Many documents have been developed to help clinical researchers at various stages of their research. Some are intended to help when designing the research, while others are intended to help ensure that the research is ethically conducted. Another large group of documents are those that are intended to help researchers to publish their research with the necessary details for others to appraise and use it appropriately. The purpose of this editorial is to encourage physiotherapy researchers to view these documents as an opportunity to add value to their research at the various stages before publication.

Readers may be familiar with some of these documents. For example, the Declaration of Helsinki is a set of ethical principles governing research involving humans, which was developed by the World Medical Association.1 Many trial reports include a statement that the research was ‘conducted in accordance with the Declaration of Helsinki2, but the reported methods sometimes show that this is not true. Perhaps these researchers read the Declaration of Helsinki many years ago and believe that it has not changed. However, it has been amended seven times since the original 1964 version. The most recent update was in 2013, so even researchers who have read it relatively recently may find that it has changed.3 Although fundamental ethical principles may change very infrequently, ethical implications of new developments in the world need to be incorporated. One such amendment was made in accordance with the introduction of clinical trial registers and the various campaigns to encourage prospective registration of randomised trials.4,5 The Declaration of Helsinki now states:

Every research study [not just randomised trials] must be registered in a publicly accessible database before recruitment of the first subject.

Yet researchers still submit manuscripts to the Journal of Physiotherapy reporting unregistered studies and claiming consistency with the Declaration of Helsinki. All authors are reminded that to be considered by the Journal of Physiotherapy and many other physiotherapy journals, manuscripts reporting randomised trials starting in 2006 or later must be prospectively registered.6 By following the Declaration of Helsinki’s recommendation to prospectively register all types of studies, a researcher would make his/her studies more appealing to editors, reviewers and readers because it proves that the research is not biased by, eg, selective reporting of outcomes.7 Researchers may also be surprised to learn that the Declaration of Helsinki states that:

In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial.

Some physiotherapy trials achieve this recommendation by using a ‘wait list’ design, where the control group is offered the treatment after the trial.8 In other physiotherapy trials, post-trial provision of the intervention is not possible. For example, interventions that are beneficial when administered before surgery may not be applicable postoperatively.6,7 An intervention applied with the intention of shortening the duration of inpatient management may have no subsequent purpose in the control group.8,9 Nevertheless, many trials that could provide the intervention after the data collection period do not do so. This item was later clarified with:

It is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

Many interpret this as a requirement to identify whether or not post-trial access to the intervention will be available, meaning that there is no real onus to do so.10 Nevertheless, researchers could use the Declaration of Helsinki to remind themselves of the importance of this issue and incorporate post-trial provision of the intervention, where possible. In addition to improving the trial’s ethical standard, it may improve the scientific standard by fostering recruitment and minimising loss to follow-up in the control group.

Reporting guidelines are another type of resource that physiotherapists could use to add value to their research. These documents are designed to help clinical researchers to publish all of the details of a research study that readers will need to understand its methods, judge its quality, and appropriately apply the results. There are many reporting guidelines related to specific types of research. For example, researchers who are writing a manuscript about a randomised trial could use the Consolidated Standards of Reporting Trials (CONSORT) statement.11 The statement is summarised into a checklist, which authors can use to identify where in their manuscript each item of the CONSORT statement is reported. The completed checklist can also be submitted with the manuscript for the benefit of reviewers and editors. The Journal of Physiotherapy has supported the use of reporting guidelines for over a decade and recently co-published an editorial reiterating their importance.12

Unfortunately, as with the Declaration of Helsinki, published reports of research often reveal that these reporting guidelines have not been used as they were intended. For example, the Journal of Physiotherapy regularly receives manuscripts that report a randomised trial and state that ‘the CONSORT statement was used to guide reporting’, but the appropriate items still do not appear in the paper. This is a problem but, at least at the editorial stage, it is
fixable. However, it suggests that some researchers view the CONSORT statement as an administrative hurdle. It may be more valuable to view it as a resource that they can use to ensure that their research is reported in enough detail to be useful to clinicians and other researchers.

A less fixable problem is heralded by the statement that ‘the CONSORT statement was used to guide the design of the trial’. The CONSORT statement is a reporting guide, not a design guide. Although many items on the CONSORT checklist are relevant for consideration at the design stage, researchers who use it in this way risk missing crucial advice about how to design their clinical trial well. Consider the issue of loss to follow-up in clinical trials, for example. In a sample of over 10,000 trials of physiotherapy interventions, more than half of the trials failed to follow-up at least 85% of their original participants. However, trials can be designed to incorporate strategies that minimise loss to follow-up. Incorporation of these strategies into the trial design is recommended in the guide to preparing a trial protocol, known as the SPIRIT statement (Standard Protocol Items: Recommendations for Interventional Trials). On this issue of follow-up, the SPIRIT statement provides helpful discussion of issues such as: choosing the trial’s duration to maximise clinically relevant outcome measurement while minimising loss to follow-up; and which strategies have been proven to minimise loss to follow-up. It is too late to do anything about loss to follow-up at the reporting stage. Accordingly, the CONSORT statement only advises about clear reporting of the extent of the follow-up, such as distinguishing unavoidable loss to follow-up from investigator-determined exclusion. Other guidelines that could be used at the design stage are those intended to help researchers in choosing the best outcome measures to use in their trials. As examples, the Outcome Measures in Rheumatology (OMAR) website could be used by researchers in arthritis (www.omeract.org), and the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) website has documents to guide pain research (www.immpact.org).

