

Impact of reporting on clinical practice



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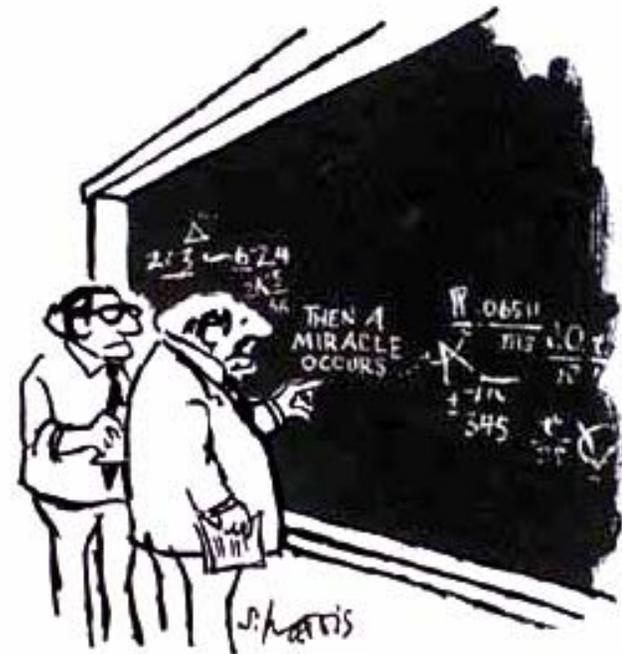


Background and Aims

CONSORT Item 4 requests:

- "Precise details of the treatments intended for each group and how and when they were actually administered".

Our aim: can we replicate the treatments studied?

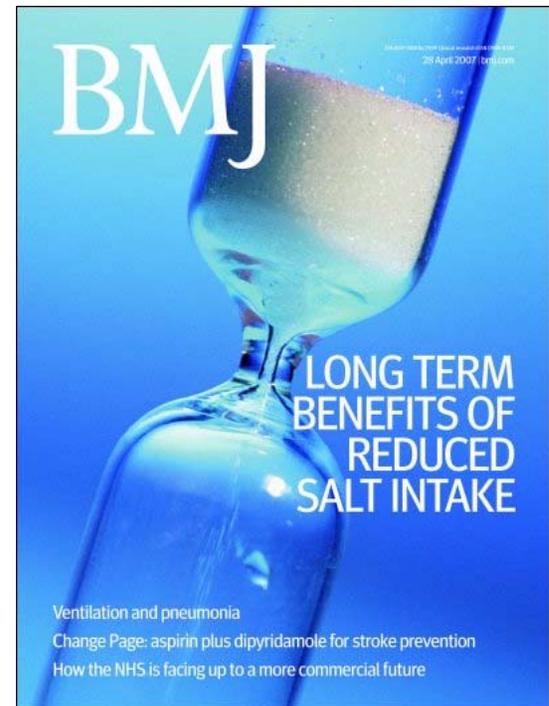


"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

What is the treatment?

- The paper's description of sodium reduction
 - "Individual and weekly group counseling sessions were offered initially, with less intensive counseling and support thereafter, specific to sodium reduction."

