TOPIC:	THE CURRENT LANDSCAPE FOR VIRAL HEPATITIS AND NON-ALCOHOLIC FATTY LIVER DISEASE IN THE UNITED STATES
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AFFILIATION	SWEDISH MEDICAL CENTER
TIME:	30 minutes

PRACTICE GAP ANALYSIS: THE CURRENT LANDSCAPE FOR VIRAL HEPATITIS AND NON-ALCOHOLIC FATTY LIVER DISEASE IN THE UNITED STATES

Describe the problems or gaps in practice this activity will address:

What are you trying to change?

Chronic viral hepatitis

Chronic viral hepatitis B and C affect over 5 million people in the United States, with an estimated 40-80% of this population unaware of their infection. This epidemiologic profile is also dynamic owing to phenomena such as immigration and the opiate epidemic. Significant intra-population disparities additionally lead to disproportionately high morbidity and premature mortality from consequent cirrhosis and liver cancer in specific groups. Key among the reasons for these negative outcomes are sub-optimal disease screening, linkage to care, and referral for treatment despite significant advances in treatment of chronic hepatitis B and particularly hepatitis C. In addition, promising research on functional cure of chronic hepatitis B may portend a dramatic transformation of this disease's epidemiology as with the recent developments in hepatitis C therapeutics.

Non-alcoholic fatty liver disease

With the decline in hepatitis C prevalence, non-alcoholic fatty liver disease is expected to be the predominant liver disease worldwide. It is already the fastest rising (and by some estimates the leading) etiology of primary liver cancer and leading indication for liver transplantation in the United States. The vast majority of patients with NAFLD are unaware of their diagnosis and population-level screening for NAFLD and its risk stratification vis-à-vis fibrosis assessment is woefully inadequate. Protocols for systematic and cost-effective disease screening, risk stratification metrics and modalities, are active areas of research. There is finally an intensive clinical research effort to identify therapeutic targets, with the first agent in over a decade, obeticholic acid, slated to receive FDA approval in March 2020.

What is the problem?

This lecture focuses on practicing clinicians thus I will not emphasize the basic and translational research efforts on this condition.

Chronic viral hepatitis B and C: The CDC and USPSTF have clear guidelines on screening patients for chronic viral hepatitis B and C. For hepatitis B, there exists a grade B recommendation to screen all persons "at high risk for infection" whereas for hepatitis C, there exists a grade B recommendation to screen all persons "at high risk for infection" and "adults born between 1945 and 1965". A revision to the latter guideline to include all individuals aged >18 years is in the public comment phase. It is expected that increased screening will lead to improved referral to care, and for the highly effective treatments widely available, thus mitigating late stage complications such as cirrhosis and primary liver cancer. Finally, several states including Washington have embarked on efforts to eliminate hepatitis C within a 10-15-year time horizon. The vast majority of infected individuals however remain unaware of their infection due to non-systematic screening, with marked additional drop-offs noted between screening and referral to care, and between referral to care and referral for treatment. Clinician education on the epidemiology, interpretation of serologies, clinical course, screening guidelines, treatment options, and treatment outcomes, are intended to improve case detection and referral for appropriate care.

Non-alcoholic fatty liver disease: There are no national guidelines on screening for non-alcoholic fatty liver disease and just one agent anticipated to be FDA approved as an adequate (if imperfect) treatment. However it is imperative for clinicians to identify the telltale risk factors for this condition, perform a judicious assessment, and ensure counseling on specific highly effective interventions such as therapeutic weight loss, optimal glycemic control. Further higher-level evaluations such as fibrosis assessments are widely available and should not be the purview of sub-specialists given the massive disease burden. Clinician education on cooperative and systematic approaches to case identification, risk stratification, and management will be discussed.

	How did you assess and/or measure these issues?	
	How was the educational need/practice gap for this activity identified? Place an X by each source utilized to identify the need for this activity.	

Attach copies of documentation for each source indicated (REQUIRED)

* please make sure when selecting your needs assessment data and references that you highlight applicable components.

	Method	Example of required document
	Previous participant evaluation data	Copy of tool and summary data
	Research/literature review	Abstract(s) or articles
x	Expert Opinion	Summary
	Target audience survey	Copy of tool and summary data
	Regulatory body requirements	Requirements summary
	Data from public health sources	Abstract, articles, references
	Other (describe)	

Describe the needs of learners underlying the gaps in practice: What are the causes of the gaps in practice? Check all that apply

x	Lack of awareness of the problem,		Poor self-efficacy,
x	Lack of familiarity with the guideline,		Inability to overcome the inertia of previous practice, and
	Non-agreement with the recommendations,		Presence of external barriers to perform recommendations
	Other		

Why does the gap exist? Check all that apply

x	Lack of Knowledge competence		Lack of time to assess or counsel patients
	Performance-based.		Cost / Insurance/reimbursement issues
	Lack of consensus on professional guidelines		Patient Compliance Issues
	Other:		

What do learners need to be able to know or do to be able to address the gaps in practice?

