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Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine

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Guest:
Dr. Mike Hallworth is Chair of the IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management.

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.

Medical laboratories provide valuable services to aid in patient diagnosis and management, but systematic evidence of laboratory medicine's specific contribution to the overall process of healthcare is not easy to come by. Even the widely quoted claim that laboratory medicine results are responsible for a 70% of all clinical decisions seems to elude objective verification.

A review article entitled "Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine" appears in the April 2015 issue of *Clinical Chemistry*. This review stems from work carried out by the IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes.

Dr. Mike Hallworth is Chair of that Task Force and lead author of the review article. He is Co-Editor-in-Chief of the journal *Practical Laboratory Medicine* and he is our guest in this podcast.

Dr. Hallworth, could you tell us some background on the main aims and objectives of the IFCC Task Force that prepared this report?

Dr. Mike Hallworth: Yes, of course. The Task Force was established as an IFCC initiative, really to try and evaluate the evidence that demonstrates the impact of laboratory medicine on patient outcomes and on healthcare in general; and also to see how we can develop more robust study designs that will generate evidence in that area.

Our overall aim was to see how we can best promote the importance of laboratory medicine to the healthcare community, to those who commission healthcare, payers, et cetera, and to governments and to the general public.

We had about ten scientists and MDs from the USA, from Europe and Asia, all working together to do some recommendations and these are the recommendations that are published in *Clinical Chemistry*.

Bob Barrett: What drove the decision to assess the impact of laboratory medicine on patient outcomes, and hasn't that been done before?

Dr. Mike Hallworth: Well, surprisingly Bob, no, it hasn't. The fact is we really don't have that much data that measures the overall effectiveness of the total testing process, how it actually impacts on patient outcomes.

As a community of laboratory workers we have been very good at assessing whether tests are reliable, whether they are efficient, do they measure what they are supposed to measure, do they reliably differentiate disease states from normal. But we have tended to leave to other people the analysis of whether performing a test actually results in better patient outcomes in terms of effectiveness, whether it results in more rapid diagnosis or more appropriate treatment or shorter stays in hospital, or better mortality figures.

It's not enough to say, as we often have done, that a test will predict a relevant outcome, we need to go that extra stage and say, if we use this test, do we actually improve patient outcomes?

Now, part of the reason for that, and part of the reason we haven't done that in the past is that outcome studies are much harder to do, they tend to require much bigger studies, and they require much more collaboration across the whole clinical team, they require more time, and they need more resources.

And they also have the fundamental problem that patient outcomes are affected by many, many variables and the lab test may be a major factor or a minor factor in producing the given outcome.

Now, all that sort of variation gets obscured by the blanket statements that we tend to fall back on, such as that 70% of clinical decisions are based on laboratory tests, which sounds great, but is in actual fact both inaccurate and potentially misleading.

Bob Barrett: Well, let's get into that, you do question that statistic that 70% of diagnosis or treatment decisions are based on lab tests. Have you made any further progress understanding the true impact of laboratory diagnostics?

Dr. Mike Hallworth: Well, yes and no, I think, is the short answer to that. The 70% claim, which all laboratorians are familiar with, was based on anecdotal reports produced in the mid-1990s. And in its original context, the context being critical decisions taken in the acute hospital setting, whether to admit or discharge, how to treat, that was probably fairly accurate, although we have never had any detailed analysis of the data being reported.

But once you generalize it out of that setting to saying 70% of all clinical decisions are based on lab testing or similarly broad claims, then it becomes very hard to defend.

In any event, any blanket figure like the 70% claim is going to be both misleading and dangerous. We have in our papers some excellent examples of situations where lab tests are essential to accurate diagnosis and better outcomes.

For example, virtually the whole of clinical endocrinology depends on laboratory medicine, and you can't practice it without lab testing.

We have also got great data on the use of testing in treatment selection, in cancer and in other modalities. But we need to deal with two main problems before we can get a real true measure of how lab medicine affects individual patient outcomes.

And the first problem relates to utilization. We know, to our cost, that simply making a test available to clinicians does nothing to benefit patients. If we are going to achieve better outcomes, the test has to be ordered on the right patient, it has to be done properly, the right result has to get to the right person, in the right timeframe, it needs to be properly interpreted, and it has to influence a decision on future management.

