

ADVANCES IN HEPATOLOGY

Current Developments in the Treatment of Hepatitis and Hepatobiliary Disease

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Examining the Recent AASLD/IDSA Guidance Test-and-Treat Algorithm Using Point-of-Care HCV RNA Testing



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G&H What are the main challenges of current hepatitis C virus treatment?

AA The biggest challenge of hepatitis C virus (HCV) treatment is not the treatment itself, as the direct-acting antiviral agents that are currently available are highly effective, very safe, and extremely straightforward to use. The real issue is getting people into treatment, which starts with getting people diagnosed. HCV is usually an asymptomatic disease, so it is critical to make sure that the people who should be screened are in fact being screened, diagnosed, and then linked to care with a provider who will be able to initiate treatment.

G&H Why was a simplified test-and-treat algorithm using point-of-care HCV RNA testing released recently?

AA This HCV test-and-treat algorithm was many years in the making. The approval of a point-of-care HCV RNA test (Xpert HCV test, Cepheid) in the United States prompted the adoption of new options for treatment within the HCV guidance. This finger stick test can screen patients for HCV infection using an RNA test so that providers can make an on-site diagnosis within 60 minutes. Once this technology became available last summer, it opened up many opportunities for making a diagnosis and initiating treatment at the same time. It has been shown, not only in HCV but also in other types of diseases, that a test-and-treat model where providers can test patients and start treating them at the same visit has a much higher likelihood of curing more people and, of course, reduces much of the risk of losing patients to follow-up.

G&H How was this algorithm developed?

AA The cornerstone of the test-and-treat algorithm started with the availability of a point-of-care RNA test. Colleagues on the HCV guidance panel from the Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD)

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and I were able to meet and develop an algorithm that would incorporate the RNA test in a safe and effective way that would also be easy for providers to use in routine clinical practice to cure their patients.

G&H What are the biggest changes?

AA The biggest change is starting with point-of-care testing. Other changes include having a mechanism in which blood is drawn to screen for cirrhosis and hepatitis B at the time of the diagnosis. However, the test results do not

need to be available at the time of initiation of HCV treatment. Finally, another big change is putting medication in the patient's hands during the same visit in which they receive their HCV diagnosis. We were aiming to create a one-stop shop for HCV diagnosis and therapy.

G&H Could you discuss research that has been conducted on the effects of point-of-care HCV testing?

AA Point-of-care testing has been studied in many different disease settings. Multiple studies, both in the United States and worldwide, have shown that point-of-care testing is a very effective way of achieving cure in people who otherwise may miss out on it, especially among patients who are at high risk for being infected with HCV and may have otherwise poor access to health care. Thus, there are a lot of data supporting this approach. However, it is important to note that just because this test-and-treat algorithm is available does not mean that it is the right algorithm for every patient, provider, and health care system. This algorithm is not meant to replace currently available HCV treatment guidance that works for many patients. It is merely another option if it makes sense for a relatively specific group of patients and health care systems.

G&H Who are the target patients for this approach?

AA As I have mentioned, this is not a one-size-fits-all approach for all patients. In my opinion, the target patients are people who are at high risk of HCV infection and may not have access to traditional health care systems, meaning that they may not have a primary care provider they are seeing and may have a difficult time accessing subspecialty care, including infectious disease, gastroenterology, and liver specialists. Those who would benefit from the test-and-treat algorithm are often vulnerable populations that are higher risk to being lost to follow-up. One example includes patients who may have difficulty getting transportation back and forth to a provider. Overall, this approach is most effective in vulnerable patients who otherwise may not be able to access health care in more traditional settings.

G&H What are the ultimate goals of this algorithm?

AA We want to have as many options as possible to get people treated and cured of their HCV infection. The ultimate goal is HCV elimination. HCV is a curable disease with highly effective and safe medications that

have been made available now for more than 10 years. By promoting a test-and-treat approach, the hope is that providers are able to help people who may get left behind in being treated and cured of this disease and that providers can give them new access to care. I think this new algorithm fits into a lot of the goals of HCV elimination. For many patients, health care providers, and health care systems, my hope is that this algorithm provides a

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way to dismantle some of the disparities being seen in the cascade of care for the patients who would normally not be diagnosed nor be able to access medications easily. Many of the patients who have access to care have already been treated and cured of HCV infection, so to achieve elimination of HCV we need to look toward people who still need our help. We will never achieve the goal of eliminating HCV unless we address the needs of the most vulnerable patients.

G&H Might there be a role for using this streamlined approach for all patients?

AA Using this simplified HCV test-and-treat algorithm for every single person in the United States and in the world would probably be the most effective way of eliminating this disease, but that is likely impractical owing to limitations in funding as well as in the workforce. Targeting specific populations, such as people who are incarcerated or people who have inadequate insurance, is an effective strategy, as these people often have higher prevalence of HCV infection and would benefit from a streamlined approach. In developing successful elimination strategies, we have to be thoughtful where we deploy our funds and workforce.

There are settings in which a traditional provider visit and laboratory-based testing are highly effective and potentially save costs. Someone who is well established with primary care and has access to providers who are well versed in treating HCV infection is likely not going

to need this streamlined approach. This approach should be thought of as a way of dismantling some of the vulnerabilities that people have within the cascade of care. For people who may not be diagnosed, this approach streamlines the process so that they can get their results and be able to access treatment. However, it is probably not as necessary, or maybe not as efficient or financially sound, as some of the traditional methods that are going to be better for other patients. Gastroenterologists already taking care of patients do not need this approach, as they have a system to treat HCV infection in their clinic. Following the traditional treatment process that they usually use and continuing to use the HCV guidance that is currently available is perfectly fine.

G&H What are the next steps for improving and expanding HCV treatment?

AA Thinking through elimination strategies, starting with micro-elimination and then expanding to larger and larger groups of people, is going to be very important. This test-and-treat algorithm is just one piece of the puzzle. If we are able to use this approach on smaller scales, I believe we can show that this can be effective and also learn a bit about how to better deploy this strategy, as well as learn about what type of workforce is going to be needed to support ongoing elimination projects.

Another important step is rethinking expanded eligibility for HCV treatment. It should be highlighted that

nearly everyone infected with HCV is going to be a great candidate for treatment. Even limited social support and ongoing alcohol or drug use are not contraindications to HCV treatment as long as the patient is willing to take their medication and come for follow-up. We should encourage all providers to expand eligibility in their minds of who would be good candidates for HCV treatment because it is truly for everyone.

Disclosures

Dr Aronsohn has no relevant conflicts of interest to disclose.

Suggested Reading

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