into how patients are different from each other. We also will not be able to determine why some patients are doing well and others are not.

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