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VOLUME 5 - ISSUE 2

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HBV: Addressing Current Gaps in Diagnosis and Linkage to Care

Our guest authors are Mindie Nguyen, MD, MAS, Associate Professor of Medicine at Stanford University, and Dr. Iris Liou, MD of the University of Washington.

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

- Identify at-risk patients for screening for chronic hepatitis B.
- Apply the appropriate screening and diagnostic tests for chronic hepatitis B, to identify those in need of hepatitis B treatment.
- Discuss the benefits of early diagnosis and treatment of chronic hepatitis B.

This discussion, offered as a downloadable audio file and companion transcript, covers the important topic of Addressing Current Gaps in Diagnosis and Linkage to Care. This program is a follow up to the Volume 5, Issue 1 eViralHepatitis Review newsletter—HBV: Current Gaps in Diagnosis and Linkage to Care

Unlabeled/Unapproved Uses
Both our guests have indicated that there will be no references to the unlabeled or unapproved use of any drugs or products in today's discussion.

MEET THE AUTHORS

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Guest Faculty Disclosure
Dr. Nguyen has indicated that she has received grant research support from Bristol-Myers Squibb, Gilead Sciences, Inc., and Janssen; and advisory board honorarium from Bristol-Myers Squibb, Gilead Sciences, Inc., Intercept Pharmaceuticals, Roche Laboratories, Dynavax Laboratory, and Alnylam Pharmaceuticals.

Dr. Liou has indicated that she has no financial interests or relationships with a commercial entity whose products or services are relevant to the content of this presentation.

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Podcast Transcript

BOB BUSKER: Welcome to this *e*ViralHepatitis Review podcast.

I'm Bob Busker, managing editor of *e*ViralHepatitis Review. Our program today is a follow-up to our newsletter on Hepatitis B: Addressing Current Gaps in Diagnosis and Linkage to Care. Our guests are that issue's authors, Dr. Mindie Nguyen, Associate Professor of Medicine at Stanford University, and Dr. Iris Liou, Clinical Associate Professor of Medicine at the University of Washington.

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Learning objectives for this audio program include:

- **Identify at-risk patients for screening for chronic hepatitis B.**
- **Apply the appropriate screening and diagnostic tests for chronic hepatitis B, to identify those in need of CHB treatment.**
- **Discuss the benefits of early diagnosis and treatment of chronic hepatitis B.**

Dr. Nguyen has indicated that she has received grant research support from Bristol-Myers Squibb, Gilead Sciences, Inc., and Janssen; and advisory board honorarium from Bristol-Myers Squibb, Gilead Sciences, Inc., Intercept Pharmaceuticals, Roche Laboratories, Dynavax Laboratory, and Alnylam Pharmaceuticals.

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Dr. Mindie Nguyen, Dr. Iris Liou, thank you both for joining us today.

DR. MINDIE NGUYEN: Thank you. It's my privilege to be here.

DR. IRIS LIOU: Thank you for having us today.

MR. BUSKER: In your newsletter issue, doctors, you reviewed the current research describing the epidemiology of chronic hepatitis B; the existing gaps in screening, diagnostic testing, evaluation, and treatment; and you discussed some of the long-term benefits of antiviral therapy. What I'd like to focus on today is helping our listeners translate some of that information into clinical practice. So if you would please, Dr. Liou — start us off with a patient scenario.

DR. LIOU: We have a 45 year old gentleman who just moved into the area and comes in to see his primary care provider to establish care and get a diabetes medication refill. On review of systems he has no complaints and mentioned that he's lost some weight recently because he had been working two jobs to support his daughter, who just started college. He has no significant medical history other than diabetes. He works as an engineer, he immigrated from China about 10 years ago. He has no family history of significant illnesses. He does not smoke or drink alcohol. His exam is unremarkable, as are his routine blood counts and chemistry panel.

MR. BUSKER: What you've just described sounds like a very typical patient being seen in a very typical primary care practice. Would you agree with that, Dr. Nguyen?

