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Andrew St John, Christopher P Price, Rogier Hopstaken, Patrick McGinley, Stacy Melanson, Maurice O’Kane, Annalise E Zemlin.

Challenges Associated with the Effective Implementation of New Laboratory Tests—The International Experience

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Guest: Dr. Andrew St John from Drajon Healthcare in Western Australia.

Bob Barrett:

This is a podcast from *Clinical Chemistry*, a production of the Association for Diagnostics & Laboratory Medicine. I’m Bob Barrett.

Implementation of a new clinical laboratory test is often a major undertaking, requiring careful planning and demonstration of positive impact. Anticipated benefits could be clinical in the form of improved patient outcomes, or financial in the form of cost savings. Stakeholders from across the healthcare system need to be engaged, including clinical laboratorians, clinicians, nurses, administrators, informaticists, and other groups, to ensure the new test achieves the expected benefit. Still, despite extensive preparation, new test implementation may not go according to plan.

How should the decision to implement a new test be made? Perhaps more importantly, who should be making these decisions? Are there common elements that can be universally applied to guide new test implementation, regardless of healthcare model? What challenges routinely prevent the successful implementation of new tests, and how can they be overcome?

A Q&A article appearing in the May 2024 issue of *Clinical Chemistry* provides a global view of best practices in the implementation of new laboratory tests by summarizing the thoughts of experts from four different countries. In this podcast, we are pleased to speak with the article’s moderator. Dr. Andrew St John is a clinical biochemist with Drajon Healthcare in Western Australia and has chaired the International Federation of Clinical Biochemistry’s Committee for the Value Proposition in Laboratory Medicine for the last six years. So, Dr. St John, why do we need a better process for how we introduce these new tests?

Andrew St John:

Well, thank you. Well, in the Q&A paper, we distinguish two processes which are associated with the introduction of a new test. The first is adoption, and that’s generally well done. It involves generating evidence to support the use of a test, and that’s a prerequisite now for reimbursement in many

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countries, including the United States. The problem we're really focusing on is the second process, which we call implementation, and that's where we introduce the test into routine practice. And we currently assume that the test will be used in exactly the same way that it was used in the trials and the other studies that form part of the evidence base which led to its adoption.

Now, numerous studies show this is not to be the case. For example, in my own country and in the United Kingdom, lots of studies have been done which show significant, unexplained variations, even when healthcare systems in those countries around the requesting and use of particular tests. And as my colleague Maurice O'Kane cites in the paper, the indicated tests are often not used-- often used in patient groups, or for indications, for which it was not intended. And I think we're all familiar with that within the profession. The second problem we have is that the types of studies we perform to generate the evidence for adoption, such as randomized controlled trials and very specific observational studies, use a very specific group of patients with quite defined conditions and symptoms, and they're often not of the same type as those on whom the test is used on a routine basis.

Now, this is not a problem just with lab tests, it applies to healthcare generally. And so, while we need trials to do the adoption process, we also need more locally based studies in order to ensure that the test delivers the same benefits when it's used locally and routinely as we do in the trials. And that's what is now being called the need for real world data, as opposed to trial data.

Now, this is not to imply that this is just a challenge for the laboratory profession to solve. The problem goes beyond the laboratory to the extent that a more fundamental problem for labs generally throughout the world, is we're operating in a climate where tests are seen as low cost and consequentially low value. The cost of a test is a fraction of many of the medical interventions, such as drugs, and other procedures. But what this ignores is that the results of certain tests often lead to clinical decisions which have significant financial consequences.

So it means that policymakers and clinical service providers appear to be much more interested in the cost and the operational productivity of the lab, rather than the value. And an example of this is quite a commonly quoted statistic from the UK's National Health Service, where they talk about the target laboratory budget being set at 1.6 of the overall healthcare providers' budget. So a number, that's the target, that's how you should operate. So, addressing this overall problem requires the laboratory to work as part of the

healthcare team and consider tests in the context of care pathways or a process of care, in the same way that we would talk about other interventions, such as using a drug or another sort of medical procedure.

Bob Barrett: Okay, I'd like to talk a little bit more about that. Why is that concept of a clinical care pathway important for better test implementation?

Andrew St John: So, care pathways are now widely adopted in many areas of medicine. Their aim is to enhance the quality of care, to make it more reproducible over time, and improve patient outcomes. It will also promote patient safety, it should increase patient satisfaction, and it should optimize the use of resources, and primarily the real *raison d'être* for them to be used is to reduce the variability in patient care.

Now, there are certain tests, and particularly with new tests that we're introducing in this day and age, where the same concept can be applied, since the test result leads to clinical decisions which change the care process. And examples which the Value Proposition Committee have written about in the last few years are, for instance, high-sensitive troponin and the use of natriuretic peptides. And we've described how those results from those tests change the pathway for the patient, but they also lead to changes for the various other stakeholders in that pathway, as well as the deployment of different resources. So those stakeholders for instance, in the case of troponin, will be ED physicians and cardiologists, but there'll be other groups, nurses, doctors, wards, clinics, laboratories, operating rooms, drugs, blood products. They're all different resources and different clinical teams that can be affected by a particular test.

We talk about sometimes in some countries, those as resource centers. The UK often uses a term called service lines, which is also used in other countries. And sometimes we talk about these in a less complementary way, in the sense of being silos and there's no communication between them. And certainly, silos can create major problems in healthcare and around attributing costs. So, the changes to the stakeholders and the resources can be measured. For example, if we take the case of natriuretic peptides, NT-proBNP used for the diagnosis, or the rollout, of suspected heart failure, the use of that test result can determine whether or not the patient requires a much more expensive intervention in terms of an echocardiogram, and process changes such as these can be measured, and by monitoring them as part of test implementation, it's possible to both determine whether the test is being used correctly and also determine the value of that test.

