Hepatitis C Training Program for Healthcare in Ontario Corrections

Designed and delivered by:

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Disclosures

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Mia Biondi, PhD, NP-PHC	Consultancy fees and/or honoraria from: Specialty Rx Solutions, McKesson Investigator initiated grants: Gilead, AbbVie, Cepheid Ad boards and speaker bureaux: Gilead, AbbVie, Abbott, ViiV
Hemant Shah, MD, MSc	Employee: Specialty Rx Solutions

Four Modules – 20 Minutes Each

1. Implications for Public Health, HCV Transmission and Prevention
2. HCV Screening, Diagnosis and Linkage to Care
3. HCV Assessment: Getting A Person Ready for Treatment
4. HCV Treatment: Making the Right Choice and Monitoring Afterwards

Module Three – HCV Assessment: Getting a Person Ready for Treatment

Updated: January 1, 2024

Learning Objectives

- If you are a **prescriber (MD, NP)**
  - Appreciate the work-up required before starting therapy
  - Recognize cirrhosis that might impact management
  - Recognize when you need to image (to rule out liver cancer)

- If you are a **nurse or allied health professional**
  - Recognize that pre-treatment evaluation is usually very simple
  - Understand the importance of pre-treatment evaluation to ensure safe treatment

Module 3 – HCV Assessment and Getting a Person Ready for Treatment

1. Hepatitis C Assessment

2. Pre-Treatment Evaluation

3. What to Watch Out For

General Assessment before Treatment

1. **Assess the degree of liver damage**
   - Do they have cirrhosis? Liver failure? Liver cancer?
2. **General Assessment**
   - Other infections especially hepatitis B (HBV) and HIV
   - Medical history
   - Careful medication history - Drugs/Recreational Drugs/Over-the-Counter
3. **Treatment Access**
   - Medications are **included on provincial corrections Medication Formulary**
   - First line covered in community under ODB programs (by Limited Use) or Trillium
   - Reinfection by Exceptional Access Program (EAP)
4. **Any reason NOT to proceed with therapy?**

When Treatment Might Not be Simple

1. **Liver-Related Concerns**
   - Decompensated cirrhosis
   - Liver cancer
   - HBV co-infection?

2. **Potential for Treatment Failure**
   - Drug-drug interactions
   - Past history of treatment completion with DAAs, relapse vs re-infection

3. **Timing**
   - Shorter stays which may affect the ability to acquire drug before release
   - Unknown length of stays – potential treatment interruption

Required tests

- **Liver Panel:**
  - Enzymes: ALT, AST (covered if you write 'insured')
  - Function: Bilirubin, Albumin, INR
- **Other:**
  - CBC (low platelets often indicate cirrhosis)
  - Creatinine, pregnancy test
- **Other infections:**
  - **Hep B, Hep A and HIV**
    - HBsAg (current Hep B)
    - Anti-HBc (past Hep B)
    - Anti-HBs (immune to Hep B)

} If negative for all Hep B markers → offer vaccination alone or with Hep A

- **Abdominal ultrasound:** *only* if cirrhosis is present

Even if you cannot start treatment, getting these tests done will enable future treatment

Relevance of cirrhosis to HCV Treatment

Presence of cirrhosis - Compensated

- Needs cirrhosis care
- Liver cancer surveillance
- Screening for varices
- Can still be treated in primary care

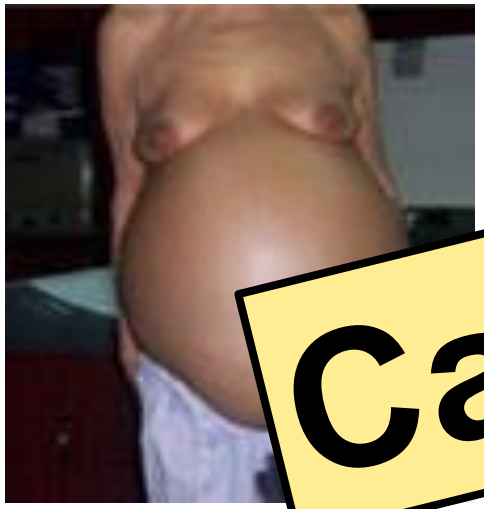
Any signs or symptoms of decompensation *(past or present)*

- Ascites, encephalopathy, variceal bleed
- **Always refer to hepatology before HCV treatment**

Recognizing Cirrhosis

Which one has cirrhosis?

Obvious



Not So Obvious

Can be both!