DR. NGUYEN: Yes, I would agree with that. This is quite common, especially in the west coast and east coast, where we have a lot of immigrants, so we see a lot of immigrant population. People generally come to see primary care doctors to establish care, to get a general checkup and medication refill, just like this patient.

MR. BUSKER: So talk to us about some of the usual things that the provider would do in this visit.

DR. NGUYEN: For a new patient like this we would do a thorough standard history and physical and routine blood tests that is appropriate for his age and gender. For his age it would be just a general hemogram chemistry, cholesterol check, check on immunizations, anything that needs to be updated, and since he has diabetes I would check a hemoglobin-A1c and urine microalbumin, refer the patient and advise and counsel the patient on a yearly eye exam, foot exam, and the importance of those things.

MR. BUSKER: Why would you consider screening him for hepatitis B?

DR. NGUYEN: He is from China, a country with a prevalence of hepatitis B that is well over 2%, which is the CDC and US Preventive Services Task Force recommendation for hepatitis B screening. I would screen him for hepatitis B surface antigen; however, I would also do hepatitis B surface antibody and hepatitis B core antibody because he's likely to still live in the environment with many immigrants. Therefore, he should be vaccinated for hepatitis B to avoid being infected to it if he has not yet been exposed.

MR. BUSKER: Dr. Liou, let me ask you: do you screen for hepatitis B in all your primary care patients?

DR. LIOU: No. As mentioned previously, we want to check it in patients who meet US Preventive Service Task Force and CDC recommendations for testing. For hepatitis B that would be, as discussed, persons born in regions of intermediate or high endemicity, where the surface antigen prevalence is ≥ 2%.

If you have somebody who is born in the US who's not vaccinated but whose parents were born in regions of high endemicity where the surface antigen prevalence is ≥ 8%, those people should also be checked.

Other people at risk include injection drug users, HIV positive persons, men who have sex with men, and people with close contact with persons known to be hepatitis B surface antigen positive. This includes households, needle sharing and sex contacts. We also recommend testing all pregnant women because of risk of vertical transmission.

The CDC also recommends testing in immunosuppressed patients and people who are at risk for flares of hepatitis B, as well as health care and public safety workers.

MR. BUSKER: This is a little off topic, but what about screening for hepatitis C?

DR. LIOU: For hepatitis C the guidelines are very similar: testing for people at risk for body fluid and blood exposures such as injection drug users, hemodialysis patients, and those who've had a history of blood transfusion before 1992; and now the US Preventive Services Task Force also recommends hepatitis C screening for all baby boomers, or those born between 1945 and 1965.

There may be certain areas such as in China where hepatitis C prevalence is high, and hepatitis C should also be tested for in those cases.

The good news is that screening for hepatitis B and hepatitis C for these high-risk individuals is now covered by Medicare, whereas hepatitis B was previously not covered.

MR. BUSKER: Do you also normally check for the hepatitis B surface antibody and the core antibody?

DR. LIOU: Oh, yes, definitely, I think those are great additions to the surface antigen test. Hepatitis B surface antibody implies immunity, so if somebody is not immune, we would recommend hepatitis B immunization, since people may live in the same household or have contact with other immigrants who have high hepatitis B prevalence.

Hepatitis B core antibody implies prior exposure or chronic infection, and that's important because people with prior exposure should still be aware that they've been exposed because they may be at risk for reactivation if they ever become immunosuppressed in the future.

MR. BUSKER: Dr. Nguyen — anything you'd like to add?

DR. NGUYEN: I would say about this patient that as care providers we would need to keep our antennae up on patients who need to be screened for hepatitis B or hepatitis C, just like how we keep our antenna up to know who to screen for diabetes and high cholesterol. Because usually these patients would not come to us asking to be tested for hepatitis B or C. So we, as providers, have to be conscious of this. And occasionally we may have patients who may not be interested or are

afraid to be tested because of stigma or some misunderstanding, so we may even have to be prepared to explain to the patients the importance of why we test for these things. It is because these diseases are generally asymptomatic, without any problems that the patients can feel for years or decades, and then they develop symptoms of cancer and liver failure and that's usually too late. So that's the whole point of screening patients at the early stage.

