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

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Session VII. Update on Pharma Marketing Strategies

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**

ICS, International Continence Society

International Continence Society Classification Lower Urinary Tract Symptoms (LUTS)

Storage symptoms	Voiding symptoms	Post-micturition
• Frequency • Incontinence • Nocturia • **Urgency**	• Slow stream • Splitting or spraying • Intermittency • Hesitancy • Straining • (Retention)	• Post-micturition dribble • Feeling of incomplete emptying

ICS definition of urinary urgency

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

1. Abrams et al. ***Neururol Urodyn*** 2002:2
2. Abrams et al. ***Neururol Urodyn*** 2006:2

The ICS 2002/2006 definition of OAB[1-2]

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”

1. Abrams et al. ***Neurourol Urodyn*** 2002:21:167   2. Abrams et al. ***Neurourol Urodyn*** 2006:25:29

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."

1. Abrams et al. ***Neurourol Urodyn*** 2002:21:167 2. Abrams et al. ***Neurourol Urodyn*** 2006:25:29

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

Neurourology and Urodynan

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*** 2011:30:1

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?

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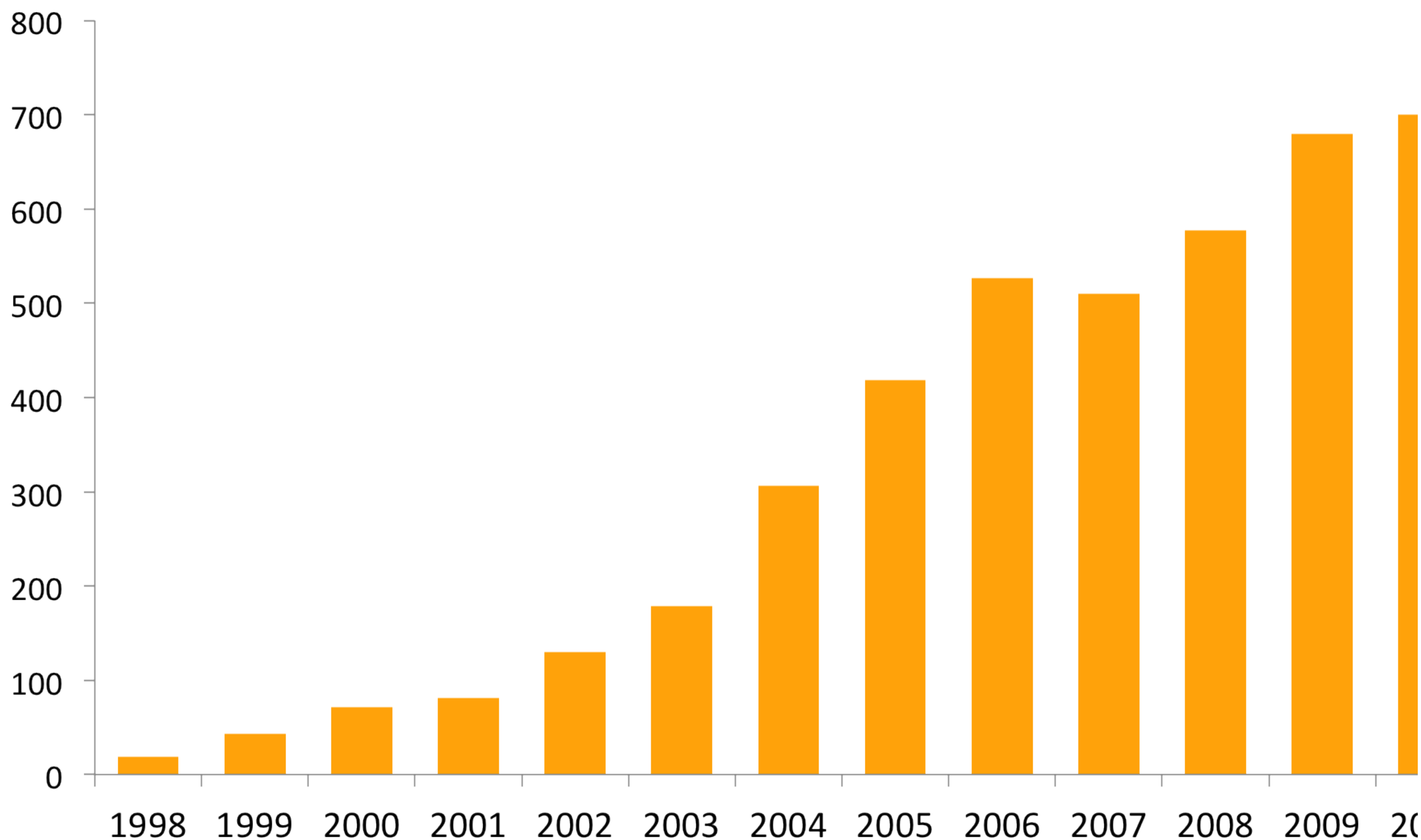
Number of overactive bladder publications



