

Imprecise definition of 'overactive bladder' serves commercial rather than patient interests



Kari A.O. Tikkinen



Dept. of Urology, Helsinki University Central Hospital and University of Helsinki, Helsinki, Finland; and Dept. of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, ON, Canada
kari.tikkinen@gmail.com

Financial disclosure

I have no conflicts of interest.

International Continence Society Classification Lower Urinary Tract Symptoms (LUTS)

Storage symptoms ("irritative")	Voiding symptoms ("obstructive")	Post-micturition

International Continence Society Classification Lower Urinary Tract Symptoms (LUTS)

Storage symptoms	Voiding symptoms	Post-micturition
<ul style="list-style-type: none">• Frequency• Incontinence• Nocturia	<ul style="list-style-type: none">• Slow stream• Splitting or spraying• Intermittency• Hesitancy• Straining	<ul style="list-style-type: none">• Post-micturition dribble• Feeling of incomplete emptying
<ul style="list-style-type: none">• Urgency	<ul style="list-style-type: none">• (Retention)	

ICS definition of urinary urgency

” Urinary urgency is the complaint of a sudden compelling desire to pass urine which is difficult to defer ”

1. Abrams et al. *Neurourol Urodyn* 2002;21
2. Abrams et al. *Neurourol Urodyn* 2006;25

The ICS 2002/2006 definition of OAB¹⁻²

Overactive bladder syndrome (OAB) is “urgency, with or without urgency incontinence usually with increased daytime frequency and nocturia.”

- “These symptom combinations are suggestive of urodynamically demonstrable detrusor overactivity, but can be due to other forms of urethro-vesical dysfunction.”
- “These terms can be used if there is no proven infection or other obvious pathology.”
- 2002 document describes also as “urge syndrome or urgency-frequency syndrome”

Complex “scientific” terminology hampered by the lack of specificity

- Overactive bladder *syndrome* (OAB) is “urgency, *with or without* urgency incontinence *usually with* increased daytime frequency and nocturia.”
 - “These symptom combinations are suggestive of urodynamically demonstrable detrusor overactivity, *but can be due to other forms* of urethro-vesical dysfunction.”
 - “These terms can be used if there is no proven infection or *other obvious* pathology.”
- “*urgency* is the complaint of a sudden compelling desire to pass urine which is difficult to defer.”

comments

OVERACTIVE BLADDER: SYMPTOM OR SYNDROME? J.G. BLAIVAS

– Joan and Sanford Weil Medical College, Cornell University, USA

Blaivas. *BJU Int* 2003;92:521

**European
Urology**

European Urology 47 (2005) 273–276

Editorial

Overactive Bladder: A Clinical Entity or a Marketing Hype?

Helmut Madersbacher

Neuro-Urology Unit, University Hospital, Medical University Innsbruck, Anichstrasse 23, A-6020 Innsbruck, Austria

Accepted 20 October 2004

Available online 10 November 2004

Madersbacher *Eur Urol* 2004;47:27



OAB. Are We Barking Up the Wrong Tree? A Lesson From My Dog

Norman R. Zinner^{*,†}

UCLA Geffen School of Medicine, Western Clinical Research, Inc., Los Angeles, California