The Spectrum of Cirrhosis: From Subtle to Overt

Compensated Cirrhosis

- Diagnosis subtle
- Few or no symptoms
- Subtle or no physical exam abnormalities
- Subtle or no laboratory abnormalities
- Most people with cirrhosis in this group

Decompensated Cirrhosis

- Diagnosis usually obvious
- Complication(s) of cirrhosis
  - Ascites/edema
  - Variceal hemorrhage
  - Encephalopathy
  - Jaundice
- Abnormal liver function (very late)
  - ↑ Bilirubin
  - ↓ Albumin
  - ↑ INR

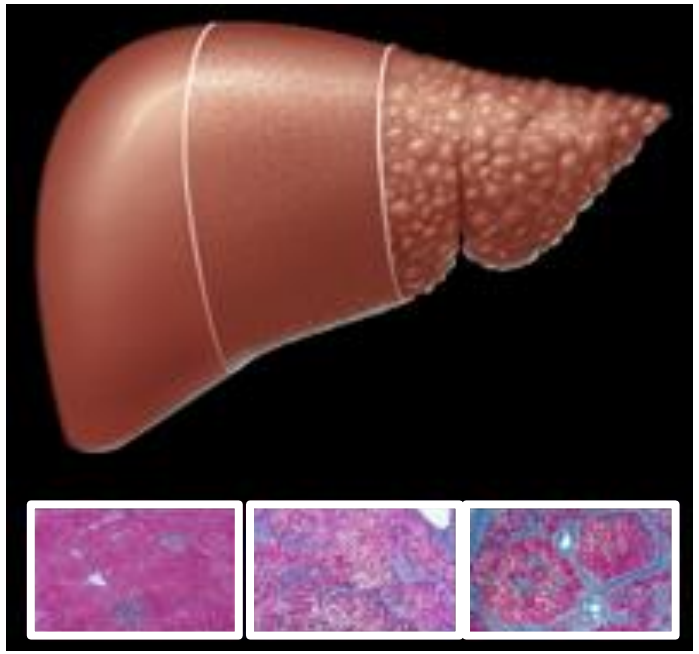
Tools to Assess Liver Damage (Fibrosis)

Clinical exam

- Normal until and often with cirrhosis **(insensitive)**
- Suggestive findings: spider nevi, palmar erythema, dilated abdominal veins, splenomegaly
- If present, findings are fairly specific, **but very insensitive**

Radiology

- Normal with F0-F3 and often with cirrhosis (F4) (insensitive)
- Helpful if shows cirrhosis (fairly specific)
  - **Nodular liver**
  - **Enlarged spleen**
  - Enlarged portal vein



F0 F3 F4
Cirrhosis

Better Tools to Assess Liver Damage (Fibrosis)

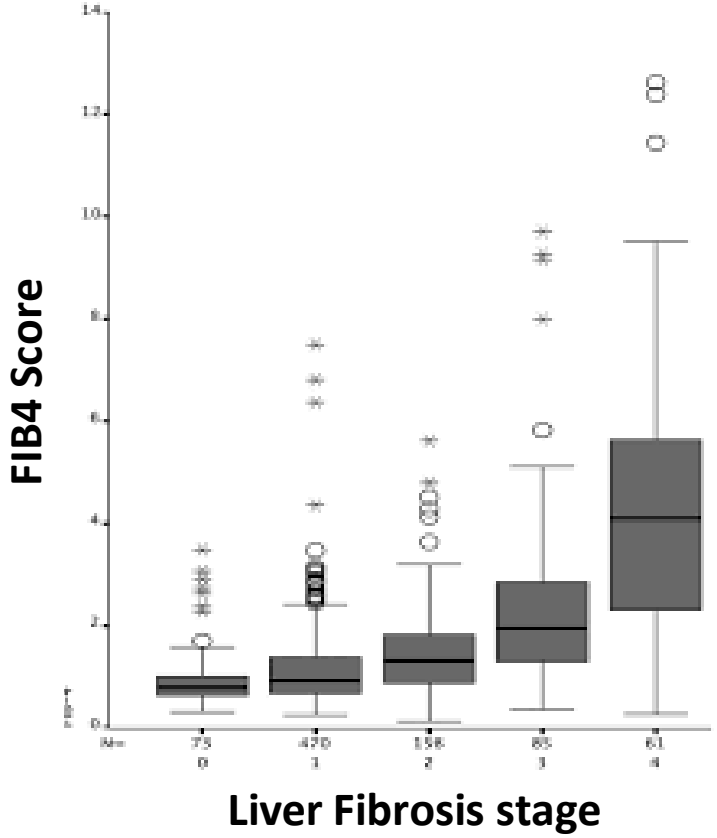
- **Laboratory tests**
  - Liver enzymes (AST/ALT) may be normal even with advanced fibrosis or cirrhosis
  - Normal ALT does not mean 'inactive HCV'
  - Liver function (bilirubin, albumin, INR) normal until advanced cirrhosis
- **Tests suggesting advanced fibrosis/cirrhosis**
  - Platelet count < 150,000
  - AST:ALT ratio > 1 (typically < 1 in HCV)
  - (Abnormal bilirubin, INR, albumin → late finding)
- **Non-invasive Special Tests**
  - **FIB-4 Score** (age, ALT, AST, platelets) **(AGES 35-65)**
  - **AST to Platelet Ratio Index (APRI) (AGES <35, >65)**
  - Fibrotest (specialized tests)
  - Fibroscan (transient elastography)