Understanding the epidemiology of viral hepatitis and non-alcoholic fatty liver disease in the United States, including specific population sub-groups

Understanding the interpretation of viral serologies

Be knowledgeable of current therapeutics for hepatitis B and C and Washington State's effort to eliminate hepatitis C by 2030

Learn about novel therapeutic targets for hepatitis B and for non-alcoholic fatty liver disease

CME OBJECTIVES : THE CURRENT LANDSCAPE FOR VIRAL HEPATITIS AND NON-ALCOHOLIC FATTY LIVER DISEASE IN THE UNITED STATES

State at least three or more things that participants should be able to do after they participate in this CME activity. Please note these objectives should be measurable, specific, actionable and timely.

Upon completion of this activity, attendees should be able to:

1	Discuss the epidemiology of chronic viral hepatitis and non-alcoholic fatty liver disease in the United States, including in specific population sub-groups
2	Correctly interpret viral hepatitis serologies and put serologies into clinical contexts such as a) treatment indicated, b) monitor, c) at risk for disease reactivation, d) prior exposure with viral clearance.
3	Identify current therapeutics for hepatitis B and C and Washington State's effort to eliminate hepatitis C by 2030
4	Describe novel therapeutic targets for hepatitis B and for non-alcoholic fatty liver disease

COMPETENCIES: THE CURRENT LANDSCAPE FOR VIRAL HEPATITIS AND NON-ALCOHOLIC FATTY LIVER DISEASE IN THE UNITED STATES

What ACGME or IOM related competency is associated with this activity? (check all that apply)

x	Patient Care	Practice-Based Learning and Improvement		Medical/Clinical Knowledge
	Procedural Skills	Interdisciplinary Teams		Teams and Teamwork
	Communication Skills	Professionalism		Systems-based Practice
	Quality Improvement	Utilization of Informatics		Evidence-based Practice

What is the activity designed to change

x	**Competence** - (knowing how to do something)

Selecting this option requires the CME activity being planned provide participants with an opportunity to:
- hear information related to advances or best practice
- hear examples of application in practice of information presented

Performance- (actually doing something)

Selecting this option requires the CME activity being planned provide participants with an opportunity to:
- practice what they have learned during the CME activity
- receive feedback about doing what they have learned during the CME activity

Patient Outcomes- (actually measure change in patients)

Selecting this option requires the CME activity track change in patient outcomes:
- provide tangible improvements and data to support overall change to patient outcomes

What potential barriers do you anticipate attendees may encounter when incorporating new objectives into their practice?

x	Lack of time to assess or counsel patients	Other – describe:
	Cost	
	No perceived barriers	
	Lack of administrative support/resources	
	reimbursement issues	
	Insurance/	

Describe how will this educational activity address these potential barriers and the strategies used?

1. Recap key recommendations on disease screening
2. Introduce samples of algorithm-based disease risk stratification which can simplify the understanding and management of the disease process.
3. Provide a detailed understanding of therapeutic options including those that are readily adoptable by primary care providers and do not need referral to specialists

RESULTS: THE CURRENT LANDSCAPE FOR VIRAL HEPATITIS AND NON-ALCOHOLIC FATTY LIVER DISEASE IN THE UNITED STATES

please describe the results expected (outcomes) for this activity in terms of specific improvements in patient care and/or other work related to the practice of medicine.

x	Your Description

1. For non-specialists to have an updated understanding of the disease burdens and therapeutic options for patients with chronic hepatitis B, C and non-alcoholic fatty liver disease.

		2. For non-specialists to develop an increased willingness to engage in the management of three high-prevalence medical conditions, chronic hepatitis B, chronic hepatitis C, and non-alcoholic fatty liver disease.
		3. To improve the rates of disease screening, risk stratification, and linkage to care, and ultimately mitigate excess disease burden and death related to chronic hepatitis B, chronic hepatitis C, and non-alcoholic fatty liver disease.
	Improvements in patient care based on evidence-based treatment	
	Reduce Health care costs	
x	Streamline care of patients	

Will use pre-and post CME activity questionnaire to measure success.