Zinner. *Neurourol Urodyn* 2011:30:14

Tikkinen & Auvinen. *Eur Urol* 2012:61

available at www.sciencedirect.com

journal homepage: www.europeanurology.com



European Association of Urology



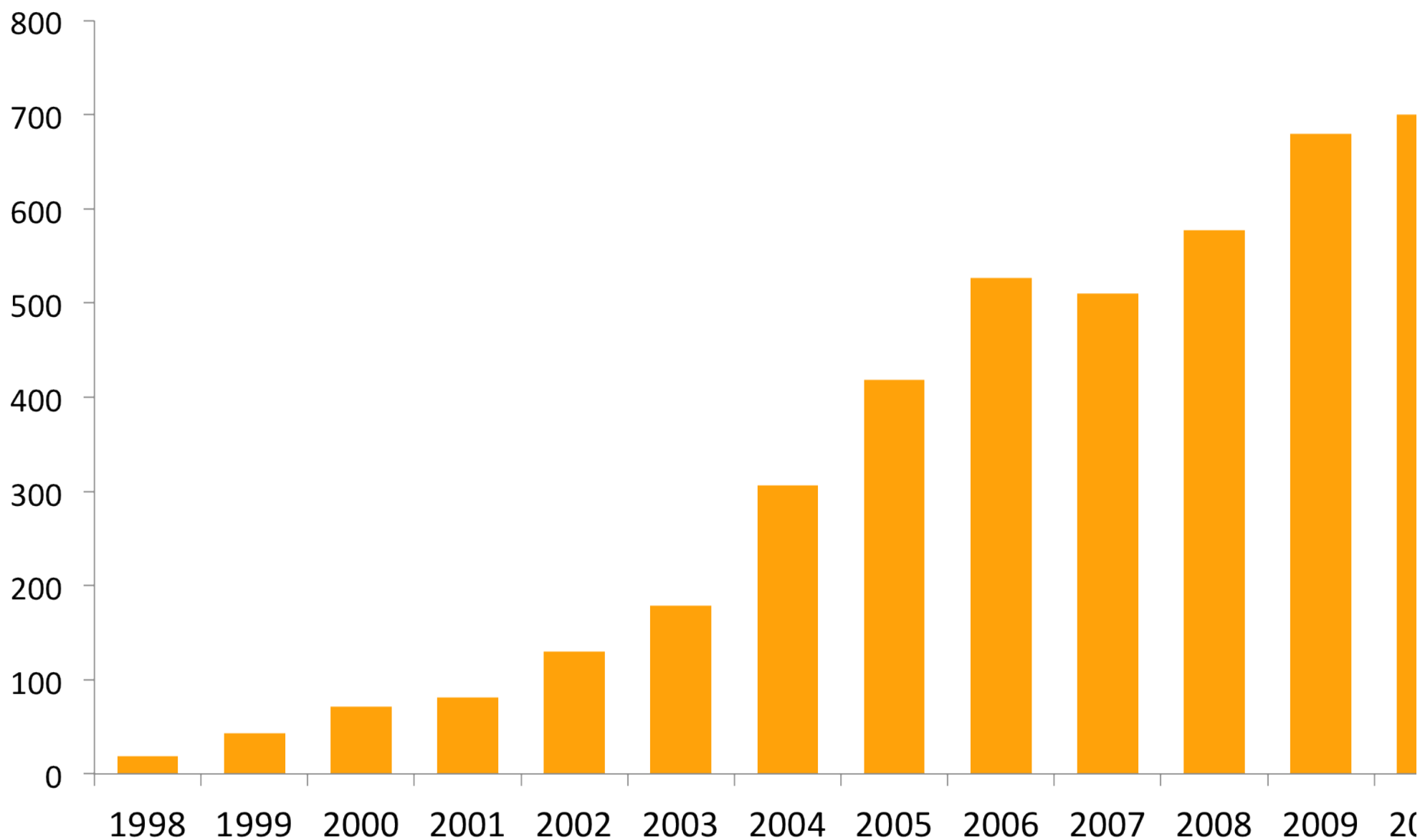
Editorial

Does the Imprecise Definition of Overactive Bladder Serve Commercial Rather than Patient Interests?

Kari A.O. Tikkinen^{a,b,*}, Anssi Auvinen^c

^aDepartment of Urology, Helsinki University Central Hospital and University of Helsinki, Helsinki, Finland; ^bDepartment of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada; ^cSchool of Health Sciences, University of Tampere, Tampere, Finland