Publications across all journals indexed in Scopus,

Tikkinen & Auvinen. *Eur Urol* 2012;61:7

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 concep and treatments work for them?

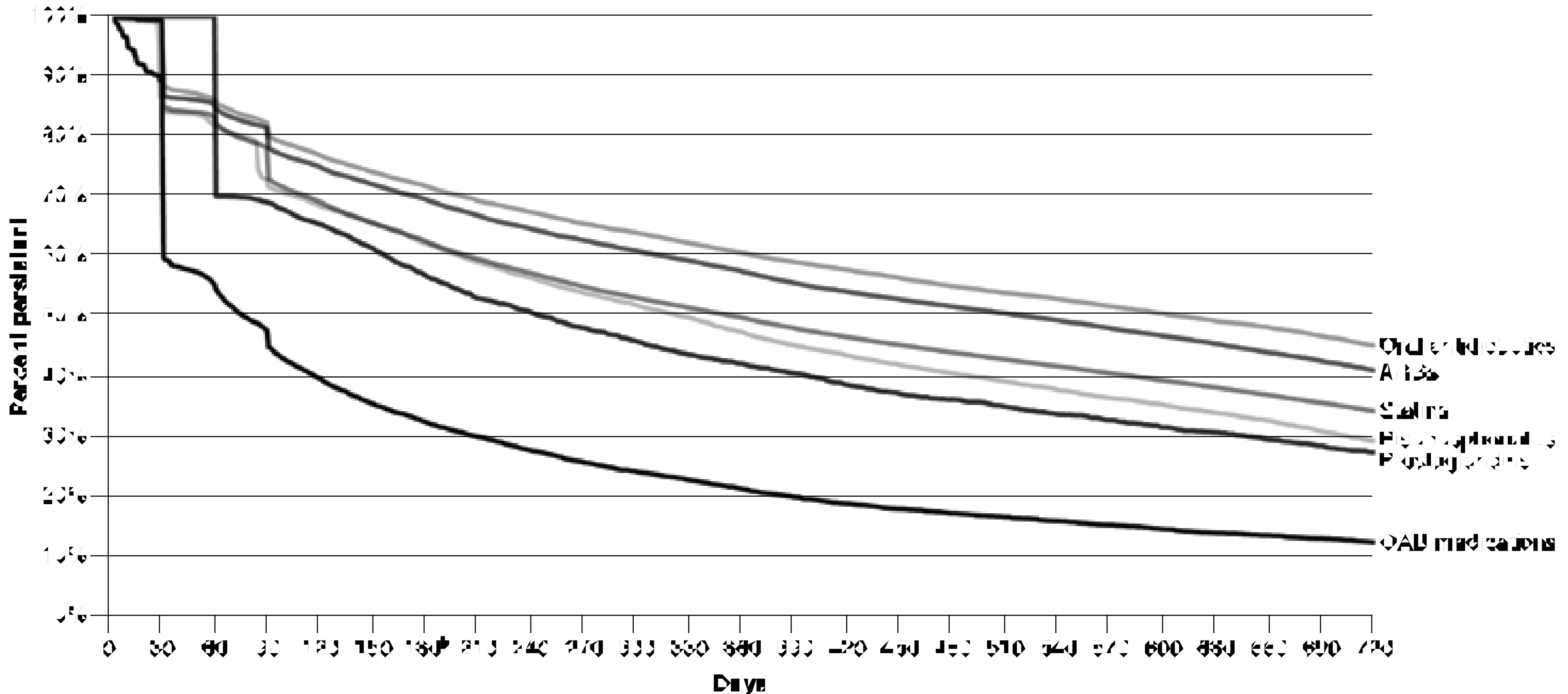
- Antimuscarinics are the first-line drug treatment for OAB
  - However, benefits are small

