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Pharmacists in the Laboratory Space: Friends or Foes?

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Guests:
Dr. Alex Adams, Executive Director of the Idaho State Board of Pharmacy and Dr. Christopher Ball, Chief of the Idaho Bureau of Laboratories.

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.

There are nearly 60,000 community pharmacies in the United States today. In addition to being sources of prescriptions and medications, they're also often a site for wellness visits, vaccinations, acute illness diagnosis and treatment, as well as monitoring of chronic disease. Pharmacies often offer a convenient alternative to physician offices because of their accessible locations and extended service hours. Approximately 18% of pharmacies in the U.S. have CLIA-waived status, which means they can perform any of the approximately 120 CLIA-waived tests. Many pharmacists help patients make drug dosage decisions in specialized centers such as coumadin in diabetes clinics. With pharmacists performing and interpreting more laboratory tests, what does this mean for the clinical laboratory community? Do pharmacists receive the proper training to perform and interpret laboratory tests? And how do we ensure the quality of testing?

The May 2016 issue of the journal *Clinical Chemistry* published a question and answer piece entitled "Pharmacists in the Laboratory Space: Friends or Foes?" The paper summarized the opinions of four experts, two pharmacists and two laboratorians, to discuss this rapidly changing space. Today, we have with us two participants in that discussion. Dr. Alex Adams is the Executive Director of the Idaho State Board of Pharmacy and Dr. Christopher Ball is Chief of the Idaho Bureau of Laboratories. And Dr. Adams, let's start with you. Currently, what types of testing are pharmacists most frequently involved with?

Dr. Alex Adams: Today, one of the things to look at are what types of pharmacies are currently doing point-of-care testing. And there's a recent study that showed 43% of supermarkets are doing point-of-care testing whereas traditional chains and independent pharmacies are much lower. If you think of the reason for that, is supermarkets tend to have health and nutrition programs, so it's perhaps natural that those

types of pharmacies are doing point-of-care tests for diabetes, they're doing finger-stick glucose tests, A1c tests and things like that.

One of the things that I've seen recently, there was big growth in pharmacies doing point-of-care testing for infectious diseases. There's been a lot of research lately with pharmacies doing testing for influenza and group A strep. There have been some other pilots actually led by the Centers for Disease Control and Prevention where pharmacies are doing point-of-care testing for HIV and hepatitis C, and then they have referral programs to connect patients who test active to more advanced medical settings.

Bob Barrett: Is this testing always in an outpatient setting or a pharmacist also involved in Point-of-Care Testing in a hospital setting?

Dr. Alex Adams: I'm most familiar with it being used in outpatient settings. Again, there's been recent studies that show there's 10,800 retail pharmacies that currently hold the CLIA Certificates of Waiver. So it's to a large extent an outpatient sport, but that's not say it can't be done or shouldn't be done in hospital pharmacies. But I think there's a recognition that in hospitals, there is much broader team of health professionals beyond pharmacists, and there might be other folks who for cost or convenience reasons, it might be more appropriate to do this today.

Bob Barrett: Well, there's no doubt that having certain lab tests available to patients at local pharmacies is convenient for patients. Are there other advantages to having pharmacists order and perform lab testing?

Dr. Alex Adams: I certainly think one of the biggest arguments for pharmacy-based point-of-care testing is the access. And there is geographic access, there is a study that showed 95% of all Americans live within five miles of a pharmacy, but it's not just geographic. It's also nights and weekends where pharmacies are open when many other health professional offices are closed. Access is a major part of the argument. There have been some studies, a CDC study on HIV testing in pharmacies, for example, found that pharmacies potentially offered less stigmatizing venues of care for folks with certain infectious diseases. So I think that's certainly a benefit. There's an argument about cost and then there is certainly an argument about time to treatment. In the example I gave about influenza, pharmacies that pair the rapid point-of-care test with a physician-led collaborative practice agreement, might be able to initiate treatment of the appropriate anti-viral much faster than other care settings. I think those are some of the primary benefits that I see.

