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Michelle Stoffel, Dina N Greene, Stacy G Beal, Peter Foley, Anthony A Killeen, Hedyeh Shafi, and Enrique Terrazas.
Direct-to-Consumer Testing for Routine Purposes
Clin Chem 2022;68(9):1121-27. https://doi.org/10.1093/clinchem/hvac106

Guests: Dr. Michelle Stoffel from M Health Fairview and the University of Minnesota and Dr. Dina Greene from LetsGetChecked and the University of Washington in Seattle.

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. Direct-to-consumer laboratory testing, or direct access testing, permits individuals to order laboratory tests directly from a laboratory without necessarily having to work with the healthcare provider. These test results may be used to monitor an existing health condition, identify a previously unknown medical disorder, or provide data regarding personal health characteristics.

While the ethical and logistical issues surrounding genomic direct-to-consumer testing have previously been raised, there has been less focus on how routine care direct-to-consumer testing presents its own opportunities to impact healthcare, as well as unique challenges that must be addressed. The quality and regulatory landscape for direct access testing is also complex with both federal and state regulations over whether testing is even permitted, and the degree of oversight for laboratories varies as well.

In a Q&A feature appearing in the September 2022 issue of *Clinical Chemistry*, five experts examined a number of facets of direct-to-consumer testing. We are pleased to have the two moderators of that Q&A article in this podcast. Dr. Michelle Stoffel is the Associate Chief Medical Information Officer for Laboratory Medicine and Pathology at M Health Fairview and an Assistant Professor in the Department of Laboratory Medicine and Pathology at the University of Minnesota.

Dr. Dina Greene serves as an Associate Laboratory Director for LetsGetChecked, a virtual care company that offers at-home testing, and is a Clinical Associate Professor at the University of Washington in Seattle. We'll start with you, Dr. Stoffel. The experts in the Q&A feature published in *Clinical Chemistry* describe how direct-to-consumer testing for routine purposes is evolving to meet consumer demand. Can you elaborate on what those demands are and why they're emerging now?

Michelle Stoffel: Yeah, I'd be happy to. Really, our experts on the Q&A paint a picture of how the consumers today really want to have autonomy over their healthcare processes. This not only relates to having a deep desire to know a lot of information about lab testing and their health, but also to want to have shared decision-making with their medical providers. And apart from the autonomy over the healthcare decision-making, another aspect that our experts describe emerging is the desire for consumers to have control over how and when they experience lab testing, so testing that works with their schedule that doesn't disrupt their lives, that fits in with what they need. And so, really, DTC testing offers a lot to meet those needs.

Bob Barrett: How has the COVID-19 pandemic accelerated this phenomenon?

Michelle Stoffel: What we saw with COVID-19 was really that a lot of healthcare systems had to adapt to meet the needs to have remote or mail-order testing options or low or no contact options in a way that that had been growing, but really wasn't moving along very quickly in many cases until places had to adapt. At the same time, also, consumers--for many people, the way they work, the way they live the way, they may have moved to rearrange their life, has changed, and they expect the healthcare they received to mirror that.

Bob Barrett: The experts interviewed in the Q&A come from the spectrum of laboratory practice, from academia to community practice and industry. Can you touch on some of the reasons why a diverse array of laboratories may choose to offer direct access testing for routine purposes?

Michelle Stoffel: Right now, we're really seeing a landscape of change in healthcare and DTC testing offers ways for laboratory systems of different types to meet the needs of their consumers or their patients. Our experts describe how laboratories may be looking to expand their footprint locally or to create more options for their consumers and their patients in terms of convenience or the needs by having DTC menus. It's something that can be an option for laboratories of all types, including community and academic ones.

Bob Barrett: Dr. Greene, let's turn to you for a moment. The article defines the distinction between consumer-initiated testing and clinician-supervised testing outside of the clinical setting, either at home or at a separate collection site. Why is this distinction important?

Dina Greene: Hi Bob, and thanks for having me here, and thanks to the editors of *Clinical Chemistry* for asking Dr. Stoffel and I to contribute to the podcast series. It's a really important distinction that we make between kind of what we classically

think of as direct-to-consumer testing and as clinician-guided patient-initiated testing. In classical direct-to-consumer testing, there is no provider that is ordering the test and there's no clinical team on the back end to help interpret those tests.

With the explosion of digital health that's particularly been the disruptive of COVID has certainly exemplified why and how, why we need more digital health access and the benefits of digital health access, both from a user standpoint and often from a clinician standpoint as well. With clinician-guided testing, you have access to a clinician, either a nurse or a physician or a team, that can help you understand your results and can offer treatment strategies for those results.

For example, one of the most commonly ordered laboratory tests is TSH. TSH has a very straightforward pathway for most people with thyroid dysfunction, and if that testing can be done from home and that's your only pathology, you can very easily interact with a clinician team virtually that can help you to receive all of the care that you need. That's different than if you're just ordering a test and you don't have any access to a clinician. You get an abnormal TSH, it stops there. The only thing you have is Google to help you figure your results out.

Bob Barrett: As direct access testing for routine purposes expands, how do you think the roles of laboratorians will evolve to adapt to meet changing needs for directorship and clinical guidance?