Number of overactive bladder publications



Publications across all journals indexed in Scopus,

Tikkinen & Auvinen *Eur Urol* 2012;61:72

Development of OAB market size in the U

in millions of US dollars

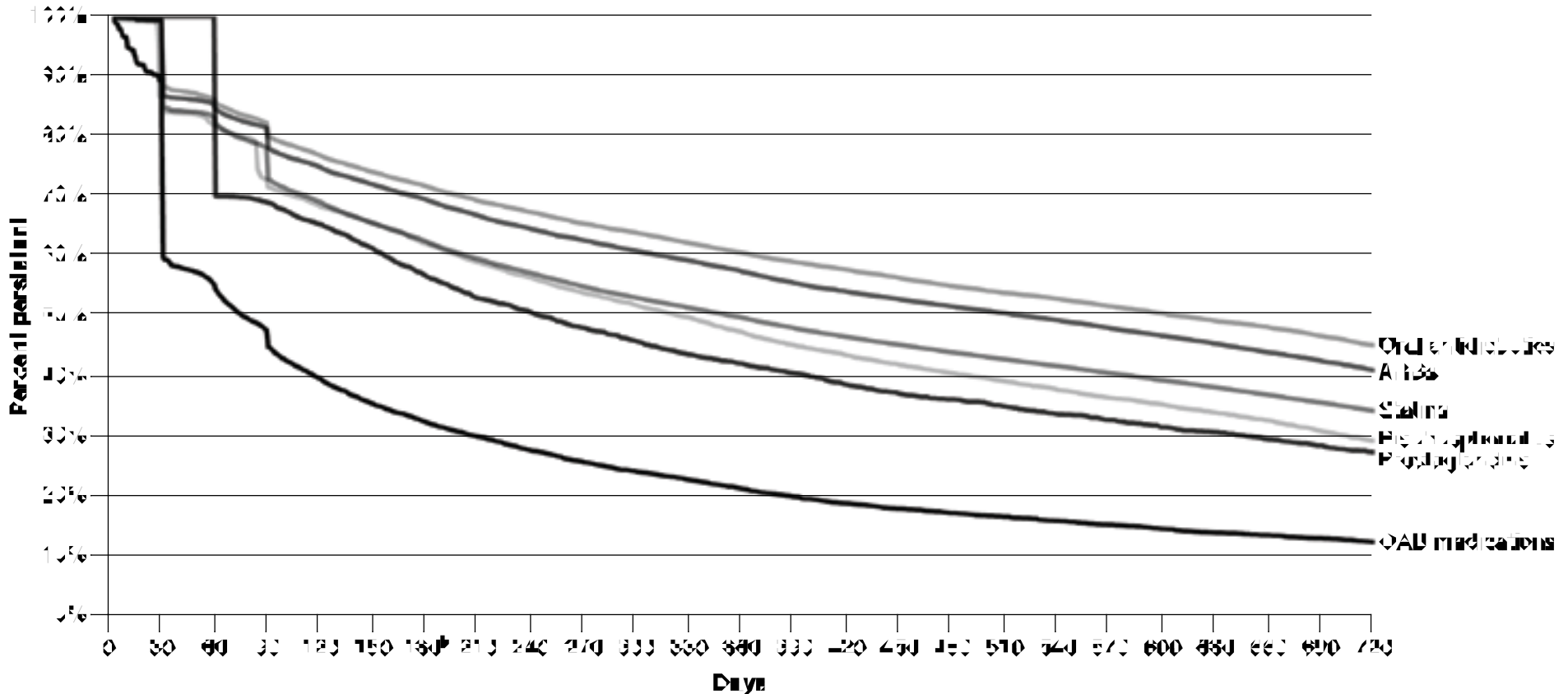


Data from *IMS Health*, available at

What about the patients - do OAB concepts and treatments work for them?

- Antimuscarinics are the first-line drug treatment for OAB
 - However, benefits are small
- Median symptom changes with antimuscarinics in RCTs
 - Urgency: - 0.9 episodes/24 hours
 - Urgency incontinence: - 0.5 episodes/24hours
 - Frequency: - 0.8 episodes/24 hours
 - Nocturia: - 0.1 episodes/night, NS

Adherence to OAB medications (anticholinergics) is low



* Discontinuation was defined as the end of any attempt for an active treatment or pharmacologic therapy, or a failure to complete a 90-day sup. therapy. A minimum of 12 months (maximum of 18 months) continued eligibility following the final day (day 0) was required. Beginning at day 350, the same procedure for the calculation of the A of all remaining eligible patients with continuous enrollment through the end of the 90-day treatment. Patients with continuous enrollment ending between day 350 and day 720 were censored at the point of their discontinuation of benefits.

* Rates for 90-day sup. therapy persistence rates were: physiotherapy 52%, oral anticholinergics 62%, AChE 65%, oral anticholinergics 74%, AChE 65%, oral anticholinergics 65%, oral anticholinergics 65%.

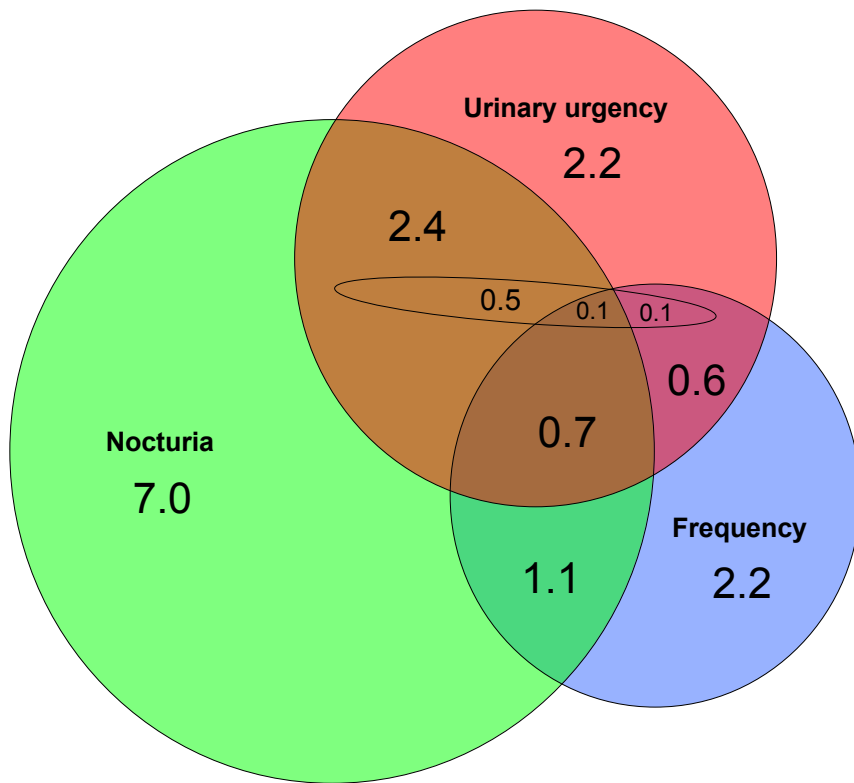
AChE = anticholinergic therapy; ACh = acetylcholine cholinergic

Reasons for discontinuing OAB medication reported by >20% of those who discontinued

