W23: How to Build an Evidence-Based Guideline – Important Epidemiological Principles

Workshop Chair: Marco Blanker, Netherlands
07 October 2015 16:00 - 17:30

Start	End	Topic	Speakers
16:00	16:05	General introduction	Marco Blanker
16:05	16:30	Impact of setting in which patients are seen	Janny Dekker
16:30	16:55	The interpretation of odds ratios for common conditions	Marco Blanker
16:55	17:25	Statistical considerations versus patient-importance	Kari Tikkinen
17:25	17:30	Questions	Marco Blanker

Aims of course/workshop

Despite the growing evidence in the field of lower urinary tract symptoms, the development and interpretation of guidelines remains difficult. Health care providers, policy makers and patients need to be aware of potential pitfalls. This workshop aims to provide ICS members with important background knowledge to enhance quality of future guidelines.
Unable to cover all aspects of guideline development, we will focus on the following aspects:

- The impact of the setting from which evidence arises.
- Interpretation of associations (risk factors), especially Odds Ratios for common conditions.
- Statistical significance and clinical relevance of treatment outcomes.

Learning Objectives

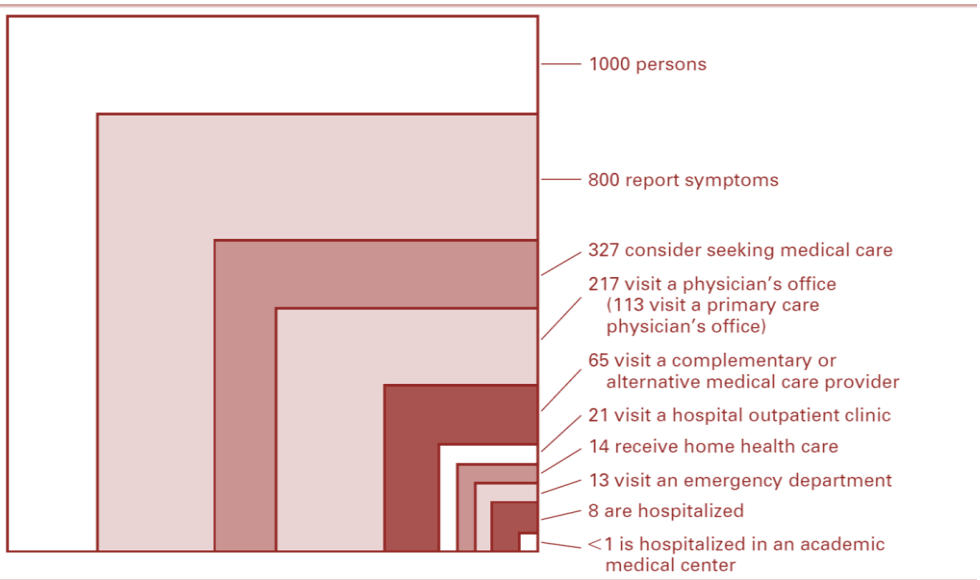
1. Interpret the impact of setting from which evidence arises, in order to know if evidence is applicable to their patients

2. Interpret and distinguish different outcome measures for associations (risk factors), especially Odds Ratios for common conditions

3. Discuss the differences between statistical significance and clinical relevance of treatment outcomes.

Part 1: Janny Dekker: Impact of setting in which patients are seen

Primary care physicians see patients that differ from patients seen by urologists and gynaecologists. In countries with a gatekeeper system and restricted referral to secondary care, this difference will be more pronounced than in countries with free access to specialist care. This selection of patients (see figure) has consequences for the interpretation of the evidence from clinical trials: is the population in the trial comparable to the population I see in my daily practice and for which I make my guideline? In which way do they differ and which inference can I make, nevertheless?



(From: Green L. The ecology of medical care revisited. NEJM 2001)

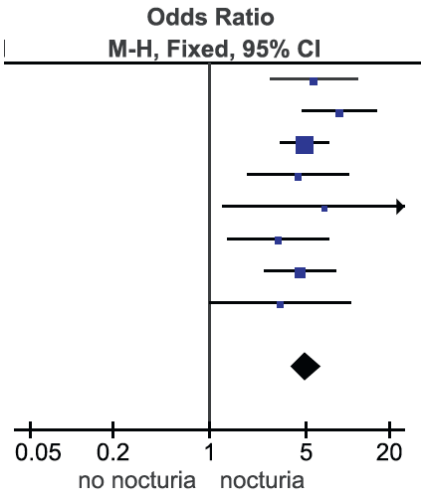
The selection also has consequences for the interpretation of diagnostic tests: the predictive value of a positive test decreases with the prevalence of a condition. Differences in severity of a disease in patient populations may even influence the sensitivity and specificity of a test.

The abovementioned problems in the interpretation of evidence derived from patient populations that are not entirely comparable to the population you make guidelines for, will be illustrated with examples from guidelines on urogynaecological conditions from different countries and settings.

Part 2: Marco Blanker: The interpretation of odds ratios and other risk estimates

Excessive nocturnal urine production is a major contributing factor to the etiology of nocturia. This title graced a publication on two large cohorts in which the prevalence of nocturnal polyuria (NP) was 64% and 88% (J Urol 2011;186:1358-63).
Do these results support the conclusion posted in the title of this publication? The cohorts appeared to be two cross sectional analyses in patients with nocturia. What about the prevalence of NP in patients without nocturia?

To further elucidate the association between nocturia and NP in men, Ilse Hofmeester et al. performed a systematic review and meta-analyses. Based on 8 studies with 2,320 participants, authors described an OR of 4.99 (3.92-6.37) of having NP when nocturia is present (compared to men without nocturia). This is illustrated in the Figure (derived from J Urol. 2014;191(4):1028-33).



What does this mean in this particular case? Do men with nocturia have a 5-times higher risk of having NP than men without nocturia? And what about the nocturnal voiding frequency in those with and without NP?

In this part of the workshop, various risk estimates will be discussed.

Part 3: Kari Tikkinen: Statistical considerations versus patient-importance

Statistical significance, represented typically by p-values, addresses the likelihood that apparent differences between groups may in fact be due to chance. P-values provide no indication of the size of an effect, the precision of the effect estimate, or the importance of the effect. Thus, a small p-value can exclude a null effect, but the true effect may still be very small, and not enough to counterbalance an intervention's adverse effects.

Point estimates and confidence intervals (the most likely true effect and the range in

which that effect is likely to lie) provide more useful information, but if presented in terms of relative effects, may still be misleading. For instance a relative risk reduction of 50% sounds impressive, but it can mean a reduction in adverse outcomes from 2% to 1%, or 40% to 20%. In the presence of appreciable adverse effects the former result may not warrant use of the intervention.

This presentation will highlight interpretation of intervention effects both in terms of statistical significance, estimation (point estimates and confidence intervals), and relative and absolute effects, focusing on the importance to patients.

ICS 2015 Montreal

Notes