- 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

Buser et al. *Eur Urol* 2012;62:1

Adherence to OAB medications (anticholinergics) is low



Yeaw et al. *J Manag Care Pharm* 2009;15:7

Reasons for discontinuing OAB medication

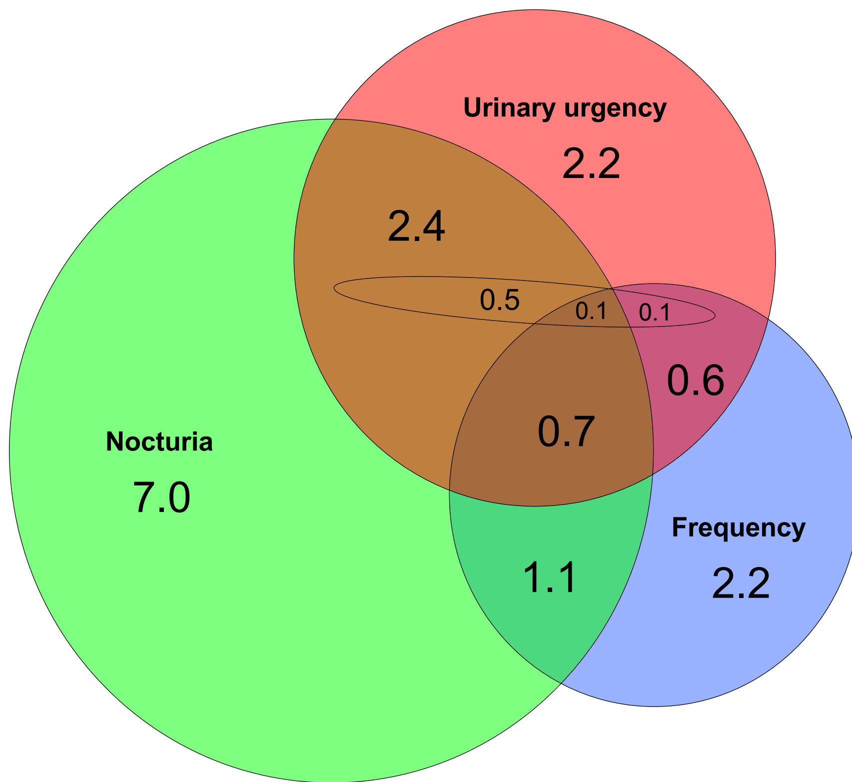
reported by >20% of those who discontinued

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)