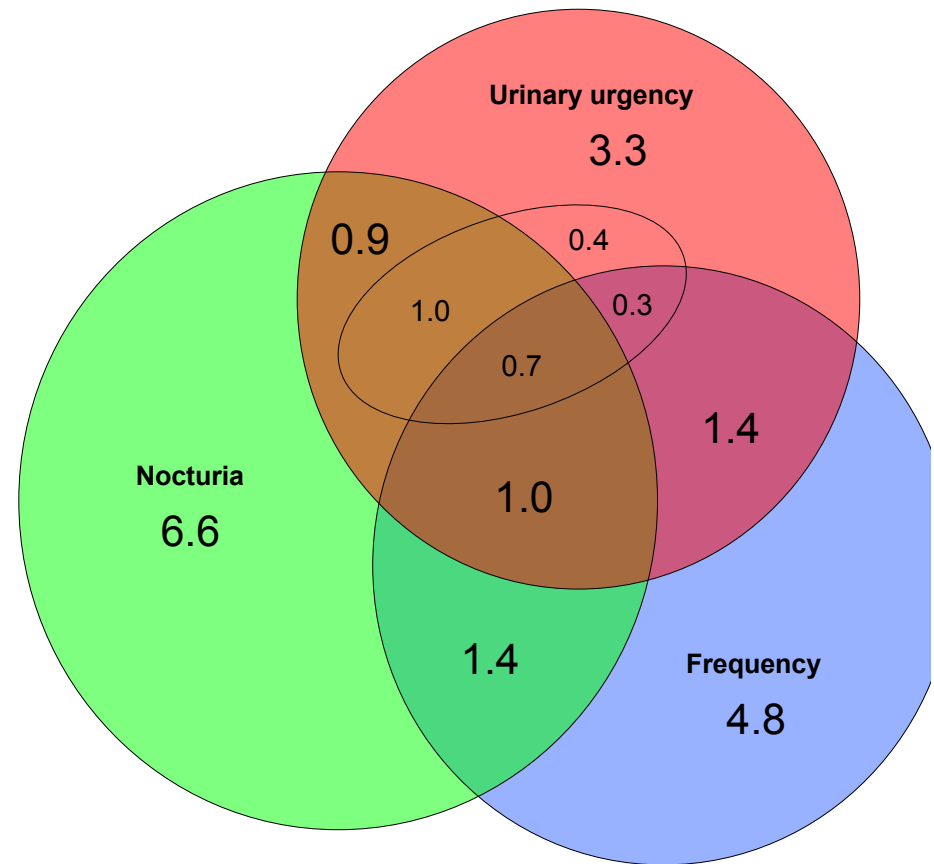
Reason	N (%)
Did not work as expected	611 (46.2)
Switched to a new medication	332 (25.1)
Learned to get by without medication	308 (23.3)
I had side effects	279 (21.1)

Age-standardized prevalence of overactive bladder symptoms

■ Urinary urgency without urgency incontinence (circle)
 ■ Frequency (>8)
 ■ Nocturia
 ■ Urinary urgency with urgency incontinence (oval)



MEN



WOMEN

“OAB is misleading because it makes it too easy for clinicians to feel they have made a diagnosis when they have not. In so doing, it curtails further thinking and does not promote the scientific pursuit of fact.”

Norman R. Zinner. Neurourol Urodyn 2011

American Urological Association 2012 Guidelines on Overactive Bladder

“OAB Diagnosis. The review revealed insufficient publications to address OAB diagnosis from an evidence basis”

Available at http://www.auanet.org/content/media/OAB_guideline.pdf

“A greater danger is in simply lumping symptoms together and giving them a new label. A wholly false concept ensues: that the diagnostic label, often glorified by the term syndrome, represents a new disease. This stultifies further thought and may inhibit research and investigation of the aetiology because doctors commonly regard the syndrome (diagnosis) as a disease.”

J M S Pearce. Pract Neurol 2011

Key Element of 'Marketing Disease'

Suggestions for Doing Better

1. Exaggerate the prevalence of disease

Create a broad disease definition

Learn exact definition and question whether it is appropriately specific.

Publicize a large prevalence estimate.

Ask: "Does the sample truly represent the general population?"

Blur between mild and severe.

Be clear about the disease spectrum.

Key Element of 'Marketing Disease'	Suggestions for Doing Better
2. Encourage more diagnosis	
Highlight that doctors fail to recognize	
Encourage people's self-diagnosis.	Acknowledge the problems of overdiagnosis.
Promote awareness 'uncritically'	Learn if awareness activities are industry sponsored.

Key Element of 'Marketing Disease'

Suggestions for Doing Better

3. Suggest that all disease should be treated

Exaggerate the benefits of the drug for everyone with disease.

Objectively report benefits and study populations; Leave industry ties.