] Online calculators

A Simple Fibrosis Test: FIB-4

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST (U/L)}}{\text{Platelet Count } (10^9/\text{L}) \times \sqrt{\text{ALT (U/L)}}}$$

- Age important factor – **validated in ages 35-65**
- Developed for HIV/HCV but well validated in HCV and fairly well in other liver diseases
- **>3.25 – likely cirrhosis**
- **<1.45 – confidently exclude cirrhosis**
- **1.45-3.25 – indeterminate (may need another test)**

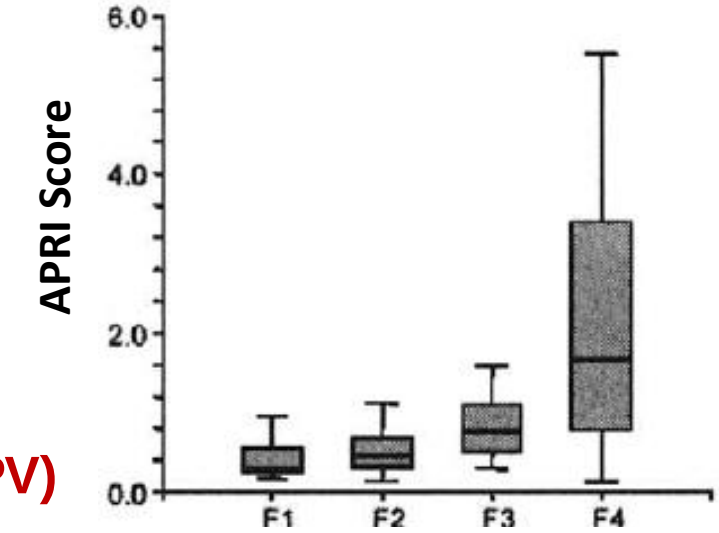


First line screening test for most people

A Simple Fibrosis Test: APRI

- Cirrhosis
  - Platelets fall
  - AST > ALT
- Limitations
- **Validated for ages <35 and >65**
  - Must be calculated
  - Does not distinguish between F1 vs F2/3
  - Be careful if AST high or platelets low for another reason (eg. alcohol)
  - But **excellent negative predictive value (NPV)**
    - **<0.5 --> NPV = 98%**
    - **<1.0 --> NPV = 93-95%**

