Clinical Chemistry

Special Report
STARD 2015: An updated list of essential items for reporting diagnostic accuracy studies

Special Report:
P. M. Bossuyt *et al*, for the STARD Group.
STARD 2015: An updated list of essential items for reporting diagnostic accuracy studies.
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Guest: Dr. Patrick Bossuyt is professor of Clinical Epidemiology at the University of Amsterdam and has spearheaded the STARD initiative for the improved reporting of diagnostic test accuracy studies and leads the biomarker and test evaluation research program in Amsterdam.

Bob Barrett: This is a podcast from *Clinical Chemistry*, sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

Incomplete reporting in scientific papers is a major source of needless waste in biomedical research. Essential information is often not provided in study reports, hindering the identification, critical appraisal, and confirmation of the work presented.

To improve the quality of reporting of diagnostic accuracy studies, about a dozen years ago the Standards for the Reporting of Diagnostic Accuracy Studies, or STARD statement and guidelines, were developed.

The STARD statement appeared in the January 2003 issue of *Clinical Chemistry* and a number of other journals. That publication was accompanied by editorials and commentaries in several other journals and endorsed by many more.

Since the initial publication of STARD, several assessments have pointed to small but significant improvements in reporting accuracy studies. Gradually more of the essential items are being reported but the situation remains far from ideal.

Over the past years, the STARD group has remained active in assessing progress, and has updated their recommendations in STARD 2015, with a list of 30 essential items that should be included in every report of a diagnostic accuracy study.

The new STARD check list appears in the December 2015 issue of *Clinical Chemistry,* as well as a number of other journals.

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The lead author of the STARD statement is Dr. Patrick Bossuyt. He is professor of Clinical Epidemiology and Head of the School of Public Health at the University of Amsterdam in Netherlands and he is our guest in this podcast and doctor, we will get basic, just what is the STARD statement?

Dr. Patrick Bossuyt: The STARD is an abbreviation that stands for Standards for Reporting Diagnostic Accuracy Studies, and it's a list of items that should be included in every report of a study that reports diagnostic accuracy.

So what's diagnostic accuracy? So diagnostic accuracy is an expression or the performance of an imaging test or another medical test like its sensitivity and its specificity. So it expresses how well the test can identify people with and without a specific disease.

Bob Barrett: Talk about the development of STARD, why was this developed and has it needed any updating?

Dr. Patrick Bossuyt: It was developed because study reports of sensitivity and the specificity of an imaging test or another test should not only include these numbers, the sensitivity itself and the specificity, but they should also include how the study was done. And that's essential because you can do a study in a right way and you could do it in a wrong way. And readers should be able to find out whether the results are valid.

Now that's not just about validity, it is also applicability. Reader should be able to learn whether the study was done in adults or in young people and whether it was done in people in the developed worlds or maybe in Asia. And that's necessary to evaluate the applicability of the study findings to the specific situation of the reader.

Now STARD was developed because many study reports do not include that essential information. They do not tell us how the study was done in sufficient detail. Actually the reports will not tell us in what kind of patients actually the study was done. Now to encourage and to facilitate more complete reporting, we developed STARD initially in 2003 to encourage authors to be more complete and more transparent in the reporting of these studies.

So if authors go through the list of the items that we have developed, they can be guaranteed that their study report contains all of the essential information for readers.

Now that was not the case before 2003 when we initially developed STARD and it's still was not the case last year when we looked at how well STARD was implemented. So that's why we developed an update and the updates include

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a couple of new items and it also re-expresses, formulates, the items in a slightly different way that we hope make the list easier to use.

Bob Barrett: Doctor, it's now been a dozen years since the initial STARD report was published, what has been its impact?

Dr. Patrick Bossuyt: That's a very relevant question because, why make such a list if it does not produce an effect? Several studies have now compared, the completeness of reporting before the development of STARD and after STARD has been released and included in the instructions for authors in multiple journals. And these evaluations have shown that the introduction of STARD has resulted in slightly more complete reporting.

So authors that have used STARD are able to produce study reports that are more informative, more complete, and contain more of the essential information. But overall the improvement has been relatively modest. It's statistically significant, so more things are now included in the study reports, but the improvement is still relatively minor.

That was one of the other reasons for developing STARD 2015 to make the list easier to use, so that more authors and more reviewers and more editors can use STARD to make sure that the study reports are fully informative and helpful for readers.

Bob Barrett: Is this the only tool of this kind available to help authors?

Dr. Patrick Bossuyt: No definitely not, actually. When authors prepare manuscripts there are many instruments to help them. So every journal has a list of instructions for authors that tell authors how to write manuscripts that are fit for publication in a journal. But these instructions are mostly technical. They tell authors how to format the references and things like that.

So for specific types of studies, several groups have developed reporting guidelines. One of the first to be developed actually, were the CONSORT guidelines for randomized clinical trials. So if you compare with treatment and intervention against an alternative, you can use the CONSORT reporting guideline to make sure that your study report is fully informative.

CONSORT was the first, but they are now over a hundred different reporting guidelines for all kinds of specific study types, for genetics studies, for observational studies, for meta-analysis and so on and EQUATOR Initiative is a resource for these reporting guidelines, on EQUATOR website you can find reporting guidelines for other studies.

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Now *Radiology* has been a strong promoter of complete and transparent reporting. So we know actually that on average the studies reported in *Radiology* are more informative and more complete than some of the competing journals, some of the other journals in the same field, and we hope that development of STARD 2015 will further help the completeness and informative study reports especially for the studies that have evaluated the performance of medical tests.

Bob Barrett: Well finally Dr. Bossuyt, we've talked about how STARD helps authors and health journal editors, how will it help readers?

Dr. Patrick Bossuyt: Well it can help readers in a couple of ways. One is an indirect way and other is a direct way. If *Radiology* adopts STARD 2015 that will mean that the authors can use the checklist, use the list of items to verify that their study report is fully informative and therefore fit for publication in the journal.

It also means that the readers will use STARD to verify that a manuscript has all the essential information, and if some of the elements are missing, reviewers for *Radiology* can point out to the authors that information is missing and they can invite the authors to include the missing information.

So the indirect result will be that readers have more informative, more complete, more helpful publications about performance of new imaging tests, and elsewhere in medicine, more informative publications of medical tests in general.

But the readers can also use STARD in a direct way if they want to make sure that an individual manuscript contains all of the essential information. They can go through the list of 30 STARD items and if they do so, if they check the manuscript to see where that information is available, they will have a very, very good impression about what the study actually did, whether or not the results were valid, what the actual results were, and whether the results can apply to the reader's own situation, were the results are applicable to the specific problem that the reader actually have when turning to the manuscript, when turning to the article to find the answers.

So there is an indirect way to better the manuscripts through the reviewing process, and a direct way, a direct use of STARD when reading articles about the sensitivity and specificity of new or existing imaging tests.

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Bob Barrett: Dr. Patrick Bossuyt is professor of Clinical Epidemiology at the University of Amsterdam and has spearheaded the STARD initiative for the improved reporting of diagnostic test accuracy studies and leads the biomarker and test evaluation research program in Amsterdam. He has been our guest in this podcast about the 2015 version of STARD Guidelines. I am Bob Barrett. Thanks for listening.

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