Understate harms of treatments

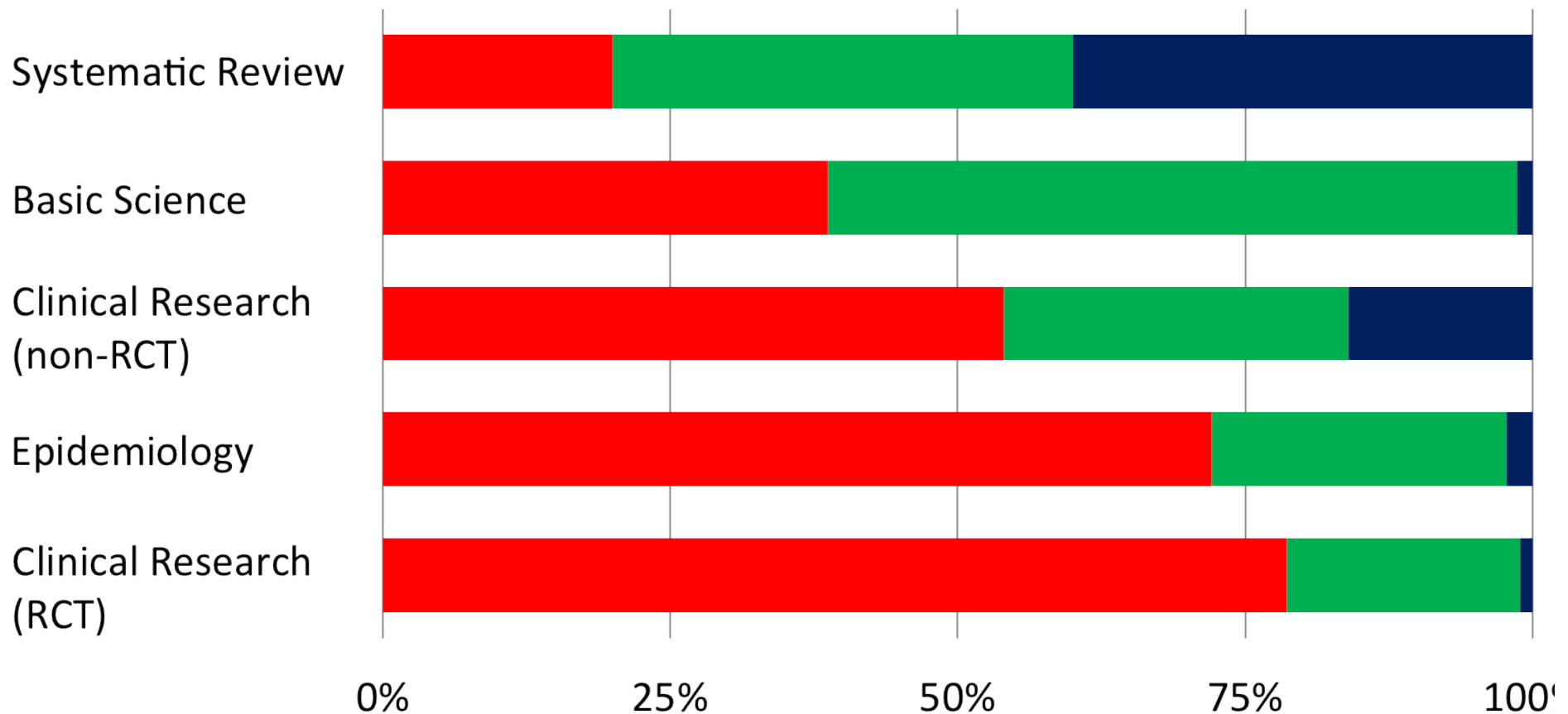
Quantify side effects

Imply that long-term treatment is safe and effective.