$$\frac{\text{AST/Upper Limit of Normal x 100}}{\text{Platelet count}}$$

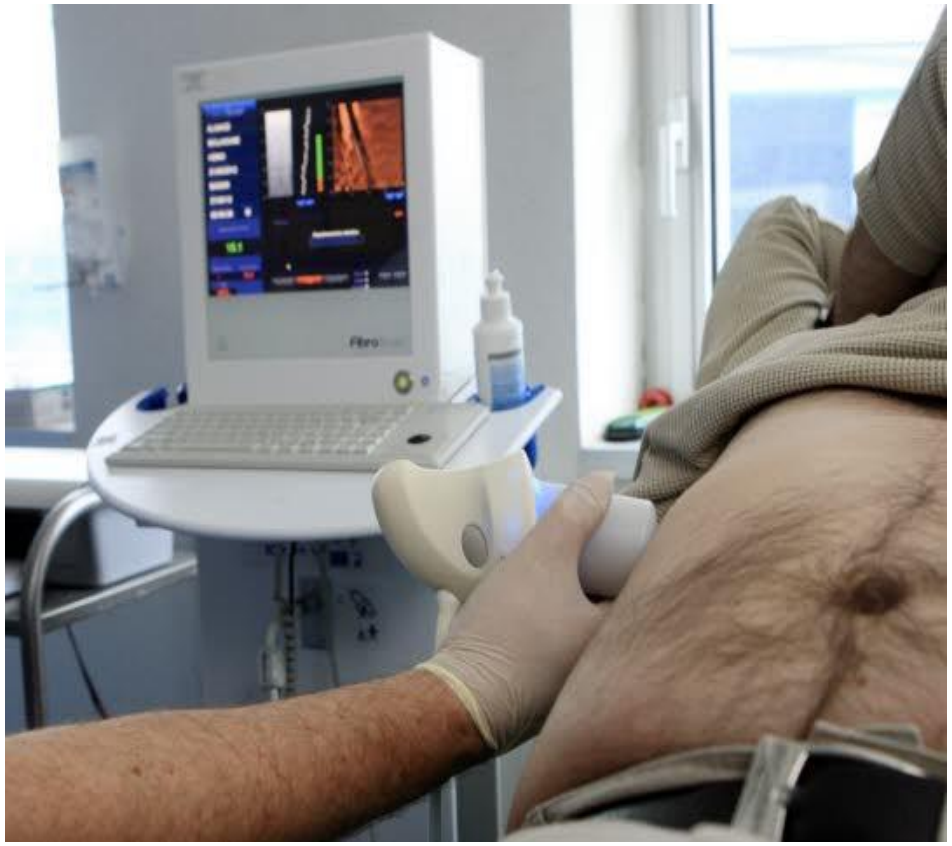


Castera et al. 2005

- Very useful test to **rule out** cirrhosis
- Not good for staging, +/- for ruling in cirrhosis (score >2)

Liver Stiffness by Transient Elastography (Fibroscan)

- Ultrasound-based technique
- Determines liver “stiffness”
- Correlates well with liver fibrosis
- Increases with worsening cirrhosis → predicts complications, such as varices
- Fast & simple to use – minimal training
- **Access is a challenge** as it is not funded in Ontario



Approach to fibrosis assessment

- Start with FIB4 (AST, ALT, PLT, Age) or APRI (AST/PLT) within past 6m

- If **low** (APRI < 1.0 or FIB4 < 1.45) → **No cirrhosis, proceed with treatment**

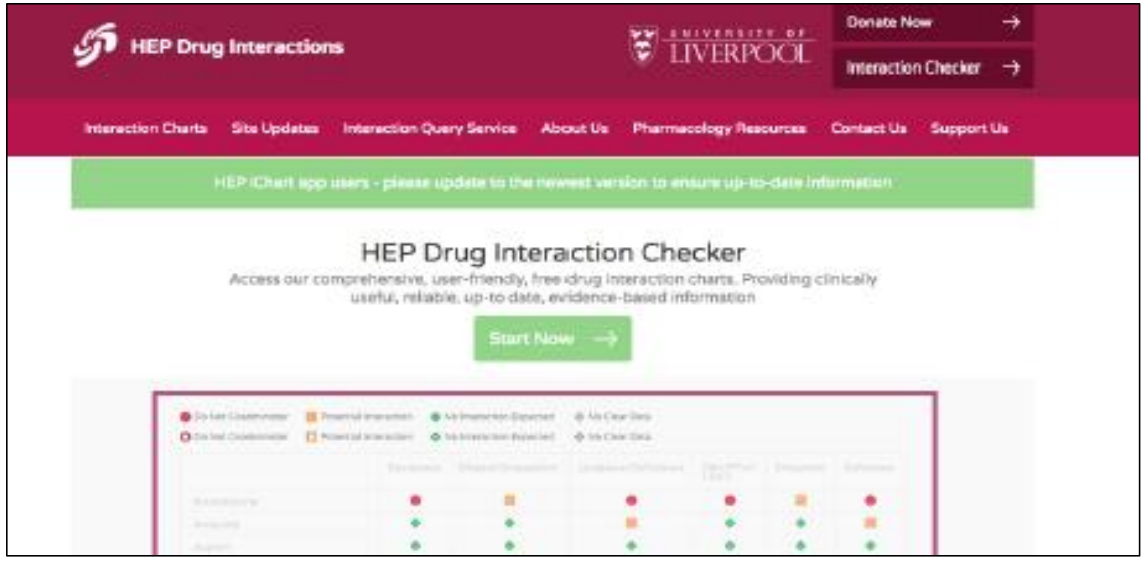
- If **high** (APRI > 2.0 or FIB4 > 3.25) → **Likely cirrhosis**
  - **Exclude decompensation** (past or present) – history/exam
  - **Ultrasound to exclude liver cancer**
  - Proceed with treatment plan