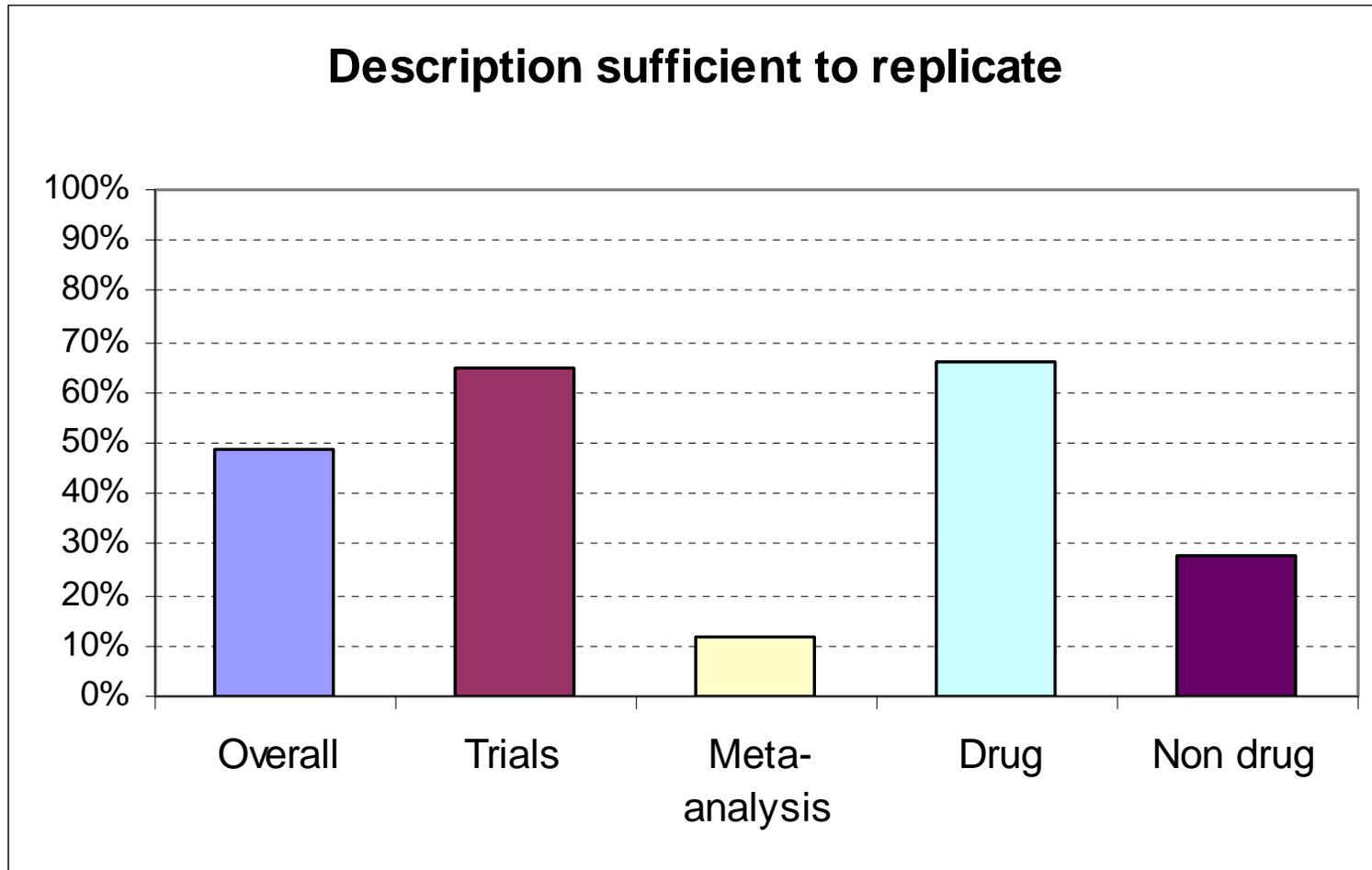
- What would you say to a patient?



What is sodium reduction?

- The paper's description
 - "Individual and weekly group counseling sessions were offered initially, with less intensive counseling and support thereafter, specific to sodium reduction."
- Previous reference
 - (i) an individual session followed by 10 weekly group 90 minute sessions with a nutritionist, followed by a transitional stage of some additional sessions
 - (ii) Topics in the weekly sessions included Getting Started, sodium basics, the morning meal, midday sources of sodium, the main meal, planning ahead, creative cooking, eating out, food cues, and social support,
 - (iii) the sessions included sampling of foods, discussion of articles on sodium reduction, and problem-solving,
 - (iv) patients kept diaries at least 6 days per week, and urine sodiums were measured.