Dina Greene: That's a really good question. How will we adapt? It's interesting, scientists aren't always the most adaptable types, neither is medicine. We design systems to support our current systems. A lot of places have their high-throughput automation is designed to support a specific tube type or a specific collection site or a specific interface. And so, I think that in order to meet these demands that laboratorians really need to think of innovative ways to automate high-throughput systems with different forms of collections and different sample types.

A lot of this has been the holy grail of lab medicine for a long time, but I think that with creative approaches and with innovative ideas, and of course financial backing, that these things are possible and can lead to a whole new world of testing that was previously thought of as impossible.

Bob Barrett: And are rapid advances in technology supporting these changes?

Dina Greene: It's interesting, the technology doesn't actually have to change that much. The technology is there as far as the analytic technology, for the most part. There's some things

that that would definitely need to advance and there's certain tests that will never be able to be offered in a…. My experience with the direct access testing right now is very focused on home collect. If you're not doing a home collect process, the technology is certainly there to do this.

But for home collect, there are some things that will always be impossible, and there are other things that are so straightforward that is kind of a little bit unfortunate that there're so many barriers around us being able to do it. For example, TSH is quite an easy one. It's stable for transport, it doesn't really get affected if you have blood that's not spun, the capillary to vein correlation is very, very good. It's the type of thing that if you are monitoring straightforward disease, that's easy.

STI, screening as well. If you're high risk for HIV and you're put on prophylactic medications for that, you need to be STI screened several times a year. It is not difficult to be able to do that from home. What's difficult is some of the regulatory barriers. None of this is analytically challenging. It's more of the way that the systems are currently defined and derived and designed strategy.

Bob Barrett: Well, Dr. Greene, one more for you. Will direct-to-consumer testing impact challenges and opportunities in health equity? If so, how?

Dina Greene: Anybody that has followed most of my work knows that my favorite thing to focus on is health disparities, health equity, and how we can improve that. I can, with 100% confidence, say that direct access testing will not fix privatized healthcare and the way that we have a fee-for-service model in this country.

But the way the direct-to-consumer testing does help to minimize disparities is for, I think of this in a few different buckets of people. You have people that are uninsured. People that are uninsured have a hard time accessing any type of care. And so, to do these types of tests, say you're a 23-year-old, you're uninsured, but you know you had high-risk sex and you want to have STI screening, and you feel uncomfortable trying to find your local clinic. This can really help people to just have an option to be able to get some of these basic lab needs met.

Say you're underinsured, and you have a huge deductible. I know in one of the healthcare systems that I worked out, I'll just keep with STI testing, it was about $400 out-of-pocket for folks to pay if they were underinsured, high-deductible plan, for their STI screens. Companies offer that for a lot cheaper if you do it online and it's the same quality, it's the

same quality test often, not always, I mean, but often it is the same exact quality test.

Then you have people that are that are well-insured, the people that are of privilege, and sometimes they have behaviors, or sometimes they're very busy and to them, it's not a big deal to pay a little bit more money in order to have something convenient, collected from home, or to avoid an embarrassing encounter. There is also services where people are only like, there's digital health services where people that are diabetic to just go to a virtual health clinic for their diabetes.

And so, again, having a mechanism for folks to do things from their home or from their office without having to get to a specific location at a specific time is the way of the future. I think that kind of folded all into it, but I think that there is ways for this type of testing to improve equity to allow people that don't have access to care, access to some care, or to allow people that are uncomfortable with either their sexual behaviors, or their gender, or if they feel discriminated against for their race, to have a unbiased place to be able to at least receive a subset of their care.

Bob Barrett: Finally, Dr. Stoffel, how can laboratorians and clinicians use the guidance offered in the Q&A feature help consumers navigate the landscape of DTC testing?

Michelle Stoffel: As Dr. Greene referred to, consumers may just find themselves facing the internet trying to use Google or whatever browser to search for answers. What they find can be a bewildering amount of information. I mean, first, DTC testing is not all equal. There are different types of testing, there's genomic testing, ancestry testing, there's wellness testing, and then there's medical grade testing, which is really what our experts are covering in the Q&A. But even if you've found the appropriate testing for your need, there are a variety of labs to choose from and consumers might just be completely overwhelmed by this.

Our experts walked through some of the ways that both consumers, as well as clinicians who are interested in learning more about DTC, can use to help guide them. And so, first of all, there's regulatory standard, so medical grade testing, should be performed by a lab that's CLIA certified and DTC labs should have that information transparent and even advertised. And so, that's one piece of information that consumers can look for.

Additionally, consumers shouldn't overlook the DTC testing lab itself as a source of information. Laboratories should really offer customer support and should be willing to answer questions that consumers have or to refer them to how to find

clinical information if they can't answer the question within the scope of their appropriate practice.

Finally, consumers, when they're in the context of being patients, should be open to having conversations about DTC testing with their healthcare provider and that can be a safe space to make shared decisions about health care, and for both patients and providers to learn the appropriate use and the benefits of DTC testing where appropriate.

Bob Barrett: That was Dr. Michele Stoffel from M Health Fairview and the University of Minnesota. She was joined by Dr. Dina Greene from LetsGetChecked and the University of Washington in Seattle in this podcast on direct-to-consumer testing for routine purposes. A Q&A feature on that topic appears on the September 2022 issue of *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.