



# **Questionable Reproducibility of Systematic Reviews: A Case-Study on treatment for stress urinary incontinence**

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# Aims

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**Present a case study to:**

- **Discuss examples of ambiguous outcome reporting found in primary studies.**
- **Explain the potential problems caused by these ambiguities, in one systematic review, and the threat ambiguities represent to the reproducibility of reviews.**



# Background - SUI

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- **Systematic review of non-surgical interventions for women with stress urinary incontinence (SUI).**
- **Variety of interventions considered (e.g. PFMT, electrical stimulation, duloxetine).**
- **Of the 12 duloxetine (drug treatment) studies included in our review, 7 had been included in a previous Cochrane Review (Mariappan 2005).**



# Background

## Quality Assessment

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- Where a Cochrane review has been conducted previously, Cochrane Handbook suggests conducting an “overview” of the original review, rather than conducting a the same review again (Chapter 22).
- This was our original intention, but we soon encountered problems.



# Methods

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- **Extracted data from the 7 primary studies, included in both our review and the Cochrane Review.**
- **Listed ambiguities within the primary studies.**
- **Compared our data with the data from the Cochrane Review.**
- **Noted differences in results caused by ambiguities from the primary studies, and the effects of these differences.**



# Results

Identified instances of ambiguous outcome reporting by primary study.

Study	Instances of ambiguity
Cardozo	7
Dmochowski	24
Kinchen	13
Millard	27
Norton	25
Van Kerrebroeck	17
Zinner	13
TOTAL	126

Vast majority caused by non-reporting of denominators of percentages.



# Results

## Identified instances of ambiguous outcome reporting by outcome type

<b>Outcome Type</b>	<b>Instances of ambiguity (number of studies)</b>
Number included in analysis	18(4)
Dosages/Compliance	12(5)
Results of clinicians' observations	43(5)
Results of Patient reported outcomes	12(3)
Adverse events/withdrawals	35(6)
Other	6(2)
<b>TOTAL</b>	<b>126</b>



# Consequences of Ambiguities

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**CONSORT Statement recommends RCTs report:**

**“Number of participants (denominator) in each group included in each analysis and whether the analysis was by ‘intention-to-treat’. State the results in absolute numbers when feasible”**



# Consequences of Ambiguities

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- For our SUI review detective work was necessary to compile data on:

$$\frac{\text{The number of events}}{\text{Number of valid observations for that time point}}$$

If the above was stated, or could be calculated, the outcome was included in our review.

- Cochrane Handbook offers two alternative solutions: “Available case analysis” or “an analysis on the total number of randomised participants irrespective of how the original study authors analysed the data”



# Effect of Assumptions Made

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- As a result, some of the outcome data in our review differed from the Cochrane Review outcome data, in 20 instances.
- So, 15.9% (20/126) of all ambiguous outcome reporting created a potential threat to the reproducibility of data in systematic reviews.



# Effect of Inconsistencies

- **Would it have made any difference to our results?**

Results for number of participants cured (based on diary data):

<b>Study</b>	<b>Using "Number in analysis"</b> (Treatment vs Placebo)	<b>RR</b>	<b>Total Randomised</b> (Treatment vs Placebo)	<b>RR</b>
Dmochowski	30/286 vs 19/322	1.78	36/344 vs 20/339	1.78
Millard	14/200 vs 14/229	1.16	16/227 vs 14/231	1.16
Norton	23/123 vs 20/132	1.23	26/140 vs 21/138	1.23

- **Did not change relative risk, but will affect confidence intervals.**



# Conclusions

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- **Seemingly innocuous reporting of percentages without denominators from which they are drawn can create complex problems that are time consuming for reviewers to solve.**
- **These data represent results from only 7 studies included in one review. This may be a more widespread problem for reviewers generally.**
- **Whilst differences in these review results had little impact on the overall effect size, this may not always be the case for reviews in other areas.**
- **Consensus on decision-making for ambiguously reported data would be helpful.**



# Thanks

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- Any questions?
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