Bob Barrett: Well finally, Dr. Adams, do you see the number of pharmacies with CLIA waivers increasing in the future?

Dr. Alex Adams: I certainly do. As I mentioned, there are 10,800 pharmacies that are currently holding CLIA Certificates of Waiver and there are 60,000 pharmacies nationwide. And just to kind of put the service in comparison to others, there have been recent studies that showed 95% of all outpatient pharmacies are now doing immunizations. By comparison, only about 18% of pharmacies today are doing point-of-care testing. I think there's a huge opportunity for growth, and in many ways, I feel like we are now in point-of-care testing where we were with immunizations just a few years ago, before the rapid growth. I do think there is a lot of upward potential and I do expect that there will be growth in the near future.

Bob Barrett: Okay. Well now, let's turn to you, Dr. Ball. As a laboratory director yourself, do you feel that pharmacists receive enough training to perform and interpret laboratory tests?

Dr. Christopher Ball: Yeah, I think that there are really no barriers when you look at the level of education attainment that pharmacists need to have in order to practice in their profession, attainment of doctor's degree is far in excess of what we see in most waived laboratories across the nation. So, I think from a capability standpoint, pharmacists working on waived testing provide a level of expertise that we don't see in other venues.

Bob Barrett: Well, should they be limited to ordering CLIA-waived tests or should they be allowed to order and interpret non-waived tests?

Dr. Christopher Ball: I think this is kind of a complicated question to answer. And I think from my capability standpoint, I want to make sure that I feel that pharmacists have all of the necessary education and skills that they need to be able to confidently perform some moderate and high complexity testing.

Where I really see a problem with pharmacies moving outside of the CLIA-waiver venue is when we start looking at the business model and how it aligns with the services that pharmacies are currently providing.

When you step up from a certificate waiver level, which by its definition, you're performing tests that are of relatively low risk of adverse consequence to patients even if they're interpreted incorrectly, to a certificate of compliance, you move into the realm of moderate and high-complexity testing where I think pharmacists have the ability to discriminate and perform this testing well. But there's a

whole set of additional administrative personnel regulatory and quality assurance and quality control costs that they may not be considering when you move to this level of testing.

Let me just give you a couple of brief examples. In order to achieve a certificate of compliance, the pharmacy would then have to have a CLIA-appropriate laboratory director, which they would have the appropriate educational attainment through their Pharm B degree. But additionally, they would need to get board-certified as a CLIA lab director and have one to two years of practical experience performing moderate or high-complexity testing in a certified clinical laboratory. Additionally, they would have to provide for a clinical consultant, ensure that they had adequate testing personnel that have appropriate training. They would have to enroll in proficiency testing. They would have to have dedicated space and instrumentation for their laboratory. They would have to incorporate new standard operating procedures, documentation, new quality assurance and quality control documentation requirements.

And when you look at all of these administrative and regulatory costs, and then you look at current insurance reimbursement rates for testing services, I think that the pharmacy would need to have an exceptionally high test volume in order to actually recover those costs.

And then, what you really look at when you're looking at all of these additional costs and requirements to move from the certificate of waiver to the certificate of compliance is, does it fit with the service delivery model that pharmacies are currently using? And I think that's where we run into some issues with the level of cost associated with bringing on this higher level of complexity may not be consistent with the service model in most pharmacies.

For me, I don't see it largely as a capability question as much as I look at it as running a high-quality certificate of compliance laboratory is a really expensive full-time business that I'm not sure is a direction that pharmacies would like to move in terms of the types of service that they provide. And I think from my perspective, that's why it's really important that we keep pharmacies in the CLIA-waived testing business where I think it's very appropriate and there's a big value addition to incorporating these folks into the continuum of healthcare services. And I think there are some very exciting work that's being done with the pharmacists and collaborative practice agreements with physicians with regard to waived testing.