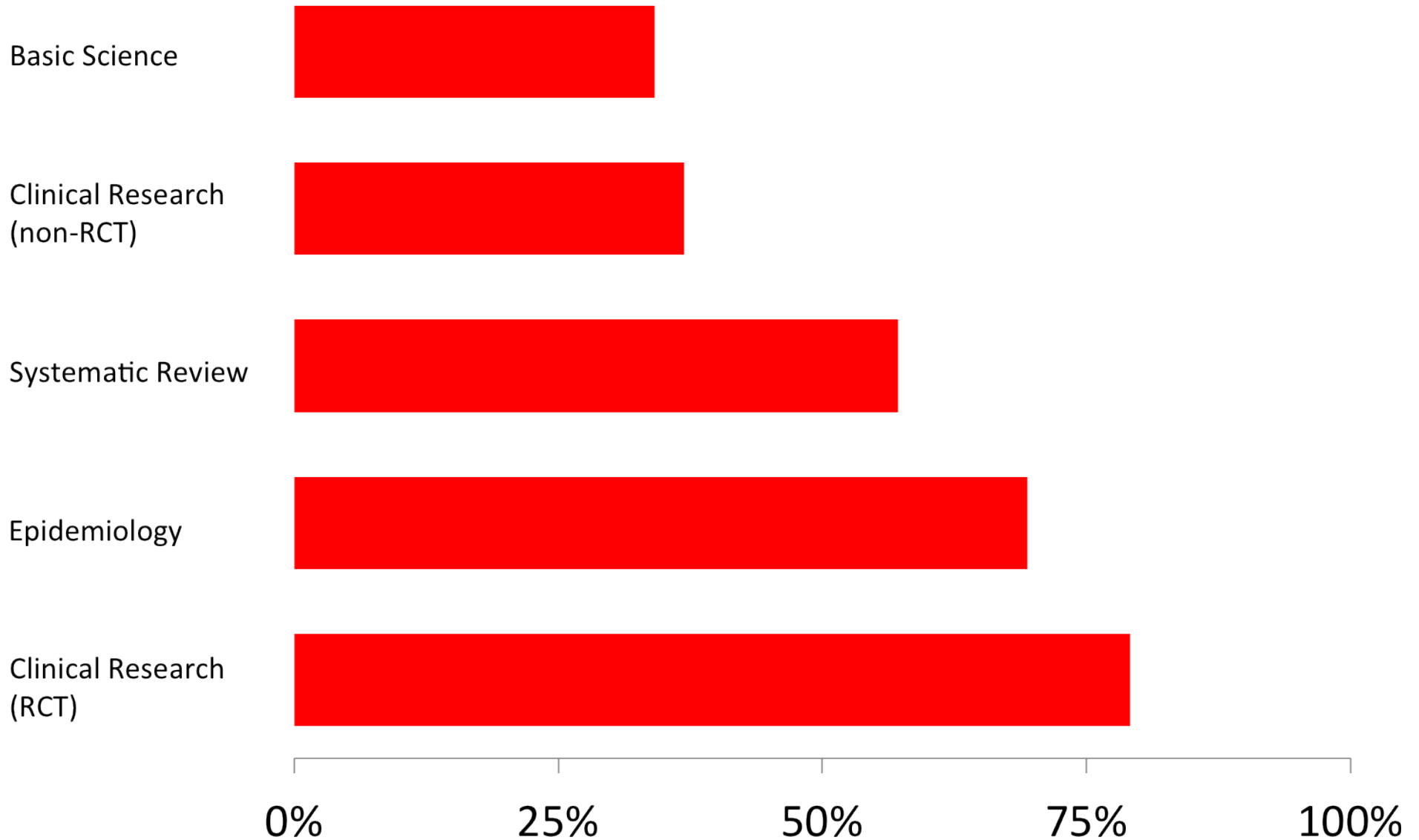
Remember that studies are typically short-term.

Reported funding sources for overactive bladder papers by subtype

- Industry funding (fully or partial)
- Non-industry funding (including charity and government) only
- No funding (explicitly declared)



Reported conflict of interest for overactive bladder papers by subtype



What is a disease? Perspectives of the public, health professionals and legislators

Kari A O Tikkinen,^{1,2} Janne S Leinonen,³ Gordon H Guyatt,^{1,4} Shani Zbrahimi,¹ Teppo L N Järvinen⁵

To cite: Tikkinen KAO, Leinonen JS, Guyatt GH, et al. What is a disease? Perspectives of the public, health professionals and legislators. *BMJ Open* 2012;6:e001632. doi:10.1136/bmjopen-2012-001632

► Prepublication history and additional material for this paper are available online. To view these files please visit the journal online (<http://journals.bmj.com/journal/2012/06/01/2012001632>).

Received 9 June 2012
Accepted 15 October 2012

This full article is available for use under the terms of the Creative Commons Attribution Non-Commercial 2.0 International license (<http://creativecommons.org/licenses/by-nc/2.0/>).

For numbered references see end of article.

Correspondence to: Dr Kari A O Tikkinen, kari.tikkinen@helsinki.fi

ARTICLE SUMMARY

Article focus

- The concept of disease lies at the heart of medicine.
- No study has addressed perceptions of all relevant stakeholders on what, across a wide range of conditions, should be classified as a disease.

Key messages

- Our survey found large differences in the view among Finnish laypeople, doctors, nurses, or parliament members regarding whether states of being should be considered diseases and managed through public revenue.
- Although doctors were more inclined to consider states of being as diseases, disagreement was still evident among health professionals as in other groups.
- Understanding peoples' attitudes about what states of being should be considered disease educates lawmakers concerning attitudes of this kind inform social discourse regarding numerous contentious public policy issues.

Strengths and limitations of this study

- This is the first study to assess whether states of being should be considered diseases and should be managed through public revenue using a national sample of doctors, nurses, laypeople, and legislators.
- Our results from the Finnish population may be less generalisable to less affluent countries or countries with different social and cultural values.

ABSTRACT

Objective: To assess the perception of diseases and the willingness to use public tax revenue for their treatment among relevant stakeholders.

Design: A population-based, cross-sectional mailed survey.

Setting: Finland.

Participants: 3000 laypeople, 1700 doctors, 1500 nurses (randomly identified from the databases of the Finnish Population Register, the Finnish Medical Association and the Finnish Nurses Association) and all 200 parliament members.

Main outcome measures: Respondents perceived us on a five-point Likert scale on (1) being, on (2) states of being, (This state of being) is a disease, and (3) (This state of being) should be treated with public tax revenue.