Half the descriptions were sufficient



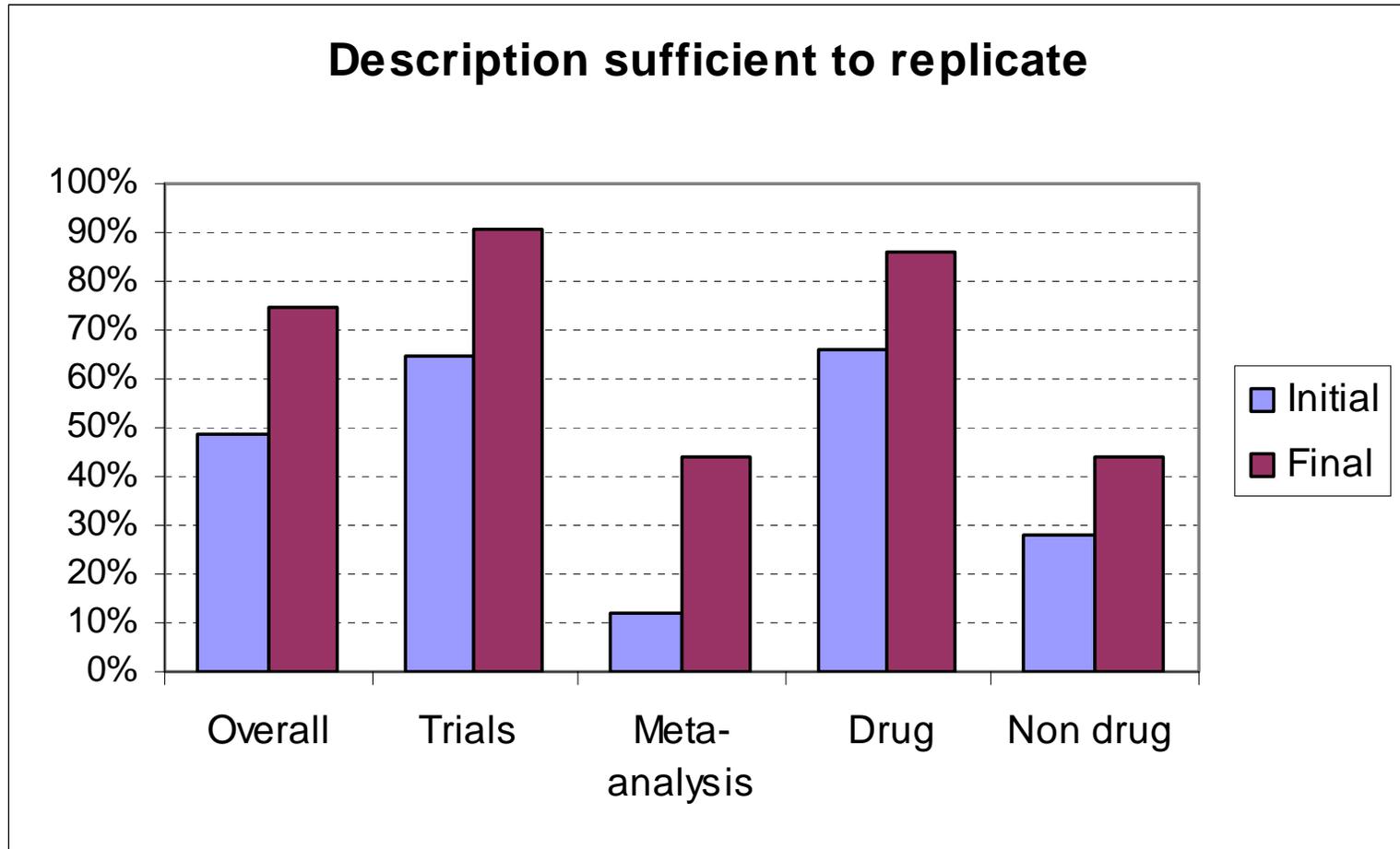
What we did

(2) Is the poor description fixable?

To get complete treatment descriptions we:

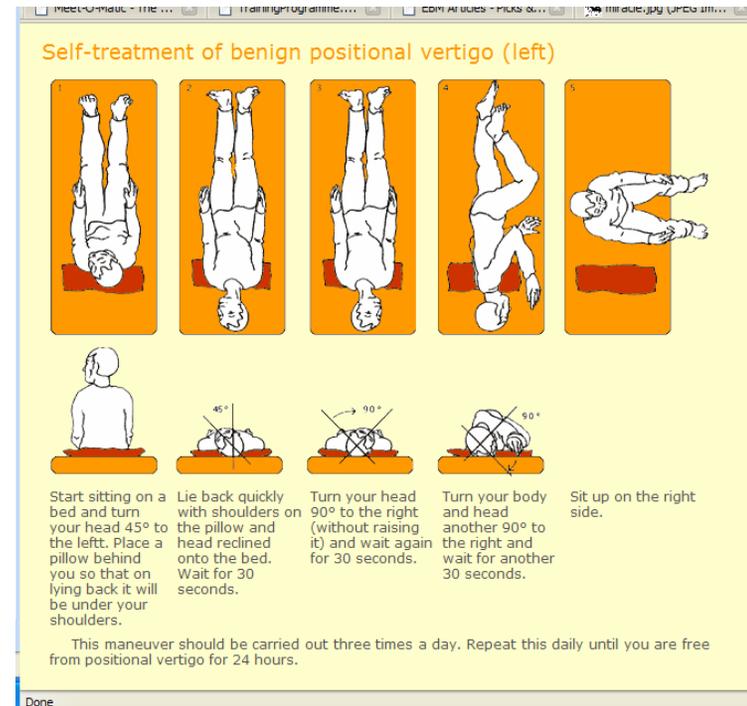
- Checked references
- Wrote to authors
- Did internet searches
- And other things:
 - ▣ Checked with local pharmacy, asked colleagues, ...