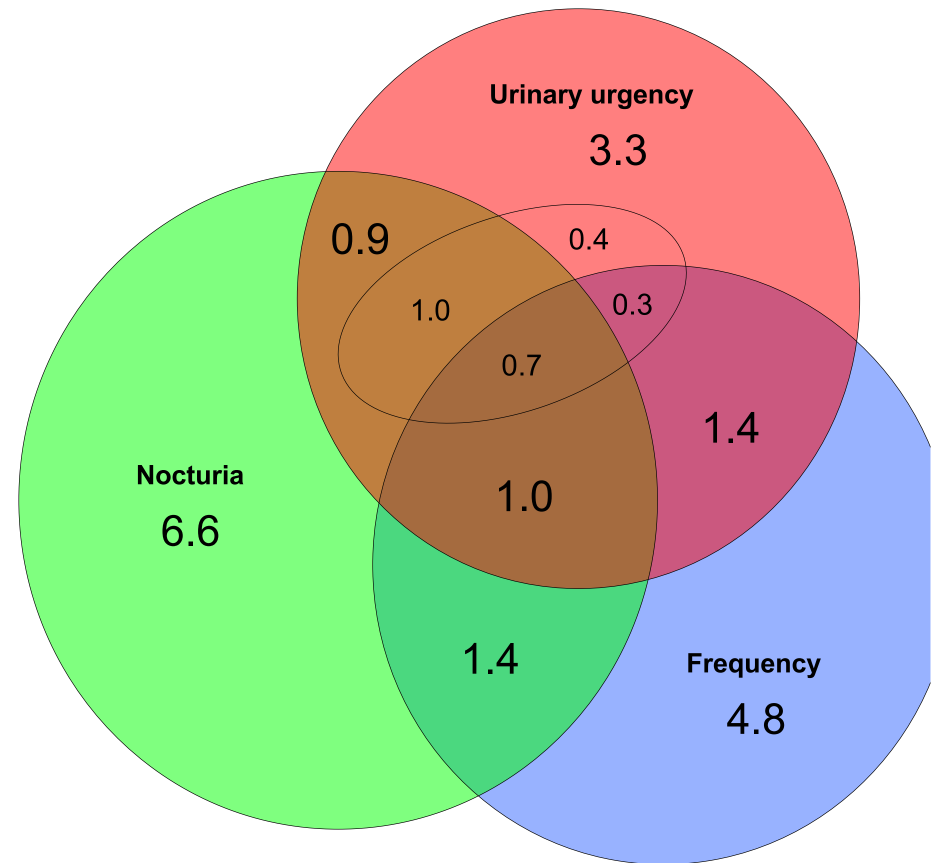
Benner et al. *BJU Int* 2010;105:1

Age-standardized prevalence of overactive bladder symptoms

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



MEN



WOMEN

Modified from Tikkinen et al. *PLoS One* 2007;2:e

"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 Bett
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 trul represent the general population?"
Blur between mild and severe.	Be clear about the disease spectrum.

Modified from Woloshin S, Schwartz LM (2006) Giving Legs to Restless Legs: A Case Study of How the Media Helps

