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### VOLUME 5 - ISSUE 8

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## Using Real World Data to Individualize HCV Management

Editor's Note: Since the recording, glecaprevir/pibrentasvir has been FDA approved.

After participating in this activity, the participant will demonstrate the ability to:

- Discuss the real-world data to support a sofosbuvir-ledipasvir treatment duration of 8 weeks versus 12 weeks.
- Summarize the current hepatitis C treatment options for patients with advanced kidney disease.
- Describe the risks and benefits of hepatitis C therapies in HIV-HCV coinfecting patients.

### Guest Faculty Disclosure

Dr. Muir has disclosed that he has served as a consultant and/or advisor to AbbVie, Inc. Gilead Sciences, Inc., and Merck & Co., Inc. He has also received grant and/or research funding from AbbVie, Inc., Gilead Sciences, Inc., and Merck & Co., Inc.

### Unlabeled/Unapproved Uses

He has indicated that there will be no references to the unlabeled or unapproved use of any drugs or products in today's discussion.

### MEET THE AUTHOR



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## Podcast Transcript

**MR. BOB BUSKER:** Welcome to this eViralHepatitis Review podcast.

I'm Bob Busker, managing editor of the program. Our guest today is the author of our recent newsletter issue: Real-World HCV Care. He's Dr. Andrew Muir, Professor of Medicine and Chief of the Division of Gastroenterology at Duke University School of Medicine.

eViralHepatitis Review is jointly presented by the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing. This program is supported by educational grants from Gilead Sciences, Inc., Merck & Co., Inc., and AbbVie, Inc.

Learning objectives for this audio program include:

- Discuss the real-world data to support a sofosbuvir-ledipasvir treatment duration of eight weeks versus 12 weeks.
- Summarize the current hepatitis C treatment options for patients with advanced kidney disease.
- Describe the risks and benefits of hepatitis C therapies in HIV-HCV coinfecting patients.

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**Dr. Muir, thank you for joining us today.**

DR. MUIR: Thank you for having me. It's a pleasure to be a part of this program.

**MR. BUSKER:** The publications you reviewed in your newsletter issue provided a lot of new and clinically important information. Our objective today is to help translate those findings into action. So please start with a patient presentation.

DR. MUIR: Our first patient is a 63-year-old African American man with hepatitis C genotype 1A infection. He got the diagnosis one year ago with a risk factor of injection drug use in his teens. He is HIV negative and does not have hepatitis B infection. FibroScan was 7.0 kilopascals and therefore not consistent with cirrhosis. His hepatitis C RNA level was 4.5 million IU/mL.

**MR. BUSKER:** HIV negative. Hepatitis B negative. He's not cirrhotic. How would you approach individualizing this patient's treatment?

DR. MUIR: You want to try to figure out what's the best thing for this patient, and we're lucky right now to have a number of treatment options. But some caveats will impact that final decision. A key thing is the genotype. There are six main genotypes around the world; for genotype 1 there is 1A vs 1B, and we have some slightly different approaches and response rates. So that's very important.

Another key factor is the degree of fibrosis. Every patient with hepatitis C needs to have their fibrosis checked, and that will sometimes impact the duration of treatment and also how we follow them after treatment. We treat the people with early fibrosis and then can discharge from the clinic. We'll follow the people with advanced fibrosis or cirrhosis for many years and make sure they don't develop other complications of liver disease.

Once we know the genotype and the degree of fibrosis, we can look at the available treatment regimens and guide the patient. Sometimes kidney function is an issue as well, and that will be a factor. If the patient has very advanced liver disease, that's going to impact some of the choices we might make. We are fortunate right now what we have a number of choices.

The final thing that's important is that the patient understand their hepatitis C, what's involved in taking a medication regimen effectively and being adherent to it, and we've prepared them to be successful. We do a lot of patient education to make sure they understand their role in their treatment and that we're supporting them so they can be successful and cured of their hepatitis C.

**MR. BUSKER: Potential medication regimens you might consider for this patient — would one of them be ledipasvir/sofosbuvir?**

DR. MUIR: Yes, that would be a very reasonable option for this patient.

**MR. BUSKER: Should this patient be considered for an eight-week treatment duration?**

DR. MUIR: For this patient, I would not consider an eight-week duration. For many patients that is a very appropriate duration. The decision about eight vs 12 weeks came up for us when the medication regimen was approved. An FDA analysis found that in patients who did not have cirrhosis but had a hepatitis C viral load less than 6 million iU, SVR or cure rates were similar to those in patients whether they received eight or 12 weeks.