Results: Of the 6200 individuals approached, 4200 (68%) responded. Of the 60 states of being, >80% of respondents considered 10 to be diseases (Likert scale responses of 4 and 5) and five not to be diseases (Likert scale responses of 1 and 2). There was considerable variability in most states, and great variability in 10 (>20% of respondents of all groups considered it a disease and 21.0% rejected as a disease). Doctors were more inclined to consider states of being as diseases than laypeople, nurses and members were informed ($p<0.001$), but all groups showed large variability. Responses to the two Likert were very strongly correlated ($r=0.96$ (95% CI 0.94 to 0.98), $p<0.001$).

Conclusions: There is large disagreement among the public, health professionals and legislators regarding the classification of states of being as diseases and whether their management should be publicly funded. Understanding attitudes of citizens can help to enlighten social discourse on a number of contentious public policy issues.

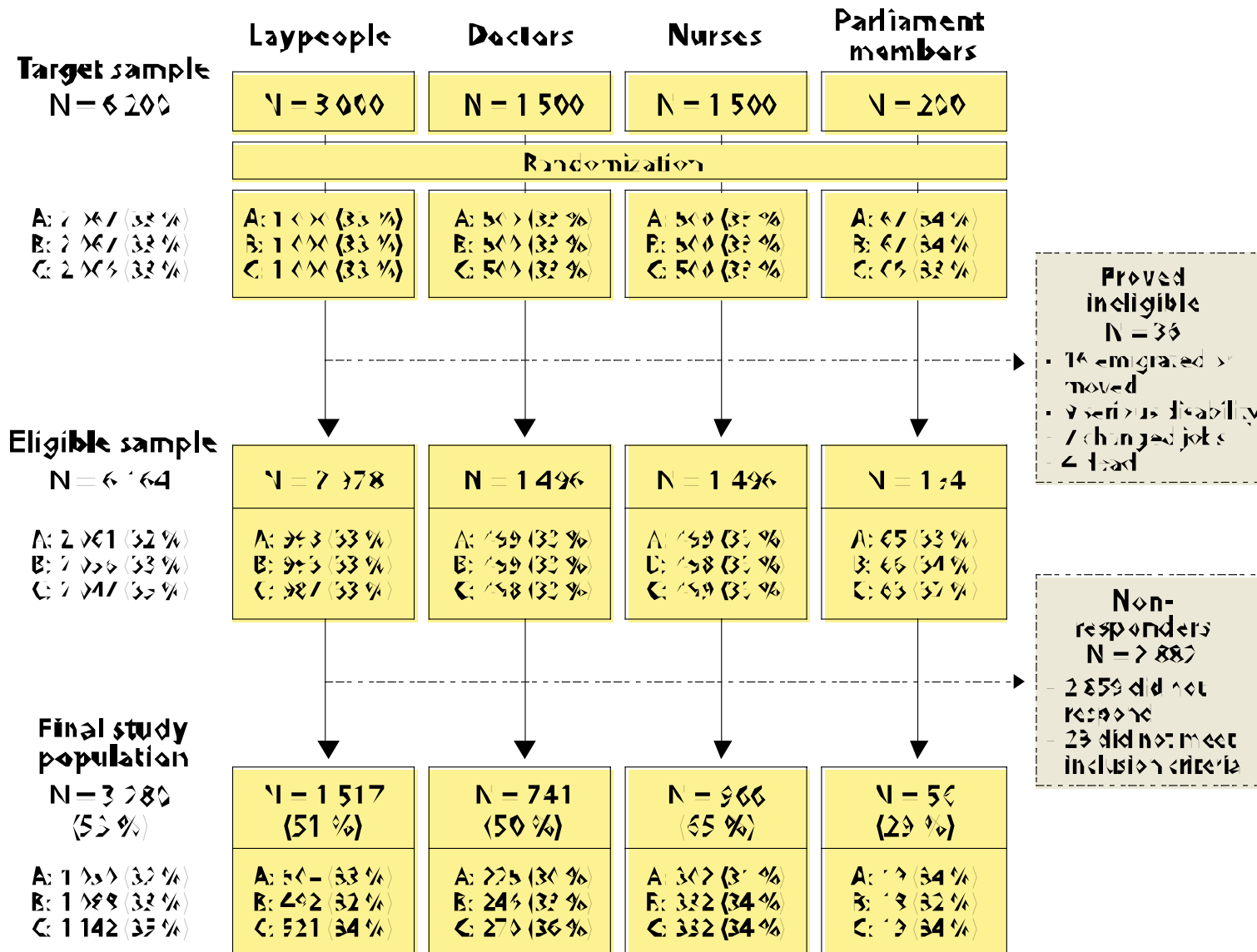
INTRODUCTION

Disease and illness are related concepts: patients suffer from 'illnesses' and doctors diagnose and treat 'diseases'.¹ Diseases are experiences of diseasemunities in states of

being and perceived role performances, which diagnosed as diseases, they suit program abnormalities in the function or structure of body systems. Disease can refer to a combination of a given symptoms, phenomena is related with a disorder or function, or structure of illness associated with a specific cause. There are, however, no universally accepted criteria for establishing disease.²⁻⁵ Indeed, the complexity of the concept of disease has led the observation that it can be as difficult defining as heavy truth or two.⁶