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

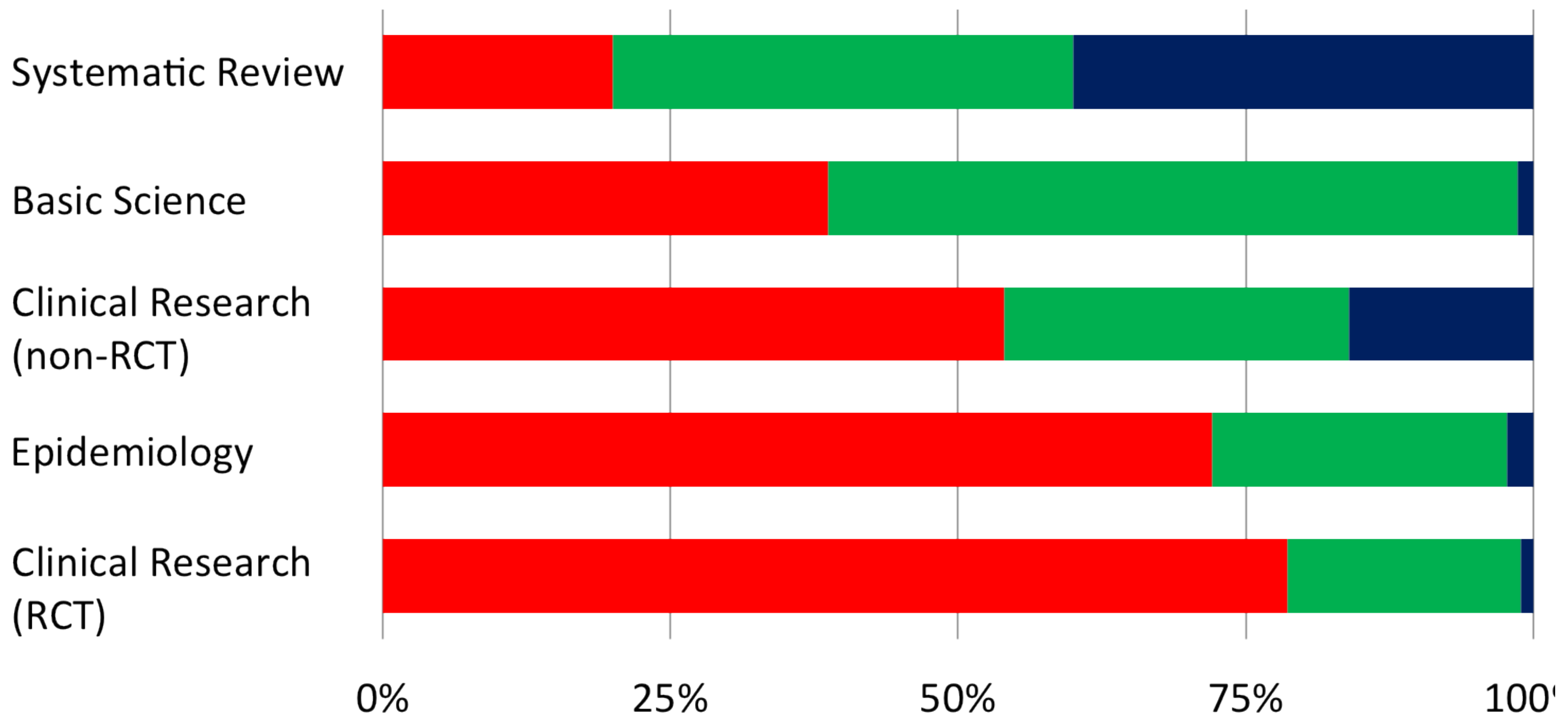
Modified from Woloshin S, Schwartz LM (2006) Giving Legs to Restless Legs: A Case Study of How the Media Helps

PLoS

Key Element of 'Marketing Disease'	Suggestions for Doing Bett
3. Suggest that all disease should be treated	
Exaggerate the benefits of the drug for everyone with disease.	Objectively report benefits and study populations; Lea 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.