The most important thing also is, we have very good, effective, and well-tolerated medications for both of these, so there's no reason why people should not be treated and these conditions cannot be prevented.

MR. BUSKER: Thank you for that case and discussion, doctors. And we'll return, with Drs. Mindie Nguyen and Iris Liou, in just a moment.

MR. BOB BUSKER
This is Bob Busker, Managing Editor of *e*ViralHepatitis Review.
*e*ViralHepatitis 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. Subscription to *e*ViralHepatitis Review is provided without charge or prerequisite.
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Thank you.

MR. BUSKER: Welcome back to this *e*ViralHepatitis Review podcast. I'm Bob Busker, managing editor of the program. Our guests today are Dr. Mindie Nguyen from Stanford University and Dr. Iris Liou from the University of Washington. We've been discussing how to address the current clinical practice gaps in diagnosis and linkage to care for patients with hepatitis B. So to continue in that practice-focused vein — Dr. Nguyen, if you would please, bring us another patient scenario.

DR NGUYEN: A case that comes to mind is a 20-something year old college student from Nigeria, who was tested positive for hepatitis B surface antigen by the school's student health office recently and then was referred to us for further evaluation.

MR. BUSKER: Dr. Liou, if you were the clinician seeing this patient, what would you do?

DR. LIOU: For somebody who has known hepatitis B infection, the tests we would order would be hepatitis B e-antigen or envelope antigen, hepatitis B DNA, and a liver function panel to assess for the level of disease activity. And for at least the first evaluation, you will also want to check CBC and INR to assess for advanced liver disease or cirrhosis. You also want to check tests for coinfections such as hepatitis D virus antibody, hepatitis C antibody, and HIV, given he is from Africa and may be at risk for those coinfections.

Being from Africa, he is also at higher risk for hepatocellular carcinoma, so you also want to order a liver ultrasound and serum alpha fetoprotein for liver cancer screening. We would also recommend hepatitis B screening for his household and sexual contacts as applicable.

MR. BUSKER: Hepatocellular carcinoma screening — would you screen everyone with hepatitis B for HCC?

DR. LIOU: Actually, the AASLD guidelines recommend screening for all hepatitis B patients with cirrhosis. If the person does not have cirrhosis, the guidelines recommend screening beginning at age 40 years for men and 50 years for women. They also recommend screening all those who have a family history of hepatocellular carcinoma. For people from Africa, however, because they are at higher risk for developing liver cancer, screening begins at a much earlier age, 18 years.

The AASLD does not recommend testing serum alpha fetoprotein, but it is widely used in routine practice because the quality of ultrasounds can be quite variable in practice and may not be sufficient alone.

MR. BUSKER: Dr. Nguyen, your thoughts?

DR. NGUYEN: I understand the AASLD recommendation in regards to starting screening at older age for men at 40 and women at 50 because the risks are much lower; however, the risks are not zero, and we all have encountered HCC patients at around this age or younger. So it is my general practice, as well as that of many other providers that I know, to screen

patients at much younger age than this recommended age threshold. In general, the patients have been very receptive and want to be surveyed, and I have not been aware of any insurance coverage issues with this.

DR. LIOU: Hepatocellular carcinoma surveillance is generally recommended at six month intervals. It is most important that this adherence requires commitment by both the providers and the patients.

DR. NGUYEN: I just would like to add a little more emphasis on the HCC screening adherence. As Dr. Liou mentioned, it really requires commitment by both physicians and patients. It sounds easy to follow, but in real life, studies have shown that adherence to HCC surveillance is extremely poor in various settings for patients with cirrhosis in general, and specifically for patients with hepatitis B, both with and without cirrhosis. In a large series of over 1,000 patients we did in the Bay Area, only about half of patients actually got surveyed every six months.

