

**Article:**

A.C. Don-Wauchope, J.L. Sievenpiper, S.A. Hill, and A. Iorio  
*Applicability of the AGREE II Instrument in Evaluating the Development Process and Quality of Current National Academy of Clinical Biochemistry Guidelines*  
Clin Chem 2012;58:1426-1437.  
<http://www.clinchem.org/content/58/10/1426.full>

**Guest:**

Dr. Andrew Don-Wauchope is Associate Professor of Pathology and Molecular Medicine at McMaster University in Hamilton, Ontario.

Bob Barrett:

This is the podcast from *Clinical Chemistry*. I am Bob Barrett.

Practice guidelines are everywhere in healthcare. They have been around for decades, but their development, dissemination, and use has grown considerably over the past 10 years.

In the October 2012 issue of *Clinical Chemistry*, researchers from McMaster University examined Practice Guidelines used by the National Academy of Clinical Biochemistry, or NACB, using an evaluation tool from the Appraisal of Guidelines for Research and Evaluation Collaboration, the AGREE Collaboration. We are joined today by the lead author of that paper, Dr. Andrew Don-Wauchope.

Dr., the AGREE II instrument has mostly been applied to clinical practice guidelines. What did you learn by applying AGREE II to the NACB guidelines that could be used to improve the laboratory practice guidelines?

Dr. Andrew Don-Wauchope: In the paper, we made six recommendations, and we would like to emphasize the third one, which is to make sure that people who are writing guidelines pay good attention to all the methodology that goes into assessing the evidence that they have put into the guideline to make recommendations.

Bob Barrett:

What is the role of the organization such as the NACB in improving the guideline development process?

Dr. Andrew Don-Wauchope: Organizations such as the National Academy of Clinical Biochemistry should develop processes by which guidelines are developed. They should develop

standard procedures which guideline writers can follow to ensure that the quality of the guideline is good for people to use.

Bob Barrett: Would you have any suggestions for NACB guideline authors, or for that matter, any suggestions for AGREE developers themselves?

Dr. Andrew Don-Wauchope: Well, for guideline authors, I think it's important that if there is a protocol they can follow to prepare the guideline, that they should pay attention to that. They should also probably look at the AGREE II tool and see how it applies to the questions they are asking and make sure they address all the issues in there.

And for the AGREE developers, this is a bit more complicated. I actually quite like the AGREE tool, but I think there is an area where probably a bit more clarity could be built into the tool to help people when they are using the tool where they can exclude certain of the questions. So for example, we had to consider excluding one item when we did our review. I think the extra clarity about how you choose those items should be made a bit more clear in the AGREE II.

Bob Barrett: Dr., a key quality point in the AGREE appraisal is the comprehensiveness of the literature search used in the guideline development. This seems to be a particularly problematic aspect in the field of diagnosis due to the lack of high quality studies. Were there any lessons from your exercise?

Dr. Andrew Don-Wauchope: The issue with the lack of, sort of, good quality studies is important for laboratory medicine. What the guideline writers need to do is to take the evidence that's there and assess it properly and use tools that are available for doing evidence-based medicine, things like systematic reviews, using tools like the QUADAS tool to assess the quality of the papers, grading the evidence using the grade tools or equivalent type of tools, using other scores that are available to people in the assessment of original work to help balance out the findings of the work and give an opinion that is weighted and measured in how they interpret it.

Bob Barrett: Clinical practice guidelines often contain recommendations for laboratory tests. How can the process of clinical practice guideline development be modified so that they are more applicable to laboratory medicine?

Dr. Andrew Don-Wauchope: The clinical practice guidelines assess many aspects of clinical practice, which includes different procedures, different medications, and so on, but part of that is the lab tests.

What we often find is that the lab tests aren't as well assessed as other aspects of the clinical practice guideline, and I would encourage writers of clinical practice guidelines to apply the same rigor to how they assess laboratory tests when they produce the guideline.