In subsequent analyses, though, we found that in African American patients in some real-world datasets did not see the same response rates. It's a small but meaningful difference, with a slightly lower response rate. Therefore, our ASLD IDSA guidance panel decided not to recommend an eight-week regimen in that particular situation for these African American patients. Because this is an African American patient, we would not recommend the eight-week duration here and would recommend 12 weeks of sofosbuvir/ledipasvir.

**MR. BUSKER: In your experience, have payers ever mandated specific treatment durations?**

DR. MUIR: Yes, some payers do mandate the treatment and its duration. It varies from payer to payer, but I have seen that come up. That can be challenging at times because we may have changes in our guidelines during the year, and at that point what the payer has mandated may no longer follow the guidelines.

We have been in situations where we've had make appropriate appeals to payers. Those are successful when there's an evidence-based appeal, such as in the examples we provided here with lower response rates, such as African Americans at eight weeks. We need to understand exactly what the payer guideline is and then react to it with the appropriate evidence.

**MR. BUSKER: What other factors might influence your treatment duration decisions?**

DR. MUIR: We have to individualize treatment duration for our patients, and a number of things affect it. That question comes up for a lot of patients with the eight-week duration of sofosbuvir/ledipasvir. As a reminder, eight weeks is not appropriate if patients have cirrhosis or if their viral load is greater than 6 million iU/mL, if they're African American, or if they have HIV. Those groups need 12 weeks.

With all the other regimens we think about the level of fibrosis; patients with cirrhosis may need longer treatment. If they've failed other treatments, that may impact how we approach them and their duration. Also — this is partly where it may not be exactly within the guidelines — but if a patient has multiple negative predictors or perhaps a borderline fibrosis stage, maybe not exactly cirrhosis on whatever test you've done, but maybe you have an instinct that they are at increased risk for a lower response. Or maybe they're obese and near cirrhosis, and that's where I think clinicians have to decide what's in the best interest of their patient. Those are some of the factors we consider, because we want to look at this individual patient and decide how can we best treat you, how do we offer you the best chance of cure.

**MR. BUSKER: Nicely said, doctor. And we'll return with Dr. Andrew Muir from Duke University School of Medicine in just a moment.**

**MR. BOB BUSKER**

**This is Bob Busker, Managing Editor of eViralHepatitis Review.**

**eViralHepatitis Review is a combination newsletter and podcast program delivered via email to subscribers. Newsletters are published every other month. Each issue reviews the current literature in areas of importance to hepatologists, infectious disease specialists, primary care physicians, nurses, nurse practitioners, and other clinicians caring for patients with viral hepatitis.**

In the month following each newsletter, a case-based podcast discussion, like the one you're listening to now, is available to help translate that new clinical information into practice. These podcasts are also available as downloadable transcripts.

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Thank you.

**MR. BUSKER:** Welcome back to this eViralHepatitis Review podcast. Our guest is Dr. Andrew Muir from Duke University School of Medicine. We've been discussing how the real-world information he described in his newsletter issue can be translated into improved clinical practice. Please continue with another patient scenario.

DR. MUIR: Our patient now is a 44-year-old man with hepatitis C genotype 2 infection diagnosed six years ago when he had progression of his chronic kidney disease and initiated hemodialysis. He is not planning to pursue kidney transplantation. He is HIV negative and hepatitis B surface antigen negative.

FibroScan was 6.3 kilopascals and therefore not consistent with cirrhosis. His hepatitis C RNA was 11 million IU/mL.

**MR. BUSKER:** What key factors need to be considered when individualizing treatment for patients with chronic kidney disease?

DR. MUIR: Chronic kidney disease will impact how we approach our hepatitis C treatment. It is particularly important that we understand the level or stage of the chronic kidney disease. In general, for most of our regimen it will be fine if we have one of the earlier stages, and I look closely at their GFR, or glomerular filtration rate. If it's above 30 mL/min, we'll be fine. Particularly with the sofosbuvir-based regimens, if they have a GFR less than 30 mL/min or are on hemodialysis, those regimens will be problematic. We have not been able to determine a safe dose of sofosbuvir for those patients. The good news is, in many cases we have other options. So that's an important thing to first consider.

For people with more advanced chronic kidney disease, especially those on hemodialysis, it's also important to know if they're considering kidney transplantation. Access to kidney transplantation right now is quite curious in that patients may be able to receive a hepatitis C positive kidney. And while the wait for some patients on the kidney transplant list can be many years, if they are willing and able to receive a hepatitis C positive kidney, their wait can be reduced significantly. So, if you treat them and clear their hepatitis C, you may impact their access to kidney transplantation. It's critical that before we start hepatitis C treatment in one of these patients, that we'd had that conversation with the patient and probably with their kidney specialist to understand if this is something they're considering.

