Reporting diagnostic accuracy studies: where are we now?

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Reporting guidelines are booming. A quick look at the EQUATOR website – the website for research reporting guidelines – revealed over 250 different guidelines, varying from the well-known CONSORT statement for reporting of randomized controlled trials and PRISMA for reporting of systematic reviews to the lesser known ones like TRI-POD for prediction models and CARE for case reports [1]. And after the development of reporting guidelines for full text articles, reporting guidelines for abstracts are now emerging [2,3].

Regardless of the number of existing guidelines, the actual reporting of the items listed in those guideline lays far behind. Several research projects have investigated the adherence to reporting guidelines in different areas of healthcare and they all reveal the same trend: although reporting may be improving in some areas, there is still much that remains unreported. This is not very different for diagnostic accuracy studies. We analyzed 112 diagnostic accuracy studies published in high-impact journals in 2012 and found that on average these studies reported only 15 items out of the complete list of 25. Although this was a significant improvement in comparison to similar analyses done in 2000 (11.9 out of 25) and 2004 (13.6 out of 25), crucial information remains unreported [4]. Even though the included journals all but one mentioned the use of STARD in their guidelines for authors.

Apparently, researchers are either not aware of the existence of these reporting guidelines, or they do not consider using them. How is this possible? What are the drivers for an author to adhere to these guidelines and how can we increase adherence?

Until now, efforts were mainly put into the development of the tools and it seemed as if the developers expected external forces, such as journal editors and peer reviewers, to force adherence upon authors. However, not all journals do include STARD in their authors guidelines and even if they do, from our previously mentioned analyses it may be concluded that not all journals indeed check the adherence to STARD. Furthermore, not all peer reviewers may be aware of the need of complete reporting, or they may find it cumbersome to check whether indeed all items of STARD have been reported. Although one may find that journals and peer reviewers should have the moral obligation to ask for complete reporting, these incentives have proven not to work sufficiently.

Although these strategies may be improved, for example by using electronic pop-ups as soon as someone submits a diagnostic accuracy paper, these external incentives only act after most of the work has already been done. Furthermore, research done in other fields shows that people need both external incentives and intrinsic motivation to change their behavior [5,6]. Intrinsic motivation to use reporting guidelines as a useful tool throughout the research project should therefore be promoted.

Intrinsic motivation for authors to adhere to reporting guidelines may come from the understanding of why complete reporting is important. There are several reasons for this and I will discuss a few. First of all, readers of these studies need to know whether the study they are reading has a potential for bias. If there is potential for bias, the study is not immediately useless. Readers must be enabled to estimate the extent of bias and the direction

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into which the results of the study may be biased. This requires information on study characteristics. Second, readers need to know whether the study they are reading is applicable to the situation they are in. Sensitivity and specificity of a test largely depend on the setting in which the test is used and the disease spectrum of the patients undergoing the test of interest [7]. The accuracy of a test may be quite different in primary care, with a wider spectrum of disease, lower prevalence and more patients with less severe symptoms, than the accuracy of the same test in an academic hospital, with a selected population of often severely ill patients. Furthermore, patients who are enrolled on the basis of previous test results may have a different accuracy than patients for whom the test of interest is the first test done. Healthcare professionals need to be able to assess whether the study at hand is applicable to their situation, which is only possible if the patient characteristics are reported into detail. A third reason for accurate reporting may be that poor reporting offers room to 'spin' the conclusions of a study [8]. If researchers do not report that the assessment of the index test was not blinded, then this will neither be listed as a limitation to the study and the conclusions may be presented in a more positive light than they actually should. Furthermore, poor reporting of the aim or hypothesis of the study makes it

easier to claim in hindsight that the accuracy of the test under investigation met the requirements for a good test. A fourth reason to report the methods and results completely, is that poor reporting may lead to selective reporting of only those results (e.g. subgroups or test variants) that had a 'nice' result, which is seriously misleading. A fifth reason may be the further understanding of variation in accuracy results between studies. For some researchers, accurate reporting may mainly serve the authors of systematic reviews, who need to assess the quality and extract data from primary studies. However, one of the objectives of a systematic review, especially one on diagnostic accuracy, has provided more insight into why study results may differ from each other. To investigate drivers of heterogeneity and thus to gain more insight in test behavior over different settings and populations, complete reporting of study characteristics is necessary.

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However, the most convincing motivation may come from the reporting guidelines themselves. Were these guidelines previously presented as something that is necessary for the reader and the scientific society as a whole, more and more reporting guidelines present themselves as being helpful for researchers and authors of scientific literature. Everyone publishing scientific reports may recognize the difficulty of being complete in their reporting. Sometimes as an author you just assume certain characteristics to be obvious; or they are even too obvious to be considered anyway. Furthermore, not everyone may be aware of the importance of blinded assessments or complete reporting of uninterpretable results. For all these authors, a reporting checklist may be useful help while writing the report, or even in the design of the study. Authors should see these reporting guidelines as a helpful tool, rather than a burden.

Assuming that the motivation to completely report diagnostic accuracy and other primary studies should come both from within and outside, there are a few things that could be improved in the current scientific systems. First of all, the 'framing' of reporting guidelines should be done more positively. These checklist are not a burden that authors should adhere to, they are helpful instruments that help authors in designing and writing up their research projects. Furthermore, one of the key elements of scientific publications, is that they must enable fellow researchers to reproduce the presented work. This is only possible if reporting is complete. It would therefore be helpful if the reporting guideline were actively promoted in courses on scientific writing and in courses on study design. Mention-

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ing reporting guidelines in courses on good scientific behavior or on the ethics of research may be helpful as well. Healthcare professionals base their decisions upon available evidence. Research reports may directly affect patients and not reporting patient characteristics or study limitations may lead to the wrong decision, thus harming patients.

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Finally, the developers of these reporting guidelines will have to increase awareness among researchers, and to make the checklists easier to access and easier to understand. People need to be aware of the checklists to be able to use them. If finding them takes too long and completing the checklist is too complicated, people will refrain from using them as well. Over the past months, STARD the reporting guidelines for diagnostic accuracy studies, have been revised into STARD 2015. STARD 2015 aims to be simpler for authors to adhere to and more in line with other reporting guidelines. But the most important feature of STARD 2015 is the simultaneous launch of online material and

examples to help authors to understand the requested items. The developers of this checklist no longer expect the world to pick up the tool and use it, but they put effort in the improvement and dissemination of the tool itself [9].

In summary, the reporting of diagnostic test accuracy studies has slightly improved over the years, which may be due to the introduction of STARD. Still, much remains unreported. To improve this, we need to draw a more positive light on the reporting guidelines and enhance the internal motivation of authors to adhere to these guidelines. But, dear authors, the next step is with you: future diagnostic accuracy studies, will be guided by the STARD guidelines from the start. Please check the EQUATOR website for STARD and other reporting guidelines: www.equator-network.org

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

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