

**Article:**

Neil William Anderson, Esther Babady, Thomas JS Durant, Ann Fisher, Norman J Moore, and Sheldon Campbell.

Centralized vs Decentralized Molecular Infectious Disease Testing.

Clin Chem 2021; 67:5 713-19. <https://doi.org/10.1093/clinchem/hvaa318>.

Guest: Dr. Sheldon Campbell is Professor of laboratory medicine at Yale School of Medicine and Associate Chief for laboratory medicine at VA Connecticut Health Care.

Bob Barrett:

This is a podcast from *Clinical Chemistry* sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I'm Bob Barrett. The COVID-19 pandemic has brought laboratory testing into public awareness as never before. Schools, workplaces, even sports teams want rapid and accessible testing services. This experience will shape clinicians' and patients' expectations going forward. In the post COVID world, decentralized testing models will be explored as never before, but new technologies come with opportunities and risks as well as possibilities and limitations. A Q&A feature appearing in the May 2021 issue of *Clinical Chemistry*, explored centralized versus decentralized molecular infectious disease testing. In that Q&A, five experts from diverse clinical settings and areas of expertise were asked to map this new testing territory to help laboratory professionals, clinical users, and administrators assess the potential clinical impacts of near patient infectious disease testing.

The moderator for that feature is Dr. Sheldon Campbell. He is Professor of laboratory medicine at Yale School of Medicine and Associate Chief for laboratory medicine at VA Connecticut Health Care. He has boards and clinical pathology and medical microbiology and his academic interests include medical education, diagnostic microbiology, point of care testing, and laboratory safety and ethics. And he is our guest in this podcast. Dr. Campbell, what exactly does decentralized molecular infectious disease testing mean and how much of it is out there?

Sheldon Campbell:

It's kind of an interest -- I was given that term decentralized when the publication was solicited, and it is kind of an interesting way of phrasing it. The usual phrasing is point of care, but decentralized makes you think a little more broadly about it. Point of care classically refers to things happening at the patient's bedside. Decentralized is a little broader, right? So, it includes maybe non-standard sites of care like pharmacies, makes you think of screening efforts and schools and other institutions, and it makes you think of home testing as well. So decentralized testing, the way I think of it, anyway, is anything beyond the standard laboratory based testing.

Bob Barrett: What value is there to decentralizing molecular infectious disease testing? And in what settings and populations might it have particular value?

Sheldon Campbell: That's certainly an ongoing thing. Right now, it's most prevalent in acute care settings, physician's offices, emergency rooms, places like that where decentralized testing allows you to get a clinically actionable result within a single patient encounter. The classic example that almost everyone has had or seen is rapid strep for a strep throat, right? So, you go to your pediatrician, and you've got a sore throat or your kids got a sore throat and they stick a swab in your throat and put it in some little doohickey and say you've got a strep throat and treat you there and nobody has to make any more phone calls and nobody has to track you down and you're all done.

Except, of course, with the rapid strep test, you don't get to say you don't have a sore throat because it's not quite sensitive enough. So, it has to be sent off for culture if it's negative to make sure that it didn't miss your strep throat. So, it's not sort of a perfect solution but we now are starting to deploy molecular based point of care systems that allow near laboratory quality testing in a more decentralized environment. They're still sort of expensive. They're still not the sort of thing you deploy for home testing yet because the capital cost for the equipment is too high but they certainly are the sort of thing that in physician's office settings allows near laboratory quality testing. Then beyond that, into the more distant future and this article was kind of written before COVID, there's all sorts of thoughts. I mean, there's been a group within the clinical microbiology community that thought that Coronavirus could just be controlled by deploying inexpensive, not necessarily super sensitive, but inexpensive tests to everybody to do every two days. And that's really an interesting and provocative idea, but we didn't get started early enough to do it that way. But for the next public health crisis, maybe that's a way of thinking about that. Maybe we could do that for something else, like influenza and really get control of influenza before we have bad influenza outbreaks.

Is very much an evolving area that we're still thinking about.

Bob Barrett: Well, as it evolves, what are the barriers to increasing the implementation of molecular tests at point of care and what risks could be associated with them?

Sheldon Campbell: Barriers are various economic barriers. They are more expensive than routine rapid antigen tests even if they are better, there's a more sort of fundamental barrier to decentralizing testing and that has to do with the fact that point of care tests don't -- they only test for one thing,

usually. So, you test for COVID or you test for flu, or you test for group A strep. But frequently patients come with a whole variety of problems, and you need to assess not only all those potential problems but how sick the patient is in general and if there are any associated comorbidities that need to be addressed.

And at that point, the menu starts to get pretty broad of things that you need to be done with the encounter and testing -- the point of care is inherently somewhat limited. If you can't finish the encounter, then why bother, right? You can just send everything up to the lab, get all the results at once and deal with it by phone. But deal with it as -- in one block, rather than half of your information trickles in care and the rest comes back from the lab. So, that's an inherent limitation. In general, point of care tests are more expensive than lab based tests, and they also take scarce medical professional time, for example nursing time or whatever to perform them at point of care.

So, you got to get a corresponding benefit out of it if you're going to do that, the risks include wasting scarce resources on points of care testing that doesn't need to be done and also include the risk that the testing won't be performed properly. Even in simple laboratory tests can be performed badly. And when done by people who don't -- whose main job is not doing lab testing well, if they put me to work doing labor and delivery, that it might not be -- I might not be as good as somebody who's trained to do that. And molecular tests in particular have issues with both an inhibition and contamination that require you to be careful with them in order to not produce false results.

That is inherent to the sensitivity and the nature of the technologies and it's really important that people who are planning to implement these in a decentralized environment do it with care and recognition that good laboratory practice isn't just some pointless regulation, but is good medical practice.

Bob Barrett: Well, finally looking ahead, what is the future of molecular testing in decentralized models of health care? Where might such testing occur? And how might healthcare change in response to these new capabilities in a few years or even 5 to 10 years from now?

Sheldon Campbell: Yeah, I mean, everything changes slower than you think it will to some extent but we are to the point now where there's molecular platforms that are quite simple and very powerful. And it may be that in combination with other changes in care, that these capabilities will help us to change models of care for some sorts of acute illnesses. One could imagine a setting where providers in combination with pharmacies and imaging

capabilities can really have a relatively small facility that has the ability to handle a lot of acute things very completely without having to send anything out and able to manage the whole encounter in a single place in a short time.

But it's going to take rethinking, to some extent, some of our models of care that are built on more centralized not only lab testing, but imaging and other capabilities. It's going to take a fair amount of new information technology in terms of being able to access this data, being able to utilize it for public health purposes. It would be a real tragedy if we suddenly started doing all of our testing for, say, sexually transmitted illnesses in a decentralized fashion, and it never got reported to public health authorities. That would not be an improvement in our management of sexually transmitted infections. It would be a step backwards. So, being able to combine these new capabilities with their interface to public health and other larger health entities is really important.

Bob Barrett:

That was Dr. Sheldon Campbell, Professor of Laboratory Medicine at Yale School of Medicine and Associate Chief for laboratory medicine at VA Connecticut Health Care. He served as a moderator in the Q & A feature in the May 2021 issue of *Clinical Chemistry* on "Centralized Versus Decentralized Molecular Infectious Disease Testing." I'm Bob Barrett. Thanks for listening.