Bob Barrett: I want to go back. You talked about the quality of the testing. How can the quality of laboratory testing in these settings be ensured?

Dr. Christopher Ball: Well, quality -- one of the things that I always tell all of my staff when we're working in our laboratory, that the value of laboratory testing goes only as far as that level of rigor and documentation that we can provide to surround the data that we're delivering. And it's the same type of business model that we see in pharmacies.

They have a very rigorous set of standards that they need to adhere to. When we're looking at waived testing, the easiest way that pharmacists can ensure that they have a quality product is to rigorously go through the manufacturer's guidelines for the test that they're implementing. Make sure that they're complying and documenting to all of the testing that they're doing, how they're doing it, recording those results, ensuring that the results are accurately interpreted and reported to the individual before moving forward with any sort of diagnostic work. And if they have any questions, there are a tremendous number of resources available to them even at the waived level.

Every state has what they call a state agency, CLIA state agency program, where there is a laboratory component where they reach out to waived labs and offer educational materials, technical consultation if there's any questions about how to deliver a quality product. I think there's a number of resources at the waived laboratory. If they wanted to move into a non-waived testing environment, then all of the previous administrative costs that I addressed in the last response, those are the requirements that are needed to make sure that laboratories are providing quality results. So in addition to having all of those new personnel and standard operating procedures and dedicated space and QA-QC documentation and proficiency testing requirements, they would also be subject to CLIA audits every two years to verify that everything was operating in a satisfactory fashion.

Bob Barrett: Well finally, Dr. Ball, looking ahead, are there ways that laboratorians and pharmacists can work together to improve patient care?

Dr. Christopher Ball: I think this is one of the most exciting areas of laboratory, pharmacy, and public health collaboration. I think that a lot of that growth that we can see from a public health standpoint is in a routine and regular information exchange between pharmacists and public health professionals. Because of the easy access and very trusted nature of the pharmacy-patient relationship, I think it puts pharmacists in

a great light to help communicate important public health findings to the populous. Also in areas where they're doing waived testing, particularly for infectious diseases, there are a number of real benefits of public health significance.

One of the ones Alex addressed earlier, and that's with regard to things like influenza testing; the relatively rapid nature of the test availability, and then the abilities based on those test results to prescribe an anti-viral or to recommend a more conventional on-the-shelf product to deal with those symptoms, could have a huge impact in state and federal antimicrobial stewardship opportunities.

In addition, in some of the work that I've seen with regard to influenza testing and the testing protocols that pharmacists are currently doing, it's not only a performance of a waived test, but there's also a physical examination that captures important clinical information that would lead pharmacists into participating in international influenza-like illness surveillance. I think there are some tremendous opportunities to expand the types of public health endeavors that pharmacists have, in addition to their already very widely known vaccination campaigns.

Additionally, if we were to look at issues like food-borne disease surveillance, this is another area where often times, getting information out is very important in early detection and then being able to put in appropriate interventions to reduce the severity of food-borne illnesses. In this case, if we had regular conversations between public health officials and pharmacists, and the pharmacists are seeing customers coming in that have compatible symptoms, they are in a great position to either recognize and refer those folks to healthcare providers, and really help us in filling out the picture or complexity of an outbreak situation.

I think there are a lot of very exciting work that can come out of a laboratory and pharmacy and public health collaboration in the future.

Bob Barrett: And that was Dr. Christopher Ball, Chief of the Idaho Bureau of Laboratories. He was joined by Dr. Alex Adams, the Executive Director of the Idaho State Board of Pharmacy. They've been our guests in this podcast from *Clinical Chemistry* on "Pharmacists in the Laboratory Space: Friends or Foes?" They participated in a question and answer article on that topic that was published in the May 2016 issue of *Clinical Chemistry*.

I'm Bob Barrett, thanks for listening!