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# New Therapies for Treating Hepatitis C Virus: Impact on Laboratory Testing Recommendations and Clinical Management

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**Guest:** Dr. Nicole Tolan is Director of Scientific and Medical Affairs at SCIEX and an adjunct assistant professor of Pathology at Tufts University School of Medicine.

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.

Hepatitis C virus or HCV infection affects close to 150 million people worldwide. In the U.S., it is estimated that as many as five million people have been infected with the Hepatitis C virus, many of whom are unaware of their infection. HCV is now the most common indication for liver transplantation, and it accounts for more deaths each year than all other reportable infectious diseases combined including HIV.

Advances in testing methods and antiviral therapies with increased development of infrastructures that improve access care now make eradication of HCV infection in well-resourced countries a realistic goal. However, challenges in implementing screening programs and continues evolution of assay methods and screening protocols raise several issues for how clinicians and laboratories respond to the changing landscape for HCV diagnosis and treatment.

The December 2017 issue of *Clinical Chemistry* includes a Q&A article with several experts who offer their insights and opinions on this topic. Dr. Nicole Tolan, one of the article's moderators joins us for this podcast. Dr. Tolan is the director of Scientific and Medical Affairs at SCIEX and an adjunct assistant professor of pathology at Tufts University School of Medicine.

So Dr. Tolan, I understand your interest in this publication started with your own studies at Beth Israel Deaconess Medical Center.

Dr. Nicole Tolan: Yeah. That's right. I'm currently employed at SCIEX, a mass spectrometry clinical diagnostics company. But this work was really in continuation of the studies that myself and Dr. Gary Horowitz had been conducting with Dr. Cami Graham at Beth Israel Deaconess. We were looking at ways to increase the identification of individuals with HCV infection in our patient population.

Bob Barrett: What was the major motivation to focus on the subject of HCV testing?

Dr. Nicole Tolan: Well, I think, you know, traditional therapies for HCV, the pegylated interferon, the ribavirin, and the protease inhibitors, they really only achieved a 50% to 70% sustained virologic response, or a negative viral load 12 to 24 weeks after completion of treatment. Many patients with these traditional therapies weren't really able to even complete the treatments due to the negative side effects, and so they weren't as effective as the new novel therapies that we have today, the direct-acting antivirals. It would be important to get some information back from our Q&A experts on how these new direct-acting antivirals that were just approved in June of 2016, how they might affect the ability to eradicate HCV.

Bob Barrett: Are we now positioned to do that, to eradicate HCV infection?

Dr. Nicole Tolan: I think we're on the right path, but the experts really highlight a number of hurdles that still remain. We need to be able to identify those individuals who are unknowingly infected, and connect them with treatment without delay. So, it's estimated that of the five million individuals that are infected with HCV, 50% to 75% of them are undiagnosed and they are really unaware of their infection because of the virus's nearly silent acute phase.

So, even with the identification of those who have been infected with HCV, there are still major barriers for patients receiving treatment. There are certain healthcare plans that won't cover the cost of these new-end treatment. The cost of this new novel therapies are declining, but there are still significant gaps that exist in getting patients access to healthcare, such that they are diagnosed and connected to various treatment options.

Bob Barrett: Doctor, what are some of the recommendations these experts have for laboratory medicine professionals?

Dr. Nicole Tolan: Well, first, it's essential to diagnose current infection with HCV viral load versus exposure to HCV infection and positive HCV antibodies. The current CDC testing algorithm emphasizes screening with HCV antibody, but upwards of 15% to 30% of individuals exposed will spontaneously clear the infection. At Beth Israel Deaconess, we found that many patients were referred to have hepatology or infectious disease only to find out that they were viral load negative.

This testing sequence has gaps in connecting patients to diagnosis and treatment. There's a real need for

considering other alternative such as HCV RNA molecular testing at the point of care and our experts talk about this. Also, as Dr. Cami Graham explains, in our practice we saw that only about 60% of patients who had HCV antibody positive results would get the viral load testing that they need, which increases again the likelihood that a patient won't be linked to the necessary care and therefore has a higher risk of being lost to follow up.

Finally, I think that the experts really go through how clinical laboratorians can work with their primary care colleagues to help support wider HCV testing and do their part to ensure timely HCV viral load testing and diagnosis.

Bob Barrett: Well, finally doctor, I understand that baby boomer birth cohort screening has increased the identification of HCV, but it may be time to change our testing strategies.

Dr. Nicole Tolan: Yeah. The mission of the CDC's recommendation for screening all baby boomers was really looking at this cohort of patients that had higher risks of contracting HCV. They were born between the years of 1945 and 1965, and we have been screening these baby boomers for a number of years, so we're facing new challenges in managing individuals who have increased risks for HCV infection, especially with increased use of IV drug use, part of the opioid crisis.

The experts emphasized the need for population-wide screening and increased surveillance of those with increased risks. Like prior to 1998, we need to now increase our testing on individuals with those risks of infection, past or present injection drug use, and importantly HIV co-infection, also, patients who are presenting with signs of liver disease. It is very important to understand if they are currently infected with HCV.

I think our experts take some time to look at new strategies for identifying individuals with HCV infection. That's been a major focus of the CDC. The experts are considering really screening for HCV in the Emergency Department. They all agree that it should be an effective strategy to reach individuals who currently don't have regular primary care. A way to access healthcare for persons that are infected with HCV remains a major hurdle and this may be one way to approach them.

Bob Barrett: Dr. Nicole Tolan is the director of Scientific and Medical Affairs at SCIEX and an adjunct assistant professor of pathology at Tufts University School of Medicine. She has been our guest in this podcast from *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.