As people in the laboratory, we have worked incredibly hard to improve the quality of the results, but all our effort is wasted if the test is done on the wrong people or if the result never gets to the right place at the right time.

In the past we have tended to see that as somebody else's problem, but I firmly believe it's our problem and we have to get a grip on it before we can claim real world effectiveness for laboratory procedures. So that's the first problem.

The second area we need to do better at involves building patient outcome measures into the ways in which we conduct test evaluations, identifying the patient metrics that are supposed to be improved by the new test, whether that

be time to diagnosis, or mortality, or length of stay in hospital, or whatever it be.

Once we have identified those and documented them at the start, then we can carry the same set of measures into routine use of the test and audit whether the markers are doing what they were supposed to do, and if they are not, how do we figure out how we fix that?

And that includes looking at a wide range of patient outcomes, including things like patient anxiety that's caused by the testing process, and including what the consequences for patients are of false negative tests or false positive tests, as well as the time when the test gets it right.

Bob Barrett: Doctor, why do you feel that lab medicine is undervalued in the healthcare community and the general public?

Dr. Mike Hallworth: The traditional answer to that Bob is that we are not very visible. We are tucked away in a lab in the basement somewhere or out of site of the public and the frontline care workers.

But I have to say I think it's largely our fault that we haven't been as active as we need to be in taking responsibility for improving the overall testing process, getting out of the lab and talking to clinicians and to patients and to administrators about how effective testing can improve outcomes and reduce costs, provided it's properly used.

We know that lab medicine is the single highest volume medical activity. When it's used properly, it's arguably the most cost-effective modality in medicine. And we need to back that up with data and we also need to know -- to make sure that people know how to use the resources that we provide to the best effect.

As medicine gets more and more scientific, as the number and the complexity of tests increases every month, physicians cannot cope with the number of tests that are now available to them. They need specialists' help to use to those tests correctly, and we need as laboratorians to be right at the forefront of providing that help, providing guidelines for investigation, helping clinicians choose the best test for specific clinical presentations, helping them decide on further studies to confirm the diagnosis, and making sure that the results get where they need to be at the right time and are properly interpreted.

Bob Barrett: Well, let's get into the paper, what are the main recommendations of the IFCC Group in this *Clinical Chemistry* paper?

Dr. Mike Hallworth: Our first recommendation is that we need to be involved in improving the total testing process right along its length, helping clinicians, as I have said, develop optimal testing strategies, getting results to the right place at the right time, working on things like what results we notify as critical results, because we know that calling too many results out to clinicians is as harmful as calling too few results out to clinicians. Because if you call too many out, clinicians get what's called alert fatigue and vital information gets lost. So we have to better with the utilization aspect and the total testing process.

But together with that we need to develop new roles for laboratory professionals that are focused on optimizing patient outcomes by adding value at every point in the process. And that means developing a new set of professionals who completely understand the brain-to-brain cycle of investigation and can audit the effectiveness of the diagnostic process.

That has to be done in collaboration with users, but I firmly believe we in the laboratory have to be at the forefront of leading that.

Our second set of recommendations are around developing a set of protocols for patient-centered studies of biomarker effectiveness, and some benchmarks for patient outcomes, which consider the overall impact of testing on all the relevant clinical outcomes.

Then we need to build those outcome measures into the published evaluations that we do of new markers, so that once they get into the real world we can audit how effective they actually are.

Bob Barrett: Finally, Dr. Hallworth, what do you think improving the understanding of the value of lab medicine will achieve for laboratorians and then for the field as a whole?

Dr. Mike Hallworth: I think that's very simple and very powerful. If we get this right, we will improve patient care, we will reduce healthcare costs, we will give laboratorians better job satisfaction, and that will help us to recruit and retain the best people to work in laboratories, and I think those are a set of goals that are really worth working for.

Bob Barrett: Dr. Mike Hallworth is Chair of the IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management, and he has been our guest in this podcast from *Clinical Chemistry* on evidence and future perspectives of laboratory medicine.

I am Bob Barrett. Thanks for listening!