Once we figure out all that and are proceeding with treatments, the genotype matters, and we have different treatment options based upon it. This is especially important for patients with chronic kidney disease who have low GFRs. Sofosbuvir based regimens will be an issue, and it will be particularly problematic for genotypes 2, 3, 5, and 6 because the current recommendation is to receive peginterferon alfa and ribavirin.

A number of our regimens include ribavirin. Ribavirin is cleared by the kidneys, so they'd have to have a dose reduction, and they still are at risk for significant anemia. We need to make sure what is their baseline hemoglobin, can they tolerate it, and if we do proceed with a regimen that includes ribavirin, we have to monitor them very closely.

A number of issues will come up, but they're important and we can manage them; it's just a matter of putting this all together and making sure we've determined the right strategy for that patient.

**MR. BUSKER:** I want to go back to the patient you described: 44-year-old male, genotype 2, HIV negative, hepatitis B negative, noncirrhotic. He's on hemodialysis. What would your treatment recommendation be at this time?

DR. MUIR: I would defer treatment because he's genotype 2 and he has advanced kidney disease. The best treatment for all patients with genotype 2 at this time is a sofosbuvir based regimen — sofosbuvir/velpatasvir. But I would not want to give him the sofosbuvir. If patients could not take that because of their chronic kidney disease, the current AASLD IDSA recommendation is that that patient would receive peginterferon alfa and ribavirin.

This is the one remaining area of our treatment landscape where peginterferon still exists: the weekly injection that has significant side effects and is a very different quality of life experience compared to the other direct acting antiviral regimens. So unless I had a strong reason that I couldn't wait for treatment and I had to proceed now, I would defer on this patient, especially because new treatment regimens will be available soon.

**MR. BUSKER:** A hypothetical situation: let's say this patient feels very strongly and he tells you "I'm not going to take

**interferon, but I want to be treated right now.” Would you offer him sofosbuvir/velpatasvir?**

DR. MUIR: Sofosbuvir/velpatasvir would be the current recommended treatment for somebody who had normal kidney function or an early stage of chronic kidney disease. Many clinicians have found themselves in the very situation you describe, where a patient is very motivated and we want to help them. There is some experience in our literature about treating patients with more advanced chronic kidney disease, including those on hemodialysis, with sofosbuvir-based regimens.

As we discussed in this issue of the newsletter, the HCV target registry of real world patients looked at this very issue and found that the efficacy outcomes were very similar for all stages of chronic kidney disease. So you can see that this might be very attractive.

The concern, however, is that serious adverse events were more than three times higher in the patients with lower GFR or worsening kidney function. When they looked at the patients who had more advanced kidney disease but were not yet on dialysis, they noted worsening renal function.

This is a registry that’s difficult to know what exactly was going on with those patients and say that the drug is responsible, but it cautions us that there are issues with giving this medicine and those that contain sofosbuvir for this group of patients. Patients need to be aware of that, and their clinicians need to guide them as they make some of these decisions. If you are talking to a patient about this right now, it’s important for them to know that we expect another regimen to be available in late 2017, it’s called glecaprevir/pibrentasvir and it is pangenotypic regimen; it covers all the genotypes, which means it will work for patients with genotype 2 infection like this patient. It doesn’t have renal clearance in large part, so it would be a great choice for this patient.\*

That’s why I said if my hand is not forced right now and the patient can wait, it’s a good thing to wait.

**MR. BUSKER: Again hypothetically: let’s change this patient from genotype 2 to genotype 1B. Would that change your treatment recommendation?**

DR. MUIR: Yes, my recommendation would be different. Genotype 1B patients have options available to them now that are quite effective. Genotype 1B patients also do not need ribavirin, so the risk, particularly of hemolytic anemia and other adverse events, are just not there. The current regimens of elbasvir/grazoprevir, as well as paritaprevir boosted by ritonavir with ombitasvir and dasabuvir, both are great choices here, and I have experience with them, as well. And the studies show that in patients with advanced kidney disease, patients do very well. So you would not have the same kind of concern and you’d be able to proceed with treatment at this time.

**MR. BUSKER: Thank you, Dr. Muir, for that case and discussion. Let me ask you to you bring us one more patient scenario now.**

DR. MUIR: The patient is a 51-year-old man with HIV and hepatitis C genotype 1A infection diagnosed four years ago. He is on efavirenz, emtricitabine, tenofovir disoproxil fumarate, with a CD4 count of 950 cells/mL and HIV RNA that is not detected. He is negative for hepatitis B surface antigen and hepatitis B core antibody. FibroScan was 15.0 kilopascals, consistent with cirrhosis. His hepatitis C RNA was 9.2 million IU/mL.