MR. BUSKER: Dr. Nguyen, let me ask you — the hepatitis B envelope antigen, HBV DNA, and the liver enzymes — why do clinicians need to check all those things?

DR. NGUYEN: We need to check these three items, the e-antigen, HBV DNA, and liver enzymes, specifically the ALT, which is the more specific test for liver inflammation, because these are the basis for treatment decision for all the current treatment guidelines, whether the US, AASLD or in Europe or Asia, they are all based on this.

The AASLD cutoff threshold for DNA for treatment recommendation would be 2,000 IU/mL for e-antigen negative and and 20,000 IU/mL for the e-antigen positive patients. For the US algorithm and the European guidelines, fortunately it's a lot simpler, it can be 2,000 IU/mL for either e-antigen negative or e-antigen positive patients because evidence suggests that these patients, despite the lower threshold, regardless of e-antigen, can be at risk for disease progression.

DNA is the actual virus count in the blood, and this is to confirm not only chronic infection but also the degree of viral replication in the patient. ALT is basically a surrogate marker for liver inflammation, and patients who have ongoing liver inflammation are at risk for building up fibrosis and eventually cirrhosis that can cause various symptoms and premature death. It is also a predictor for liver cancer, together with HBV DNA.

One thing I really want to emphasize about ALT is that the upper limit of normal ALT is not what the report prints out by the reference lab, but it should really be 30 for men and 19 for women, because we have very good data to show that in patients who are truly healthy, not drinking significant alcohol, and not significantly overweight, those are the true normals.

Other tests that are not really part of the various treatment guidelines but can be used to supplement them is noninvasive liver fibrosis testing. Many of us now have access in our centers to FibroScan or ultrasound elastography. Usually we don't need to get MRI elastography, but it's available, although I would not recommend that as the first line because of the cost. But these tests can give us estimates of the degree of fibrosis, usually stage 2 or higher is considered significant.

Liver biopsy would be gold standard, but in general, it's not really necessary to use this for staging of fibrosis in most cases.

MR. BUSKER: Along similar lines, Dr. Nguyen — besides the usual liver enzymes, and here I'm talking AST and ALT — should clinicians also check CBC, albumin, and total bilirubin?

DR. NGUYEN: That's a great question. The AST and ALT are more markers of inflammation, and unless it's extremely severe, inflammation does not hurt us or kill us in the short run. So we also need to perform other tests for a more global evaluation. In general we check CBC because if the patient has enough cirrhosis to cause portal hypertension, then usually they would have sequestration of their cell counts and we would have anemia, low white blood count, and especially low platelet counts. For patients without cirrhosis at least initially and every three months for patients with cirrhosis, I routinely also check albumin, total bilirubin, and INR. These are markers of synthetic functions of the liver.

INR would be the first test that would become abnormal because the half life of factor VII is only seven hours. Albumin has a very long half life, around 120 days, so if the disease is acute we may not see that yet; but if someone has cirrhosis or has had this for a couple of months, we will see an effect in albumin.

MR. BUSKER: Thank you for that case discussion, doctors. I think we've got time for one more patient scenario — so if you would, please, Dr. Liou.

DR. LIOU: Oh, good, we should have one here that will be familiar to many providers. We have a 38 year old woman who is a native of Hong Kong and is referred for evaluation and management of hepatitis B. She received a diagnosis of hepatitis B during prenatal testing about 10 years ago. She feels well, is not limited by anything, and works as a software engineer. She does not smoke or drink alcohol. She has two children, she does not have or has ever had any symptoms of liver decompensation such as jaundice, ascites, encephalopathy, or variceal hemorrhage. She has never had a liver biopsy, has never been on any antiviral therapy. Of note, her brother also has hepatitis B and her mother had liver cancer diagnosed in her 50s.

MR. BUSKER: She's got hepatitis B, but she's got no symptoms, and no problems that appear to be hepatitis B-

related. How do you approach treatment in a patient like this?

