Impact of reporting on clinical practice

Paul Glasziou, Carl Heneghan, Emma Meats, Sasha Shepperd, Sara Schroter

Centre for Evidence-Based Medicine, University of Oxford
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?
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?

TOHP Study BMJ, Apr 2007; 334: 885
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.
How often is the treatment replicable?

80 consecutive treatment reports selected for the EBM journal (10/’05-10/’06)

For each study 2 active clinicians were asked:

“Could you use this treatment with a patient if you saw them tomorrow?”
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?

Description sufficient to replicate

- Overall
- Trials
- Meta-analysis
- Drug
- Non drug

- Initial
- Final
Missing patient handout: in reference

- **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!


- **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

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