Although randomised trials have been used as an example above, equivalent documents are also available for other study designs: observational studies, systematic reviews, qualitative studies, diagnostic studies, prognostic studies, economic evaluations, and so on. Researchers can find many of these documents on the Equator Network website. As well as the main reporting guideline for each study type, the Equator Network also compiles extension documents. These are companion documents with extra detail that is only pertinent (but still very valuable) to some studies with a particular characteristic. For example, there is an extension to the CONSORT statement that is specifically designed for non-pharmacologic interventions. This is particularly relevant to physiotherapy intervention trials, because it more thoroughly addresses issues such as the difficulty of blinding physical interventions and the importance of reporting the skills, experience and any specific extra training of the physiotherapists who apply the study interventions such as manual techniques. Despite its relevance to physiotherapy, few authors mention this document in their published trial reports.

As noted above, one of the areas in which the CONSORT statement is too cursory is in its guidance about what intervention details to include in the published trial report. Specifically, the CONSORT statement only states:

Describe the intervention for each group with sufficient details to allow replication, including how and when they were assessed.

This lacks detail for a researcher who wants to ensure that they include all the necessary details of an intervention for clinical physiotherapists to be able to apply it to their patients. But it isn’t just the CONSORT statement; it is a problem that has affected several of the reporting guidelines to some extent. This deficiency may explain the recent finding that 85% of published trial reports lack enough detail for the intervention to be replicated. To rectify this, the Equator Network has recently added an extension document called the Template for Intervention Description and Replication (TIDieR). It also comes with a checklist containing explicit instructions such as:

Describe the number of times the intervention was delivered and over what period of time, including the number of sessions, their schedule, and their duration, intensity or dose and

If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.

That is, it guides a researcher to include all the practical information that clinicians need to apply the study’s intervention. The TIDieR checklist is designed to be used in conjunction with checklists for any study types that involve an intervention. This would include the CONSORT and SPIRIT statements for randomised trials, but could also apply to the reporting guidelines for observational studies where the participants are receiving an intervention, a case report of a patient who was receiving a treatment, systematic reviews of such studies, and so on. In this way, the TIDieR checklist can help researchers to overcome cursory guidance about reporting interventions in these other checklists, ensuring that the reporting of the intervention is thorough.

Some other resources have been developed to guide researchers on some specialised research issues outside the Equator Network. A recent example is the second version of the Pragmatic-Explanatory Continuum Index Summary (PRECIS-2). This tool helps researchers to understand how different aspects of a trial’s design influence whether that trial estimates efficacy (the effect of an intervention when it is administered exactly as intended, i.e., an explanatory trial) or effectiveness (the effect of the intervention when applied in everyday clinical practice where factors such as poor adherence potentially reduce its effect, i.e., a pragmatic trial).

Guides for reporting are not strictly limited to clinical research. The Guideline for Reporting Evidence-based practice Educational interventions and Teaching (GREET) has been developed to guide the reporting of educational interventions for developing foundational knowledge and skills in evidence-based practice. Like TIDieR, GREET can be used in conjunction with checklists such as CONSORT to ensure thorough reporting of the educational intervention. The final point to make is that these documents are helpful. For example, since the CONSORT statement was published, there has been improved reporting of many of the items it recommends for physiotherapy trial reports. Researchers should consider them as valuable resources to improve their research, not just as extra paperwork. Some junior researchers even say the checklists help them to overcome difficulty in knowing where to start when writing a study protocol or report. Therefore, researchers are encouraged to explore each document that is available in relation to their current and future studies, to read and use each document carefully – and most crucially – to ensure that each document is used for its intended purpose.

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People’s Choice Award for 2014

The Editorial Board is pleased to introduce the annual People’s Choice Award, which recognises the paper published in Journal of Physiotherapy that generates the most interest by readers of the journal. The winning paper is chosen based on the number of times that each paper published in a given year is downloaded in the six months after its day of publication.

The winning paper is ‘Current evidence does not support the use of Kinesio Taping in clinical practice: a systematic review’ by Patrícia do Carmo Silva Parreira and colleagues from the Universidade Cidade de São Paulo in Brazil. This systematic review examined the 12 randomised trials that provided published data by June 2013 about the effect of Kinesio Taping on pain, disability, quality of life, return to work and global perceived recovery in people with musculoskeletal conditions. These trials provided data on 495 participants. Studies were excluded if they were conducted on healthy participants or only reported data on physical performance (eg, vertical jump test). The 12 trials covered a range of musculoskeletal conditions. Among these trials, Kinesio Taping had no benefit over sham taping or other active treatments to which it had been compared, the benefit was too small to be clinically worthwhile, or the trials were of low quality. Therefore the evidence did not support the use of Kinesio Taping for musculoskeletal conditions.

The Journal of Physiotherapy has subsequently received and published two more high-quality randomised trials comparing Kinesio Taping to sham taping: one for swelling after ankle sprain by Nunes and colleagues and one for low back pain, which again has Patrícia do Carmo Silva Parreira as the first author. These two trials further reinforce the findings of the review by demonstrating that Kinesio Taping was no better than sham taping for these conditions.

The winning paper also generated the highest activity on social media among the papers published in 2014. The Editorial Board of Journal of Physiotherapy congratulates Patrícia do Carmo Silva Parreira and colleagues on their success.

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