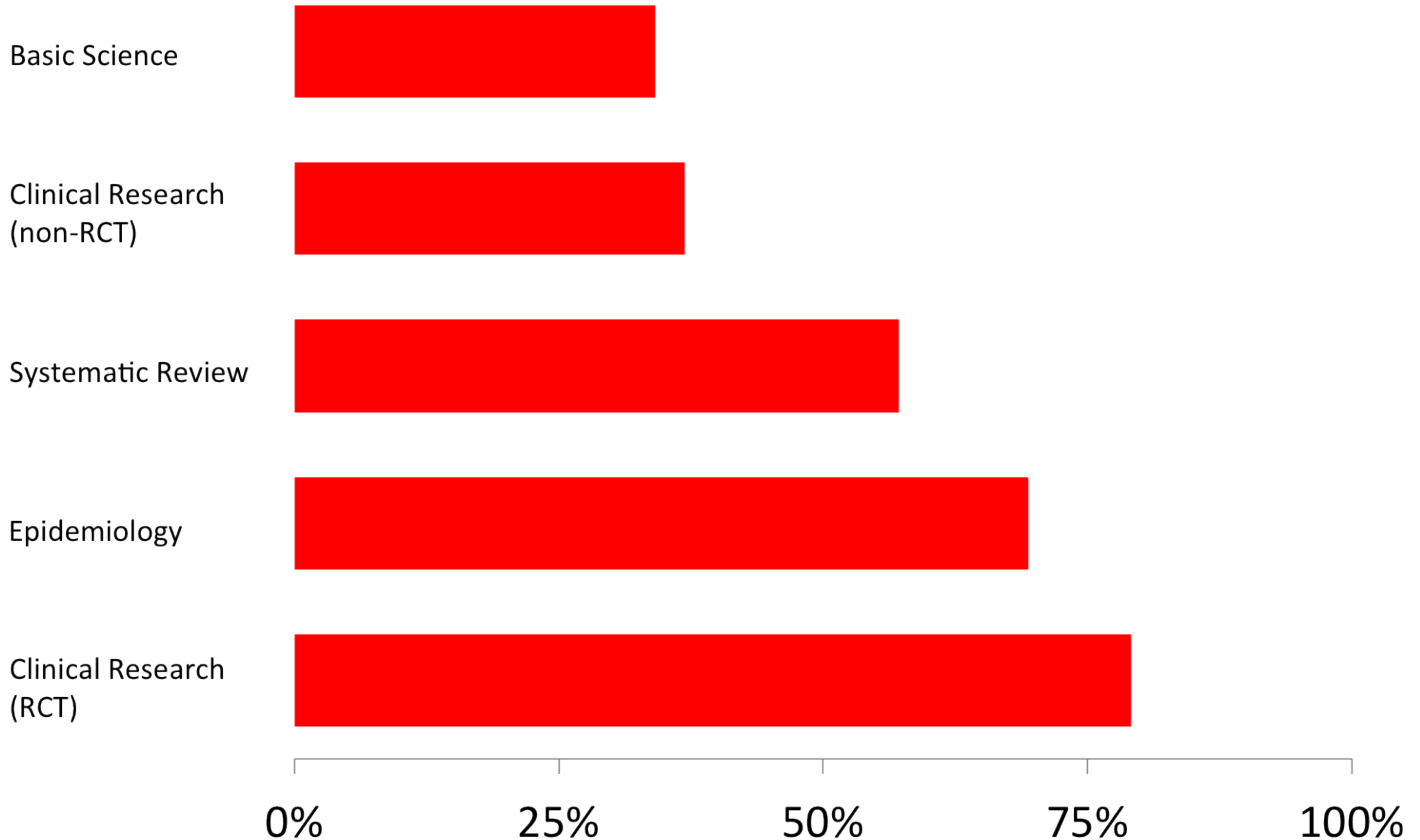
Modified from Woloshin S, Schwartz LM (2006) Giving Legs to Restless Legs: A Case Study of How the Media Helps

Reported funding sources for overactive bladder papers by subtype



Tikkinen & Auvinen. *Eur Urol* 2012;61:7

Reported conflict of interest for overactiv bladder papers by subtype



Tikkinen & Auvinen. *Eur Urol* 2012;61:7

Do terms matter?

Open Access

BMJ Open

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] Shanil Ebrahim,[1] Teppo L N Järvinen[5]

ABSTRACT

Objective:

Design:

Setting: Finland.

Participants:

Main outcome measures:

Results:

Conclusions:

ARTICLE SUMMARY

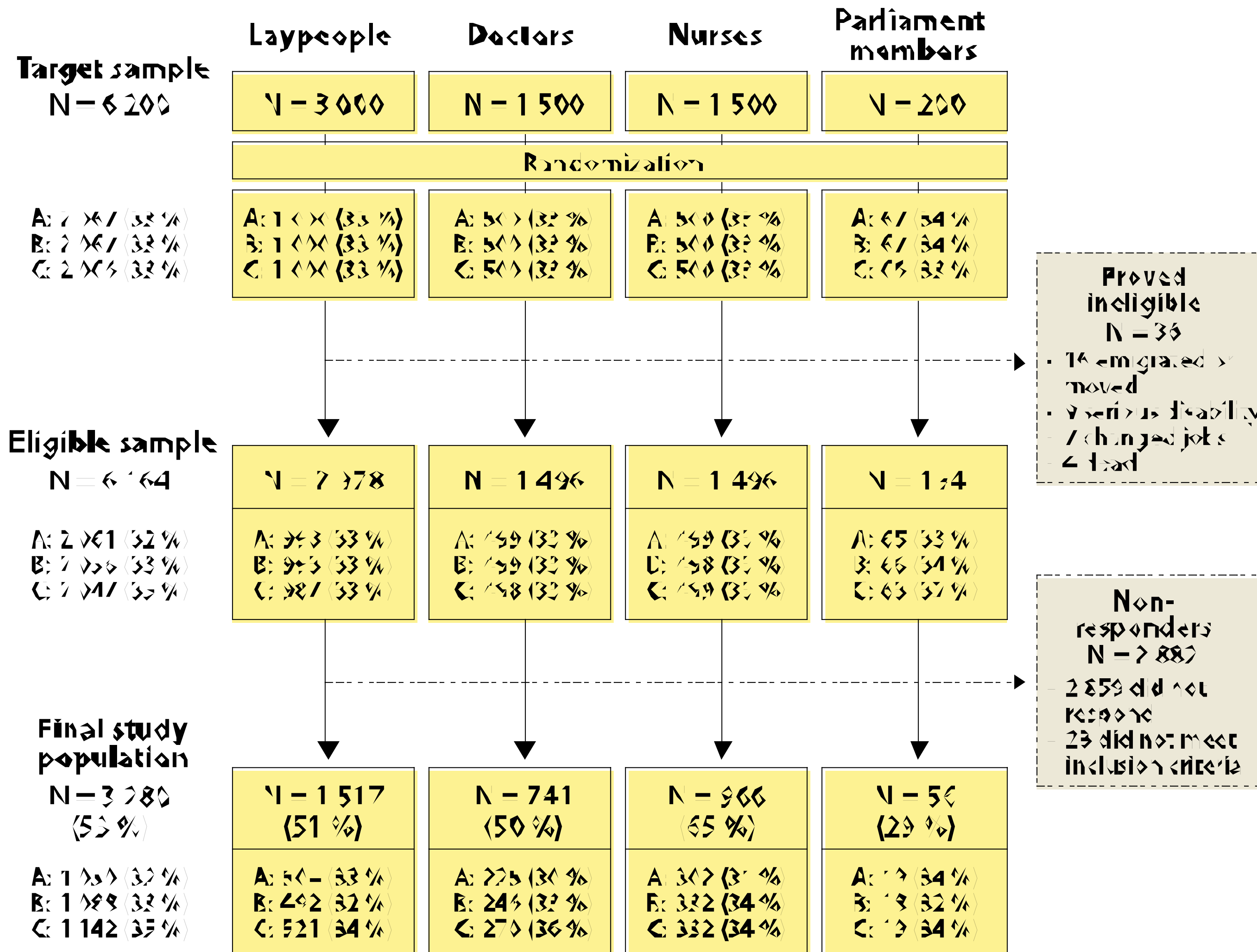
Article focus

Key messages

Strengths and limitations of this study

INTRODUCTION

Finnish Disease (FIND) Survey flow char



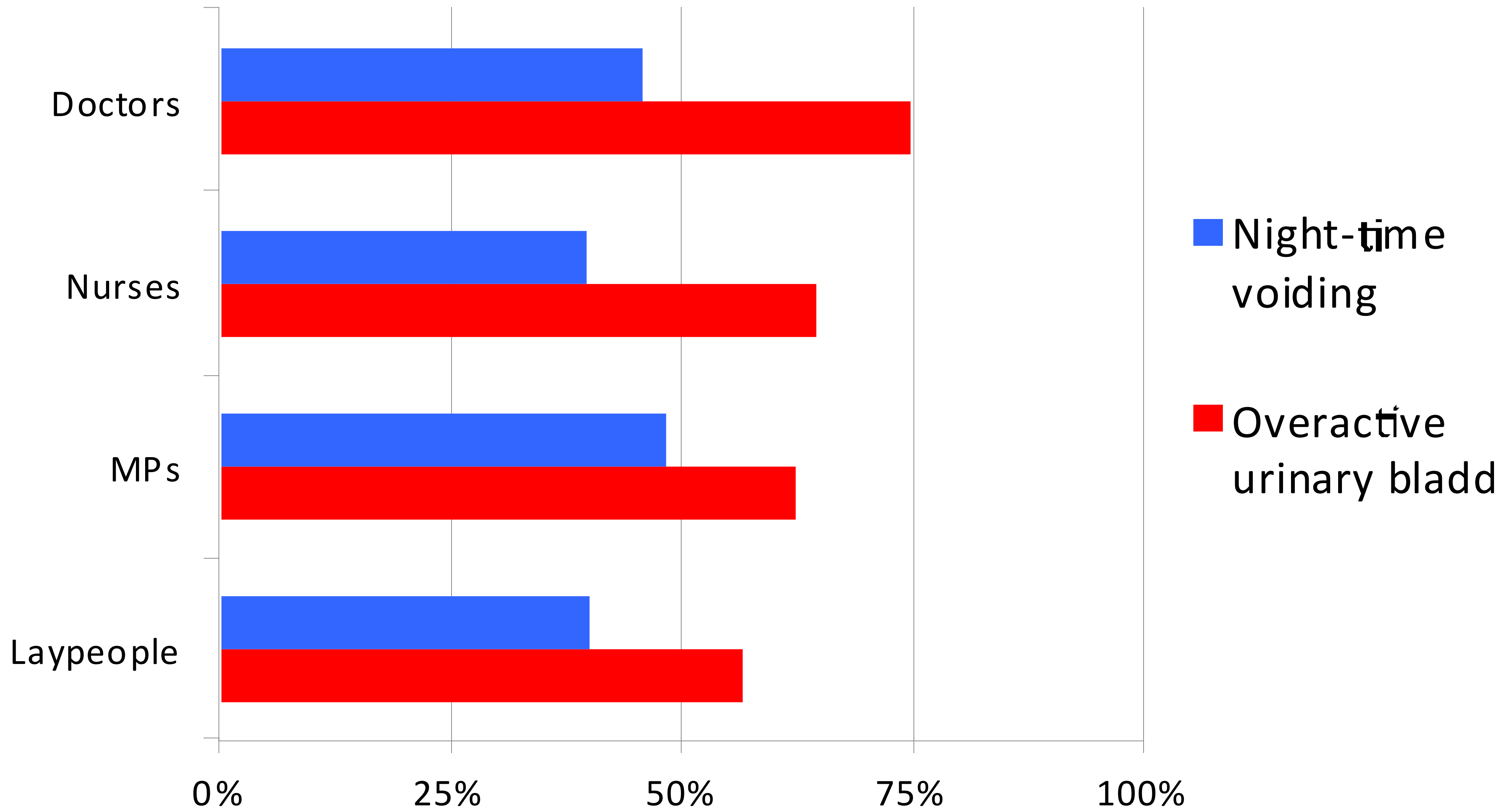
Tikkinen et al. *BMJ Open* 2012;2:e00016

Finnish Disease (FIND) Survey

Tikkinen et al. ***BMJ Open*** 2012;2:e00163

Proportion considering as a disease

Finnish Disease (FIND) Survey



Tikkinen et al. *BMJ Open* 2012;2:e00163

So, whom does the definition serve best?

1. Excellent for disease awareness campaigns bu also for *disease mongering* and *selling sicknes*
2. Does not optimally promote the scientific pursu 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