**MR. BUSKER: What factors most influence your decisions in individualizing treatment for a patient like this?**

DR. MUIR: In general, we want to treat all patients with hepatitis C, but in some cases, we feel more motivated, or perhaps we feel we need to proceed at a faster pace. This patient represents one of those times.

We know that patients who have both HIV and hepatitis C are at greater risk for progression to cirrhosis, and they’re at greater risk for the complications of cirrhosis. This patient is already at this point, but let’s say he was an earlier stage of liver disease. We’d still be very motivated to get him on treatment. And if here were reticent about treatment for some reason, we’d want to make sure he understood the implications and why we want to proceed with the hepatitis C treatment.

Now this patient does have cirrhosis according to the FibroScan that was performed. Any value higher than 12.5 kilopascals in hepatitis C patients is a concern that they have reached the point of cirrhosis. When cirrhosis is present, we want to make sure we understand where we are within that.

One group of patients that we call compensated and another that we call decompensated. Compensated means that if I were to biopsy a liver or look at it under a microscope, I would see the features of cirrhosis, but when I examine and talk to the patient, they haven’t had any of the complications of liver disease. This is in contrast to someone with decompensated cirrhosis, who does have some of those complications.

Maybe they have ascites, they’ve had hepatic encephalopathy, or they’ve bled from varices. Those patients have crossed a line and their liver is thicker, and that will impact how we think about their treatment and which treatments we might offer them.

**MR. BUSKER: Just for clarity: this patient is cirrhotic, but he has not shown any signs of decompensation. Is that correct?**

DR. MUIR: Yes, that is correct.

**MR. BUSKER: How would your approach be different if this patient was decompensated?**

DR. MUIR: When a patient has decompensated cirrhosis, we need to consider if now is the right time to proceed with hepatitis C treatment, or do we need to think about a transplant evaluation. This is one of the current challenges for us in liver disease.

On the one hand, we don't have as many liver transplant programs offering transplants to HIV/hepatitis C patients, but there are a number now around the country and that is something that should be considered for each patient. Perhaps they are either near a center or might be interested in pursuing transplantation.

If they're not either interested in or able to undergo liver transplantation, we need to think about treatment for them and make sure we're doing right by them in that respect. Once they have reached that point of decompensated cirrhosis, the choices for some of their antiviral regimens for hepatitis C become more limited.

This is particularly around those regimens that involve a protease inhibitor. These drugs are not recommended in patients who have advanced liver disease, and that includes decompensated cirrhosis. Package inserts will often talk about not being recommended in patients with a Child-Pugh B or C, and it's a safety issue. They get accumulation of the protease inhibitor and they're at risk for toxicity. So we'd be offering them regimens that do not include protease inhibitors.

**MR. BUSKER: If this patient is going to accept hepatitis C treatment, how would you alter his HIV regimen?**

DR. MUIR: When considering treatment for the hepatitis C in the patient who has coinfection with HIV and hepatitis C, it's important to look at the HIV drugs. We know that there are a number of drug/drug interactions between the HIV meds and the hepatitis C agents and we'll make drug choices based on what is eligible. Even within what's known about these drugs, some questions came up out of the clinical trials about whether there still might be some issues between certain agents.

This particularly came up for the efavirenz-containing regimens. The ION-4 study looked at sofosbuvir/ledipasvir in patients with HIV and hepatitis C, and one of the things I noticed was that all 10 of the relapses were African Americans, but eight of these patients were receiving efavirenz-containing regimens. And so this was something that was still out there and a concern as the regimen entered clinical practice. But as we discussed in the newsletter, a report out of the Veterans Affairs Clinical Case Registry looked at this very question and found no difference according to not only race, but also whether the patient was on an efavirenz-containing regimen. So our real-world data was supportive and helped resolve an issue that was left over from the clinical trials.

Another question that came up was whether there might be an issue with renal function for patients who are receiving tenofovir-containing regimens. One of the concerns there is that ledipasvir will increase the level of tenofovir. The question was, would it be a concern and would it somehow impact the safety and the renal function of the patients receiving that regimen. Our registry showed that it was safe, that it was not a concern that was borne out. That's given clinicians more confidence to offer this regimen to their patients who have HIV and are also on these tenofovir-containing regimens.

**MR. BUSKER: What do the data show comparing cure rates between patients who have hepatitis C alone and those who have HIV/HCV coinfection?**

DR. MUIR: In the past we would have told patients with HIV/hep C that their chances of cure for hepatitis C treatment was lower than someone who just had hep C. But in the direct acting antiviral era we have found that the response rates are essentially the same for HIV/hep C or hep mono-infection. I tell all patients that their chances of a cure are around 95%. This is very powerful for patients to hear, especially for these patients with HIV/hep C to know that their chances of cure are just as great as somebody else's.