- If **Intermediate** (APRI 1-2 or FIB4 1.45-3.25) → **Indeterminate**
  - **Consider another test** – Fibrotest or Fibroscan (depending on access)
  - If not available, ***reasonable to assume no cirrhosis and proceed***

Relevant Medical History

- Past medical history
  - Co-morbidities
  - Most are not an issue but still important to document
- Mental health – Adherence
  - Active substance/alcohol use
  - Social considerations – food security, housing
- Pregnancy/Contraception
- Medications – Drug-Drug Interactions

Drug-Drug Interactions



http://www.hep-druginteractions.org/

(or just google Hep C drug interactions - a few different options)

Don’t trust your memory – look up all drugs including OTC!

Active Substance Use

- **Not a contraindication to treatment**
- Treatment is highly effective in people with active/daily substance use - ***But,*** important to discuss
- HCV treatment success greater with opiate agonist therapy (OAT) → may be a good time to start both!
- Discuss harm reduction – **transmission and reinfection risk**

The Individual – The Whole Person

HCV in the context of other ***medical*** **illnesses**

- Not always a priority to treat HCV
- Availability of treatment is not an indication for **urgent** treatment

HCV in the context of ***psychiatric*** **illness**

- Since newer therapies are brief, better tolerated and safe, treatment **is recommended** for people with psychiatric illness

HCV in the context of ***social*** **issues**

- People who use drugs (PWUD)
- Alcohol use
- Housing, food security
- Legal issues

How much support will someone need?

- ‘Stable’ social situation
- No active substance use or adherence concerns

→

- Proceed with therapy
- Still ensure linkage at release

- Some red flags
- ? active substance use but supports in community

→

- Ensure supports in place
- Proceed with therapy
- Warm hand-off at release

- Very unstable
- Poor supports, active substance use/psychiatric issues

→

- Ensure supports ready
- Treatment inside may be helpful
- Warm hand-off critical

Treatment Access Criteria in Ontario (ODB)

- Access for all!
  - No fibrosis restrictions
  - No sobriety restrictions
  - Limited provider restrictions
- **All patients with chronic HCV are eligible for treatment**
  - Limited use codes – very easy!!
  - GI, ID ***or "provider experienced in HCV treatment"***
  - Chronic HCV (longer than 6 months)
    - HCV RNA x 2 more than 6 m apart **OR**
    - 1 HCV RNA within 6m + evidence of longstanding infection
      1. Presence of liver fibrosis
      2. Presence of non-liver-related complications (e.g. cryo, DM?)
      3. ALT elevation x > 6 mo.
      4. HCV Antibody-positive > 6 mo.
      5. Risk factors for HCV acquisition > 6 mo.

Practically speaking… almost all eligible at first RNA +

Accessing Medication

- HCV Medications **are included on SOLGEN's Medication Formulary,**
- In the Community (may come with meds or need on release):

Private Insurance

- Complete or Partial coverage (co-pay)

Public Payer (most people)

- Trillium & OHIP Plus
- Ontario Drug Benefit Program
  - Ontario Disability Support Program
  - Ontario Works
  - Age>65
- First Nations through NIHB (Non-Insured Health Benefits)
- Exceptional Access Program (EAP) for reinfection

Very important to consider to avoid interruptions on release

Patient assistance programs can help with deductibles/co-pay

Summary

Fibrosis assessment critical

- Cirrhosis or no cirrhosis
- Serum tests (APRI/FIB-4) adequate most of the time
- Ultrasound alone is not adequate

Other pre-treatment work-up is minimal

- Basic labs (CBC, Liver Enzymes, Liver Function, Creatinine)
- HBV, HIV
- Ultrasound only if cirrhosis present

Need to put hepatitis C in context of the whole person

- Psychosocial issues – substance use, housing, incarceration
- Medical issues (rarely an issue) except for drug interactions
- Funding and continuity

Module 3: 3-Minute Self-Reflection

1. What hepatitis C assessment tests are accessible in my workplace?

2. How can I ensure patients get diagnosed and get a full assessment while they are in the correctional system?

3. How can I connect with community healthcare providers to transition people to care outside of the correctional system upon release?

Next Steps

This completes **Module Three.**

After considering the reflection, please continue to the next module in the training program.