Please provide 3 questions and answers that will asked to the audience before and after your talk. The answer to these questions should be in your presentation. Please highlight the correct answer and limit your possible answers to a maximum of 4 with only one correct answer. The others can be partially correct or wrong

Question 1. A 50-year-old woman from Eritrea presents to establish care. You notice prior laboratory testing showing a positive hepatitis B core antibody (total), positive hepatitis B surface antibody, and negative hepatitis B surface antigen. Your interpretation and management plan is:

	Answers
1	The patient has chronic hepatitis B and should be evaluated for treatment
2	The patient has prior exposure to hepatitis B and does not require treatment
3	The patient has prior exposure to hepatitis B but is at risk for hepatocellular carcinoma and should undergo screening for liver cancer every 6 months
4	The patient has chronic hepatitis B but treatment is not indicated

Feedback:

1. The patient has chronic hepatitis B and should be evaluated for treatment: Wrong Answer
   incorrect interpretation of serology, the patient has negative surface antigen meaning absence of chronic infection. Treatment decision even if patient had active disease would require DNA level and ALT measurement.

2. The patient has prior exposure to hepatitis B and does not require treatment: Correct Answer.
   correct interpretation of serology, based on persistence of hepatitis B core antibody (total) despite negative hepatis B surface antigen

3. The patient has prior exposure to hepatitis B but is at risk for hepatocellular carcinoma and should undergo screening for liver cancer every 6 months: Wrong Answer
   incorrect as patients with isolated core antibody (prior exposure) are not necessarily at risk for liver cancer and guidelines do not recommend screening these patients.

4. The patient has chronic hepatitis B but treatment is not indicated: Wrong Answer
   incorrect interpretation of serology, the patient has negative surface antigen meaning absence of chronic infection. Treatment decision even if patient had active disease would require DNA level and ALT measurement.

Question 2 . A 64-year-old man presents for management of his hypertension and type 2 diabetes. He has a body mass index of 34 and central obesity. He reports never using illicit drugs, alcohol, tobacco, nor has he been incarcerated. Which of the following are USPSTF-recommended screening tests?

	Answers
1	Abdominal ultrasound for evaluation of one-time assessment of fatty liver disease given >2 risk factors
2	One-time hepatitis B surface antigen and antibody test
3	One-time hepatitis C antibody test
4	One-time liver fibrosis assessment using any modality

Feedback:

1. Abdominal ultrasound for evaluation of one-time assessment of fatty liver disease given >2 risk factors; Wrong Answer
   incorrect, there is no USPSTF guideline to screen patients for fatty liver disease irrespective of risk factors.
2. One-time hepatitis B surface antigen and antibody test: Wrong Answer
   this patient is not in the "high risk" group as defined by USPSTF for hepatitis B screening

3. One-time hepatitis C antibody test: Correct Answer.

correct, USPSTF recommends all individuals born 1945-1965 should receive a 1 time HCV antibody test (and reflex to PCR for confirmation if positive)

4. One-time liver fibrosis assessment using any modality: <mark>Wrong Answer</mark>

incorrect, there is no USPSTF guideline for liver fibrosis assessment

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Question 3: Which of the following is true regarding non-alcoholic fatty liver disease (NAFLD)?

Answers

1	There is currently no effective treatment for patients with non-alcoholic fatty liver disease
2	Liver fibrosis is the most important predictor of disease progression
3	An ALT level >2x upper limit of normal is highly sensitive and specific for NAFLD in patients with risk factors
4	Patients with normal BMI of 18-25 need not be screened for NAFLD

<mark>Feedback</mark>:

1. There is currently no effective treatment for patients with non-alcoholic fatty liver disease: <mark>Wrong Answer</mark>
   – incorrect, weight loss of 7-10% of body weight every 6 months until baseline lean weight or a normal BMI is highly effective for reversing hepatic steatosis.

2. Liver fibrosis is the most important predictor of disease progression: <mark>Correct Answer</mark>.
   correct, multiple studies confirm liver fibrosis to be the single most important predictor of negative outcomes in NAFLD including liver cancer, death, and all-cause mortality

3. An ALT level >2x upper limit of normal is highly sensitive and specific for NAFLD in patients with risk factors: <mark>Wrong Answer</mark>
   incorrect, ALT is not a sensitive marker for NAFLD, as many as 10% of patients may have normal ALT values.

4. Patients with normal BMI of 18-25 need not be screened for NAFLD: <mark>Wrong Answer</mark>
   incorrect, "lean NAFLD" particularly in Asian sub-populations which tend to have lower normal BMI's makes traditional BMI-driven risk stratification of NAFLD inappropriate