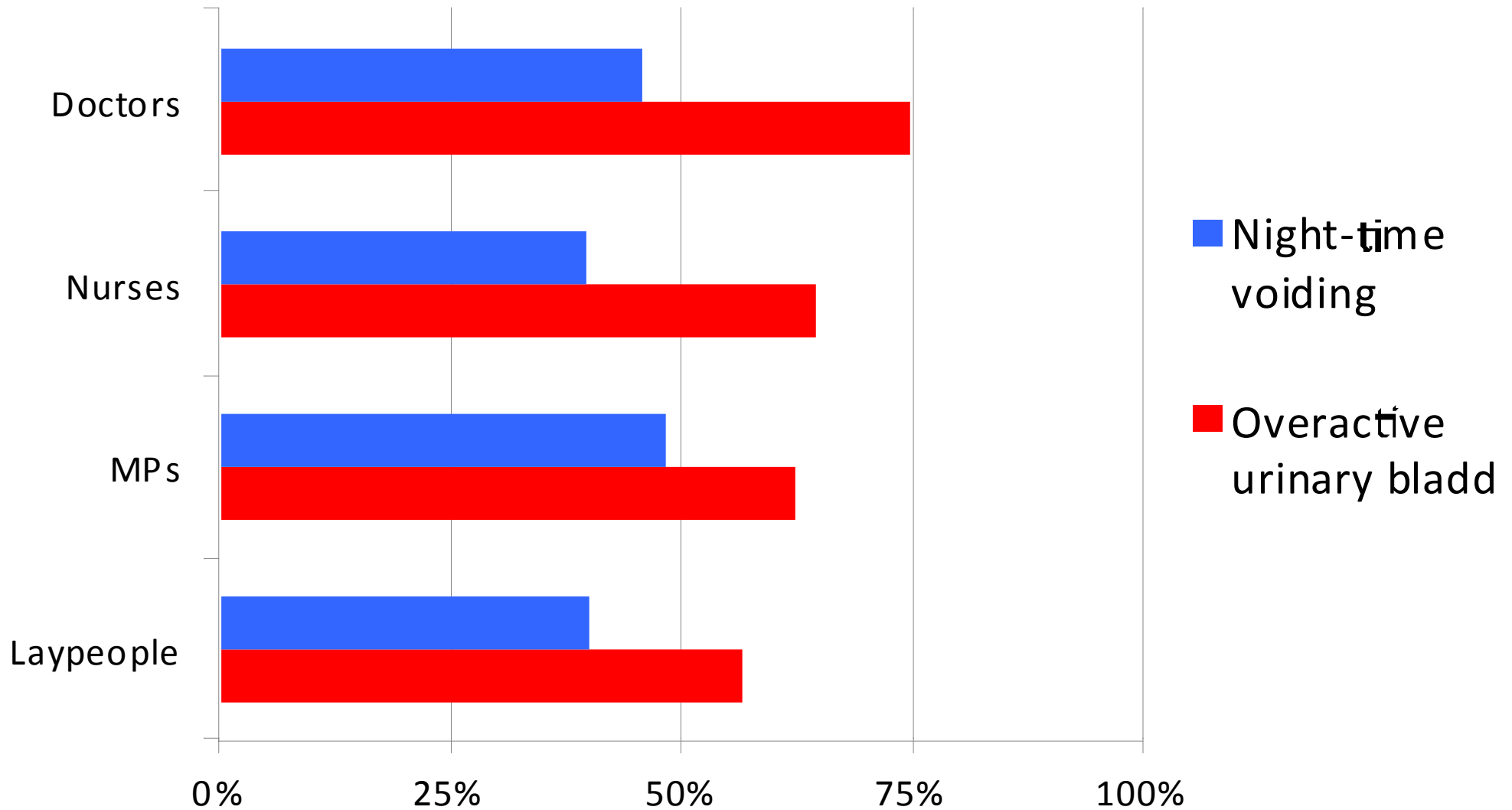
Do terms matter?

Finnish Disease (FIND) Survey flow chart



Proportion considering as a disease

Finnish Disease (FIND) Survey



So, whom does the definition serve best?

1. Excellent for disease awareness campaigns but also for *disease mongering* and *selling sickness*.
2. Does not optimally promote the scientific pursuit of fact
 - May be harmful for further thinking
3. Is 'patient-friendly' but maybe also (patient-)misleading

Take Home Messages

Be aware that

- Overactive bladder is not a disease
 - Overactive bladder is the name given to a group of troubling urinary symptoms
 - These symptoms may (or may not) have same etiology
- Term 'OAB' implies a mechanism
 - We often don't know the mechanism of these symptoms
- Term 'OAB' is a perfect term for disease-branding and drug-mongering to expand market