Bob Barrett: The views and preferences of patients have been sought in clinical practice, but how appropriate is it to get patient preferences for laboratory tests which are used and interpreted by physicians and usually not directly available to the patient?

Dr. Andrew Don-Wauchope: Well, this is an interesting concept. I think patients are always interested in how things are put to them by their physicians, and obviously the physicians tend to interpret the laboratory tests. But patients are being tested, and so I think they should have a say in this.

And what's probably most important is to get the opinions of patients, represented of groups that may have interest in the type of testing. So there are often different groups associated with different diseases that have an interest and they represent the patient perspective on that, and I think it would be important to include their opinion in how you produce the guideline, at least let them have a look at it and make some comments on it.

Bob Barrett: Will this be different when screening for disease?

Dr. Andrew Don-Wauchope: Well, screening for disease is slightly different from some of the other ways in which we use laboratory testing. And here often we get big population or interest groups that are going to lobby for the use of a test or against the use of a test.

And so it's important here to make sure that those people who are lobbying for something to be put into practice or taken out of practice, that they have looked at the evidence appropriately and it's not just being driven by something that's politically important or something that they feel is going to be a benefit without any evidence behind it.

Bob Barrett: The AGREE process describes different options for the management of the condition or the health issue, how can this be modified to make it more applicable to laboratory medicine?

Dr. Andrew Don-Wauchope: Well, this is the one where we had a problem with one of the guidelines that we couldn't really interpret this question in the guideline, which looked at quality of laboratory testing.

But it is important to consider when you are using a test that testing can be used with different aspects of medical care. So for example, we have talked about screening; it can also be used in making a diagnosis; and it can be used for monitoring a disease or for monitoring therapy that's being used in a disease, or even guiding therapy in certain situations.

So when people are laying out the questions for the guideline development, they should consider which aspect of medical care is going to be impacted by the test, whether it be screening, diagnosis, monitoring of therapy, or even guiding therapy. And in that context set the question correctly, so they can answer it with appropriate evidence.

Bob Barrett: The AGREE collaboration values editorial independence in clarity around conflict of interests. Well, the same question, how relevant are these items in the field of laboratory medicine?

Dr. Andrew Don-Wauchope: In some ways I think this is maybe even more important in lab meds, and obviously we are very aware of this when it comes to pharmaceutical companies and the independence of physicians and when they are setting the guidelines from the influence of the different pharmaceutical companies.

When it comes to laboratory medicine, there are a number of big diagnostic companies, and unfortunately, funding for lab-based research is not that easy to get out of public funds, so often it is coming out of the diagnostic companies. And so I think this is a really critical side of how you produce your guideline team and how you get the guideline reviewed. And obviously they need to have some input into it, but they shouldn't be influencing the overall decision. And so making sure that there is good editorial independence and that the people who are participating in the guideline deter all their potential conflicts of interest, I think is really critical in lab medicine.

Bob Barrett: Well finally, Dr., healthcare funding, of course, is undergoing change in the United States. How can such guidelines inform payers and healthcare professionals and patients about the value of laboratory testing?

Dr. Andrew Don-Wauchope: Patrick Bossuyt in the editorial that accompanies the paper in *Clinical Chemistry* mentions overuse and underuse of tests and potentially how guidelines can influence this. This is really where it is important to see utilization of testing and the correct utilization of laboratory testing.

So when funding becomes more restricted, making the best use of other tests becomes more important and so this is where guidelines can really help. So there are tests that will save other costs in the healthcare system and therefore, they should be used more. And there are others that are not helpful at all in the diagnostic process or any care in medicine and then those should potentially be removed.

And so this is where the guidelines, if produced correctly, can really help inform the policymakers, the physicians, other healthcare providers, and the patient groups about the correct choice of laboratory testing.

Bob Barrett: Dr. Andrew Don-Wauchope is Associate Professor of Pathology and Molecular Medicine at McMaster University in Hamilton, Ontario. He has been our guest in this podcast from *Clinical Chemistry*.

I am Bob Barrett. Thanks for listening!