

Measuring change in alcohol brief intervention trials: How are consensus core outcome sets developed?

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The challenge of complexity

- “Trials are only as credible as their outcomes”
(Tugwell 1993)
- Beyond trials
 - Funding
 - Reviews
 - Understanding
- Service user views



Why is it needed?

- Raise hand if you have done a meta analysis on any topic related to alcohol
- How much of the data could you use from the papers in your meta analysis?
- We use different measures, and this affects the potential to synthesise the evidence (inconsistency problem)

Systematic review evidencing outcome reporting bias

- The problem of significance
 - Trial more likely to be published
 - Outcomes more likely to be fully reported
- 40–62% of publications had 1+ primary outcome changed, newly introduced or omitted compared to protocol

[Dwan et al, *PLoS ONE* 2008]

Core outcome set

- Consider both benefits and harms
- The minimum (other outcomes can be collected)
- Focus is on trials of effectiveness
- “What” to measure, then “How”

How ORBIT will approach this complexity is crucial



The masterplan

Systematic Review

- What
- How



Delphi

- Two round
- Consensus meeting



Dissemination

- Publication
- Guidance

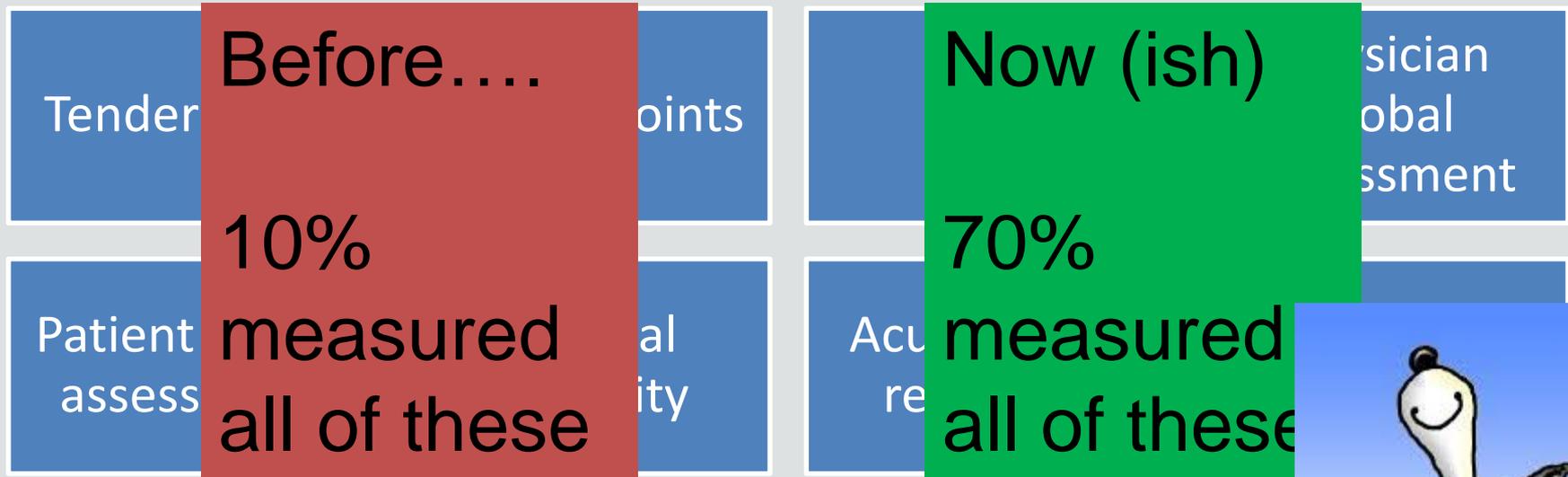


Why INEBRIA is important

- We need your input
 - Delphi
 - Outcome challenges
 - Concerns
 - Please get in touch with me (and can be confidential)

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An example from OMERACT: What do we gain from COS generation



What it might look like

tees.ac.uk

2009/10
THE AWARDS
Times Higher Education
UNIVERSITY OF THE YEAR



Inspiring success

Description of Measure
at Specified Time

Level 1
Domain

Anxiety

Depression

Schizophrenia

Level 2
Specific Measurement

Beck Anxiety Inventory

Hamilton Anxiety Rating Scale

Fear Questionnaire

Level 3
Specific Metric

End value

Change from baseline

Time to event

Level 4
Method of Aggregation

Continuous

Categorical

Mean

Median

Proportion of participants
with decrease $\geq 50\%$

Proportion of participants
with decrease ≥ 8 points

Figure 1. An Example of the Four Levels of Specification in Reporting Outcome Measures.

Zarin et al 2011; DOI: 10.1056/NEJMsa1012065

Advantages of core outcome sets

- Increases consistency across trials
- Strengthen evidence base
- Much more likely to measure appropriate outcomes (stakeholders)
- Major reduction in selective reporting

In conclusion

- Benefits: What is meaningful change, and to whom does it have meaning?
- Please get in contact
 - Take part in the Delphi (both waves), give me your views (good, bad, indifferent, where outcomes are useful for you)
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