It's also been extremely important and encouraging that these data were not only in clinical trials, but as these medications have come out into the real world, our registries are showing this.

**MR. BUSKER: I want to thank you, Dr. Muir, for today's cases and discussion. One more question for you, and it's about the near future. In the next year or so, what major developments might be expected in hepatitis C treatment?**

DR. MUIR: It's very exciting. New regimens are coming out that will help us further advance hepatitis C treatment. One of the key things is a salvage regimen that is currently under FDA review. It is the current combination of sofosbuvir/velpatasvir, but with the addition of voxilaprevir, a protease inhibitor. This will be important for people who've failed one of our current therapies. We now have something that has been shown in clinical trials that is very effective in that group, as well.

So for that very small percentage of people who failed the current strong therapies we had, we have a therapy that can cure over 90%, 95% of patients. It's given us more confidence to be able to tell patients that even if you are one of the small number of people who failed a current treatment, we have something else coming for you. That's very important to be able to share with patients.

The other reason for enthusiasm is another pangenotypic regimen in the offing: glecaprevir/pibrentasvir. As discussed earlier in this podcast, this does not have significant renal clearance, so it will be available to all degrees of renal function, particularly for group of patients who may be recommended to get peginterferon alfa and ribavirin. Now we'll have an interferon-free, potent DIA regimen out there for patients with hepatitis C.

We're seeing choices and we're strong regimens, and the importance of being able to offer every patient the chance for cure of their hepatitis C has been great.

**MR. BUSKER: Thank you for sharing your insights, doctor. Let's wrap things up now by reviewing today's discussion in light of our learning objectives. To begin: the real-world data that support a sofosbuvir-ledipasvir treatment duration of eight weeks versus 12 weeks.**

DR. MUIR: Multiple real-world cohorts have demonstrated that eight weeks of sofosbuvir/ledipasvir is reasonable for many patients with genotype 1 infection if they do not have cirrhosis and their HCV RNA is less than 6 million iU/mL.

It's also important, though, that one key finding was a small but meaningful difference, with lower SVR rates in African Americans. As a result, recent update to the AASLD/IDSA guidance does not recommend eight weeks for African Americans and instead would recommend 12 weeks when using ledipasvir/sofosbuvir.

**MR. BUSKER: Our second learning objective: the current hepatitis C treatment options for patients with advanced kidney disease.**

DR. MUIR: Assessing renal function is important for all patients, and all regimens are safe and well tolerated if the GFR is more than 30 mL/min. Sofosbuvir containing regimens, however, cannot be recommended in patients with a GFR less than 30 mL/min or if the patient is on dialysis.

In the HCV TARGET database among patients with lower GFRs treated with sofosbuvir-containing regimens, serious adverse events were more than three-fold higher, and worsening renal function was noted in those patients not on dialysis receiving these regimens.

Patients with genotypes 1 and 4 have multiple effective regimens without sofosbuvir available to them, but patients with genotypes 2, 3, 5, and 6 and low GFR have not had an interferon-free regimen available to them. But glecaprevir/pibrentasvir is expected to be available in late 2017 and will meet this need.

**MR. BUSKER: And finally: the risks and benefits of hepatitis-C therapies in HIV/HCV coinfecting patients.**

DR. MUIR: Hepatitis C therapies are highly effective in patients coinfecting with HIV/hep C, and they rank similar to efficacy in mono-infected patients. Patients with HIV/hep C on HIV antiretroviral therapy need review of potential drug/drug interactions when considering the various hep C regimens.

There was early concern about lower response rates in ION-4 with sofosbuvir/ledipasvir for African Americans, and this raises the question of lower response on patients receiving efavirenz. But real-world studies have now shown no differences in SVR among African Americans or for those patients receiving efavirenz-containing regimens. These therapies have been safe and well tolerated among patients with HIV/hep C infection.

In particular, there was concern that ledipasvir increased tenofovir exposure, but real-world studies have shown no changes in renal function during hep C therapy.

**MR. BUSKER: Dr. Andrew Muir from Duke University School of Medicine — thank you for participating in this eViralHepatitis Review podcast.**

DR. MUIR: Thank you for the opportunity to be with you. This is a great program, and it's important to see how these agents have been working in the real world.

**MR. BUSKER: To receive CME credit for this activity, please take the post-test at [www.eviralhepatitisreview.org/test](http://www.eviralhepatitisreview.org/test).**

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