Is the inadequate description fixable?



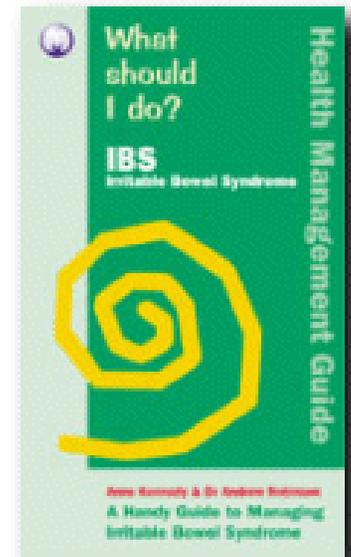
Missing patient handout: in reference

- ❑ STUDY: Self-treatment for benign paroxysmal positional vertigo of the posterior semicircular canal. Neurology 2005.
- ❑ TREATMENT: "Each head position has to be maintained for more than 30 seconds. ***Patients received illustrated instructions*** for the specific maneuver ..."
- ❑ PROBLEM: Instructions not in article but available in reference 5:
 - Radtke, A. Neurology 1999;53:1358



Missing guidebook: hard to track down!

- ❑ STUDY: Self-help interventions in patients with a primary care diagnosis of irritable bowel syndrome. Gut 2006.
- ❑ TREATMENT: Patients received a **comprehensive self-help guidebook** produced following a series of focus group meetings with other IBS patients ...
- ❑ PROBLEM: Missing details of guidebook.
 - No response from author to 3 emails
 - Colleague said booklet was on sale
 - Google search found the book



Price: £8.99



Missing booklet & software: unusable

- STUDY: Randomised trial of telephone intervention in chronic heart failure: DIAL trial (BMJ 2005)
- TREATMENT: “ ... patients allocated to the intervention **received an education booklet**. Nurses ... did frequent telephone follow-up from the telephone intervention centre. “Nurses had **special software** with which they recorded data on every call.”
- PROBLEM: missing booklet and software. Response from authors
 - Is the education booklet available?
 - *“yes, but it is in Spanish”*
 - What is the software program that was used, and is it available?
 - *“It is available but not for public use”*
 - What was the nurse training?
 - *The training included classes, reading materials and role playing. We have the guide that they used to interview each patient, but in Spanish*



Systematic review: what specific regimen?

- STUDY: meta-analysis of behavioural interventions for insomnia adults
 - “.. confirms the efficacy of behavioral interventions for person with chronic insomnia.”

- PROBLEM: No regimens for ‘behavioural intervention’ described
 - Author asked: “what specific treatment regime (or regimes) would you recommend based on your review?”
 - Author response: “It was found that cognitive, behavioral and relaxation therapies all in general lead to similar improvements in sleep outcomes---although cognitive approaches might have been a bit better. The references for these studies are found in the article. ”

Rx

“Behavioural Intervention”



Treatment checklist

I keep six honest serving-men

(They taught me all I knew);

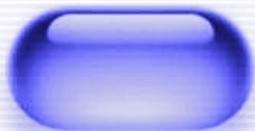
Their names are What and Why and When

Setting	Is it clear where the intervention was delivered?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Recipient	Is it clear who is receiving the intervention?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Do you need to know more about the patients eg which drugs they are taking, what they were told?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Provider	Is it clear who delivered the intervention?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Procedure	Is the procedure (including the sequencing of the technique) of the intervention sufficiently clear to allow replication?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Materials	Are the physical or informational materials used adequately described?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Intensity	Is the dose/duration of individual sessions of the intervention clear?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Schedule	Is the schedule (interval, frequency, duration, or timing) of the intervention clear?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Missing	Is there anything else missing from the description of the intervention? If yes, what? <input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Control	Is it clear what the control group received during the study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If No, what further information do you require? <input type="checkbox"/>	



Conclusions: what is in the non-pill?

1. Descriptions of treatment are often insufficient to permit a clinician to use in practice.
2. Readily available details could improve about half the descriptions
3. Inadequate treatment descriptions represent a vast waste of research resources and a lost opportunity to improve patient care.



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Some Recommendations

□ Journals

- should request sufficient detail to allow use of the treatment

□ Authors

- Should provide such descriptions but avoid journal copyright.

□ Non-pharmacopeia

- A web-based “open source” repository of treatment descriptions is needed