DR. LIOU: With anybody who has hepatitis B, we want to start with the basics, so we want to check laboratory tests to assess the status of hepatitis B infection and to assess for severity of liver disease. So we check hepatitis B DNA and hepatitis B e-antigen, as well as standard labs such as CBC, comprehensive metabolic panel, INR, and serum alpha fetoprotein, which goes along with an abdominal ultrasound for liver cancer screening, given her family history of hepatocellular carcinoma.

We also want to ask her if she's planning on having more children and if she's on any birth control, as both could affect treatment decisions down the road. You may also want to consider checking for hepatitis D as well as for hepatitis C coinfection, though it is rare in that part of Asia.

MR. BUSKER: So take us through the process, Dr. Liou. You perform the tests you just talked about on this patient — what are her results and what do they mean?

DR. LIOU: Her CBC, most of her liver tests, and INR are all normal. Her liver ultrasound and serum alpha fetoprotein are normal, so this indicates her liver function is normal. There's no evidence of cirrhosis and no evidence of hepatocellular carcinoma. Her ALT is 45, which is elevated as the upper limit of normal for women is 19, her hepatitis B DNA is 152,000 IU/mL, and she is hepatitis B e-antigen negative.

Based on those three values, she meets the criteria to start antiviral therapy, which is essentially an ALT more than two times upper limit of normal, hepatitis B DNA greater than 2,000 IU/mL for hepatitis B e-antigen negative patients.

MR. BUSKER: So this is a patient who should start antiviral therapy. But what if she wants have more children? Dr. Nguyen, how does potential pregnancy factor into initiating antiviral treatment?

DR. NGUYEN: If she does plan to have children, I would probably consider postponing her treatment for a couple of years if she does not have advanced disease yet. I would do an ultrasound elastography to see how much fibrosis she may have. If she has cirrhosis or close to it, then I probably would recommend getting treatment now because we are aware that pregnant patients with cirrhosis and hepatitis B can decompensate during pregnancy, and that would be dangerous. And also while waiting for pregnancy they can also have disease progression, so we need to move ahead with this group of patients.

MR. BUSKER: And if she does not plan to have more children — and if she agrees to start medication — which medication would you recommend for this patient?

DR. NGUYEN: The first line therapy for patients in general would be pegylated interferon, entecavir or tenofovir, and a new medication, TAF, which is one of the new derivatives of tenofovir. TAF has not made its way into any recommendations or guidelines yet because it's new, but it's expected to perform as well as tenofovir.

This patient is Asian, so most likely she has genotype C and has had this infection most of her life, so she's unlikely to respond well to interferon, and I generally do not recommend it for this group of patients.

Then the choice would usually be entecavir or tenofovir. It's really pretty arbitrary which one we use, except for some very specialized groups of patients. A woman of childbearing age is one such "special population." Even though the patient does not plan to have children or get pregnant, things can happen, so I still feel more comfortable using a medication that would be safer if happens to become pregnant while on treatment. I would not recommend interferon or entecavir because these are category C for pregnancy; I would probably recommend tenofovir for her for that reason.

MR. BUSKER: I have one more question on this patient, and I think it's a very important one because it goes to a situation many clinicians are likely to face. So: She should be treated, but what if she doesn't want to be treated? What would you tell her, Dr. Nguyen?

DR. NGUYEN: You are right, this is a very common question I have to respond to all the time. Most patients, because they feel well and many are young, don't want to be on a medication, especially since we have to tell them they'll be on it for years or practically for most of the rest of their lives. I explain to them the risk of liver cancer based on DNA level. Sometimes it's helpful to pull up some slides that we can easily find on the internet to show that the rising risk of HCC depending on HBV DNA levels. We explain this to the patient, but I think showing a picture is very important and I find it very helpful. People say a picture is worth a thousand words, so I will show a patient what the liver looks like when it's cirrhotic and what a normal liver looks like and show patients what ascites looks like, what varices look like, to show the patient what can happen if the disease progresses to such a stage.