Bob Barrett: In your Q&A article, you looked at how tests are introduced in different countries. What did you learn from that comparison?

Andrew St John: Well, it was clear from the work that we've been performing as part of the IFCC's Value Proposition Committee that the success or otherwise of promoting better test implementation really will depend on the nature of the healthcare system in which that laboratory is operating. And these systems obviously vary widely. If we would just look at the United States and the United Kingdom, two very different healthcare systems and the way they operate. But as well as looking at different countries, we also wanted to think about different stakeholders in terms of the care pathway, and not just the laboratory professionals, but other stakeholders, such as clinicians and for instance, finance departments and so on.

So, we learned from the five countries which are represented by the moderators, Chris Price and myself, and the contributors, that there was some awareness of both adoption and implementation across those countries. And there was a clear acknowledgment that we don't implement tests in the best possible way, and we have problems with poor test value for the reasons I've talked about earlier. But perhaps there was more importantly in all those countries, a clear acknowledgment that laboratories appear to be managed more about operational productivity, with very limited interest in delivering value. And as Patrick McGinley, UK Health Finance Manager who contributed to the paper, he says the laboratory budget in any healthcare organization is relatively small, as we talked about earlier, and that tends to inhibit interest in using testing to deliver value.

However, despite that, what we've discussed with Patrick, and he also talks about in the paper, there's plenty of potential for testing to be used to drive improved outcomes for patients and healthcare organizations generally. Now, the other non-laboratory stakeholder involved with the paper was Dr. Rogier Hopstaken, who's a family physician, or a general practitioner, in the Netherlands. And what Rogier highlighted, the issue that even when you've got good evidence for adoption around the benefits of the test and it may be formally adopted, you really need additional efforts to get the test into routine practice.

So, as well as that confirming the importance of the implementation process, it also highlights a vital role for the laboratory professional to work in collaboration with people like Rogier and clinical staff to deliver more value-based care and get tests implemented. And so while we heard a lot about the challenges to implementation that exist internationally, we also learnt that some countries are addressing the problems through specific initiatives. So Dr. Annalise Zemlin

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from South Africa mentioned the use of audits as quality improvement tools, and they're also used extensively in the UK and European laboratories.

So the challenges with those sort of audits relates to the clinical pathway concept, and that the outcomes and process measures that we're really interested around implementation are ones that occur outside of the laboratory. They occur in the clinical pathway, on the wards, related to the patient, related to the clinical teams. And these are much harder to measure, particularly for the laboratory, than parameters such as inappropriate test requesting and turnaround time. That's not to say they're not important, but they're not the real ones we need to measure, determine about implementation. And so it's critical, we need to try and expand audit outside of the lab if we are to achieve better test implementation.

Bob Barrett: Well, finally, Dr. St John, how do you think laboratories can improve their implementation of the new tests?

Andrew St John: So, from our experiences in developing the concepts of better test implementation, we've learned that this requires considerable resources. That's quite obvious, and we are realistic enough to know that such resources will not be easily gained, and we have to work largely with an existing, or in some cases reduced, budgets and that means changing the focus of our activities. It's possible to conceive of improved test implementation really as a quality improvement exercise, something that's very familiar to lab professionals already. But to date, quality improvement in laboratory medicine has primarily been about practices in the lab. Whereas, of course, as I mentioned earlier, we're talking about the real value of test implementation being delivered outside of the lab, impacting on the decision making and the uses of resources of the other stakeholders in the provider organization.

Now, lab professionals devote a lot of their time to quality, primarily around analytical quality, some pre- and post-analytical as well. But I think it's of interest that there is an ongoing debate in the profession on whether what seems to be an ever-increasing focus on analytical quality is delivering any substantial increasing benefit. And I know that's acknowledged to be a contentious view, but it's certainly a view that's out there and I think it's worthy of debate. So in the light of that debate, we would argue from our perspective that some of the quality budget should be devoted to improving the quality of test implementation and ongoing test utilization. Having said that, other resources and new relationships with clinicians and other stakeholders are needed, and it really makes collaboration with clinical colleagues and other stakeholders in the care pathway absolutely crucial. And there are challenges with that that we

clearly accept, and that challenge you know, amounts to stakeholders being very protective of their budgets, especially if they're managed according to what Patrick McGinley would talk about, the gospel of operational budgeting.

So an interested healthcare finance manager is critical. We would say that everyone in the lab needs somebody like a Patrick McGinley who's interested in using tests to influence the financial budget. And the other important resource we need are good information systems, where they can capture the process measures in relation to the changes in the care pathway that we described earlier. And they're much more easily captured if we've got good IT systems rather than having to do chart reviews or manual review of case notes and so on. The lack of those systems has clearly been a major stumbling block in our efforts to provide practical demonstration of our concepts. So some might see this as an insurmountable list of challenges. But in response, I'd like just to quote one of our contributors, Stacy Melanson from the Brigham and Women's Hospital in Boston, who said in the paper that laboratory medicine should not continue to allow new testing without demonstrating its value in a real-world setting. And to do that requires us as lab professionals to consider how we can improve the way we implement new tests.

Bob Barrett: A wise man once said, the answer to all of your questions is money.

Andrew St John: Indeed, indeed.

Bob Barrett: That was Dr. Andrew St John from Drajon Healthcare in Western Australia. He served as moderator for a Q&A article on the effective implementation of new laboratory tests in the May 2024 issue of *Clinical Chemistry*, and he's been our guest in this podcast on that topic. I'm Bob Barrett. Thanks for listening.