Descriptions of non-pharmacological interventions in clinical trials
Reporting must improve

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Clinical trials are the standard for establishing the relative effectiveness of two interventions. Although work is being done to maximise the reporting of trials, thus minimising publication bias, other sources of bias lurk within trial reports. In a linked article (doi:10.1136/bmj.f3755), Hoffmann and colleagues report on the description of non-pharmaceutical interventions in published trials and conclude that fewer than 40% were adequately described. Because more than 40% of published trials are non-pharmaceutical, this is an important group. Furthermore, the findings have improved little over time.

These are crucial omissions. Without adequate description it is difficult—if not impossible—to repeat the trial, and, more importantly, clinicians do not know how to deliver the tested intervention to their patients. This can have serious consequences for patients’ safety and is part of the growing agenda to reduce waste in clinical research.

For the results to be interpreted accurately, all arms of a trial must be adequately described. If active interventions are poorly described, descriptions of the control are likely to be even worse. Hoffmann concentrated on the intervention—the “new” procedure. Our experience is that the comparator is often described as “treatment as usual” or “usual care,” without there being any recognition that care may vary by centre and clinician, and over time. Without characterising the control it is impossible to know whether it overlaps with the intervention being tested. Consequently, even if the tested intervention is shown to be superior, we don’t know what it’s superior to.

The problem is partly explained by the difficulties of completely describing most non-pharmaceutical interventions. These are usually complex, comprising several components, each with a possible impact on outcome. For example, to describe a surgical procedure, the investigator should provide full details of preoperative care, the management of anaesthesia, intraoperative care, the surgical procedure itself, configuration of any device, postoperative care, and the surgeons’ and surgical team’s expertise and volume of care they deliver. This list is not exhaustive.

Hoffmann’s findings on contacting authors are interesting. Such contact increased the proportion of adequate descriptions by about 20%. This raises two questions: firstly, why weren’t adequate descriptions provided in the first place; and, secondly, should the 40% of published trials lacking adequate descriptions of their interventions be counted as published if no one can interpret them? Of course, it is not practical for practising clinicians to contact trial authors to clarify the exact intervention. It might be thought that lack of space in conventional journals pushes authors to skip elements of their reports, and that descriptions of interventions are an easy victim of this. But a look at a journal with no word limits (Douet and colleagues, unpublished data), and at other journals with more relaxed word limits or that offer online appendices, shows that this is not the case.

Reporting guidelines, such as SPIRIT (which is used for clinical trial protocols) and CONSORT (which is used for trial reporting) currently gloss over this problem. For example, CONSORT says that reports of interventions should have “sufficient details to allow replication, including how and when they were actually administered.” In the light of Hoffmann and colleagues’ paper, this is vague, insufficient, and may be undermined by the difficulty of implementing reporting guidelines. The extension of CONSORT to non-pharmaceutical treatments expanded this item and highlighted the need to describe all components of the intervention clearly—both the experimental treatment and the comparator. The characteristics of centres delivering care, such as details of the care providers and how their delivery of care was assessed, must also be detailed. There is also a requirement to specify how interventions were tailored to patients and what efforts were made towards standardising the intervention. However, this does not seem to have influenced the reporting of the studies reviewed by Hoffmann and colleagues.
The traditional six page academic paper is a cramped way of reporting something as complex as a clinical trial. Although it has been shown that limitations of space do not contribute directly to inadequate description of interventions (Douet and colleagues, unpublished data), changes in the academic publication environment could aid description. Trial reporting is slowly developing into publication of a network of outputs—the protocol appears first, followed by a paper setting out short term clinical findings, then a longer term follow-up, and maybe a paper on economic analysis. This network could include a separate publication describing the intervention (which occasionally happens now, especially in manualised psychological and social interventions) or, if the intervention is well established, there could be a reference to pre-published descriptions.

The most important remedy is to instil awareness within consumers of research that descriptions of interventions may not be as complete as desirable.

Action should be taken at four levels. Firstly, methodological research is needed into how interventions should be reported. Surgical and psychological interventions are good candidates for further exploration. Secondly, trialists, funders, and sponsors should ensure that interventions are well described from the outset. The interventions must be delivered as described and the descriptions made available alongside or within the trial report. Thirdly, publishers should enforce the adequate reporting of interventions and possibly consider hosting an online repository, as described by Hoffmann and colleagues. Finally, and most importantly, clinicians and patients should complain to trialists and publishers if trials are published with inadequate descriptions of their interventions. Clinicians and patients are the last line of defence against poor reporting.

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2 AllTrials. All trials registered. All results reported. www.alltrials.net/