It's also important to explain to the patient that the medication we are recommending can prevent and decrease the risk of all of these things. It's also very important to tell the patients that we will decrease the risk significantly, but we will not completely eliminate the risk of cancer or even the risk of cirrhosis.

That's very important because whether they are on treatment or not, liver cancer surveillance needs to continue.

MR. BUSKER: Dr. Liou, your thoughts on how to respond to a patient who should be on medication but refuses. What do you do?

DR. LIOU: This is a very important point. The goal of treatment is to decrease the risk of progression to cirrhosis and hepatocellular carcinoma, and emphasizing those points to the patient and reviewing the duration of therapy, the class of therapy and how we can sometimes apply for assistance to overcome some financial barriers, are all very important points to get across to convince patients that there is a benefit to treatment.

MR. BUSKER: I want to thank you, doctors, for today's cases and discussion. What I'd like to do now is wrap things up by reviewing today's conversation in light of our learning objectives. So to begin, Dr. Liou — identifying at-risk patients for screening for chronic hepatitis B.

DR. LIOU: We hope that we have conveyed the importance of screening immigrants from endemic areas as well as those with high risk behaviors or a history, close contacts, and pregnant women. These are people who can be asymptomatic or may not even know that they have or are at risk for the infection. So it's important to know the risk factors to screen for.

It's also important to know the appropriate tests to order. The most important one is hepatitis B surface antigen, at a minimum. But optimally it should also include hepatitis B surface antibody and hepatitis B core antibody to assess for need for immunity or just knowledge of prior exposure to hepatitis B.

MR. BUSKER: And our second learning objective: applying the appropriate screening and diagnostic tests for chronic hepatitis B to identify those in need of treatment.

DR. LIOU: It is important that you check tests not only to determine the stage or the status of hepatitis B infection, but also the status of the liver disease. Tests should also include CBC, total bilirubin, albumin, INR, and elastography or FibroScan when available. We want to check ALT, hepatitis B e-antigen, and hepatitis B DNA to determine if patients meet guidelines or criteria for antiviral therapy.

We want to make sure that patients with hepatitis B are reviewed to see if they need hepatocellular carcinoma screening and surveillance and what tests to use, specifically liver ultrasound and serum alpha fetoprotein every six months.

It's important to know that certain patient characteristics guide the need for hepatocellular carcinoma screening. These include age, sex, ethnicity, family history, and severity of fibrosis, and all patients with cirrhosis should be screened.

MR. BUSKER: Finally, the benefits of early diagnosis and treatment of chronic hepatitis B. Dr. Nguyen?

DR. NGUYEN: Early diagnosis is very important for a disease like hepatitis B because its complications include cirrhosis and liver cancer. Once those things occur, it's a little late, because we don't really have very good treatment for those conditions. A patient can get a transplant, a patient can get treatment for liver cancer, but those are not optimal, and the treatments are not available for everyone. So it is best to prevent disease progression in patients who are already infected.

It is very important for patients who have been screened and have a diagnosis to be linked to proper care and appropriate evaluations. The minimum should be, check ALT levels, HBV DNA, and fibrosis level because these will determine who will need antiviral therapy. And antiviral therapy, if started early enough, can prevent progression into advanced fibrosis and liver cancer, or prevent most of it. So that is very important.

And antiviral therapies, if chosen appropriately, can be safe in a woman of childbearing age or even during pregnancy, if needed. And it is important to consider this as a separate special population group, but it could be done safely when needed.

And we have many data in the past three to five years that have shown again and again from different geographic locations and populations that antiviral therapy can decrease significantly the rate of liver cancer and disease progression in hepatitis B patients.

MR. BUSKER: Dr. Iris Liou, Dr. Mindie Nguyen — thank you both for participating in this *e*ViralHepatitis Review Podcast.

DR. LIOU: Thank you for having us. We had a really good time here today.

DR. NGUYEN: Likewise, and I really appreciate the opportunity to be discussing these very important topics.

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