Welcome to the Continuing Professional Development Learning Series for Hope to Health Staff

Pre-Learning Questions

Please consider the following questions in preparation for reviewing the Hepatitis C: Diagnosis and Management presentation:

- Why is it important to learn about Hepatitis C treatment in 2020?
- What are the current recommendations for screening for Hepatitis C?
- What is the baseline work up for Hepatitis C treatment?
- What are the main treatment options for Hepatitis C in 2020?

Hepatitis C: Update on screening and treatment

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January 20 2020

Disclosures

- Speaking engagements and/or consultancy meetings from the following: Gilead, Merck, and Viiv.

Potential conflict of interest:

- Dr Hull has received honoraria from companies (listed above) whose products will be discussed during this program.

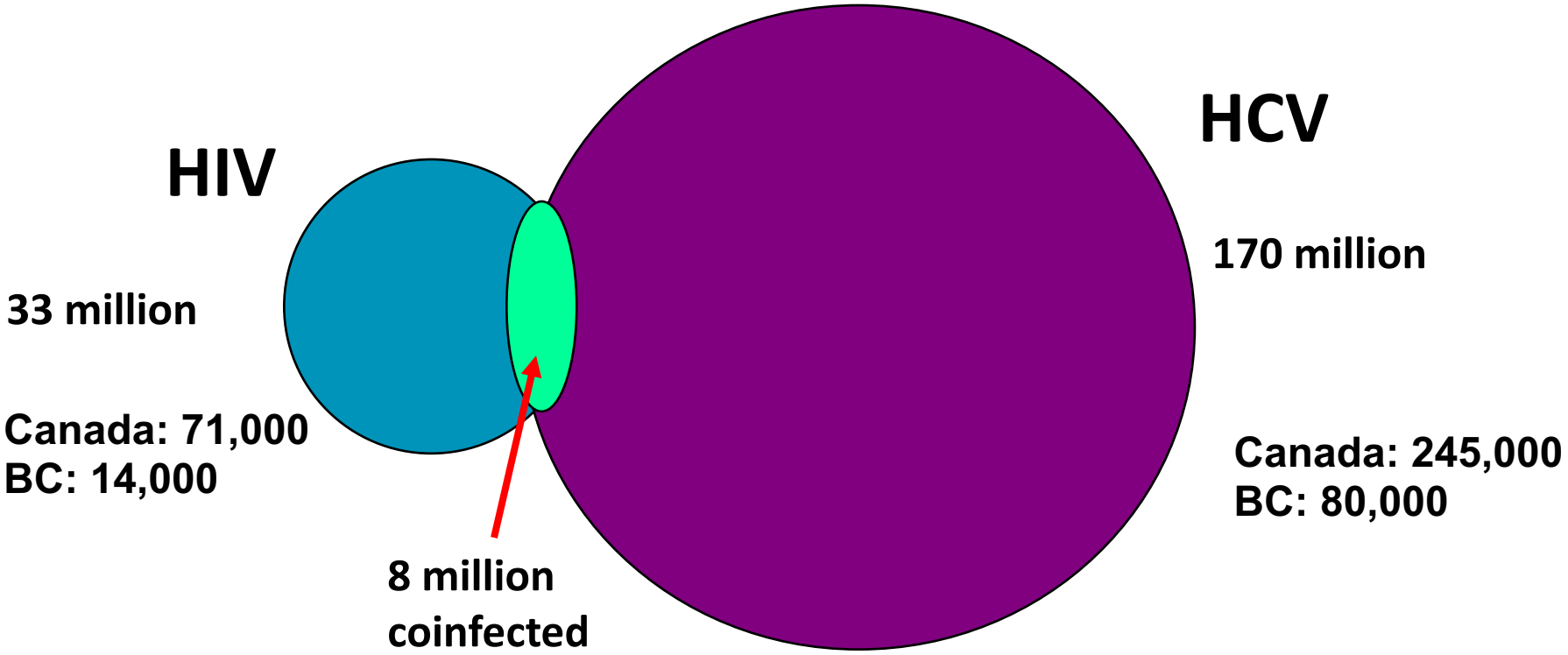
Mitigating Potential Bias

- All honoraria are paid to Dr. Hull's institution.
- On-label recommendations following national/international guidelines.
- No recommendations made regarding specific choice of agents in this program.

Objectives

- Why should we care about Hepatitis C in 2019.
- Review current recommendations for screening for Hepatitis C.
- Review work up for therapy.
- Review treatment options and outcomes of therapy.

Overlapping Global HCV and HIV Epidemics



HIV in Vancouver's PWID

VIDUS Youth

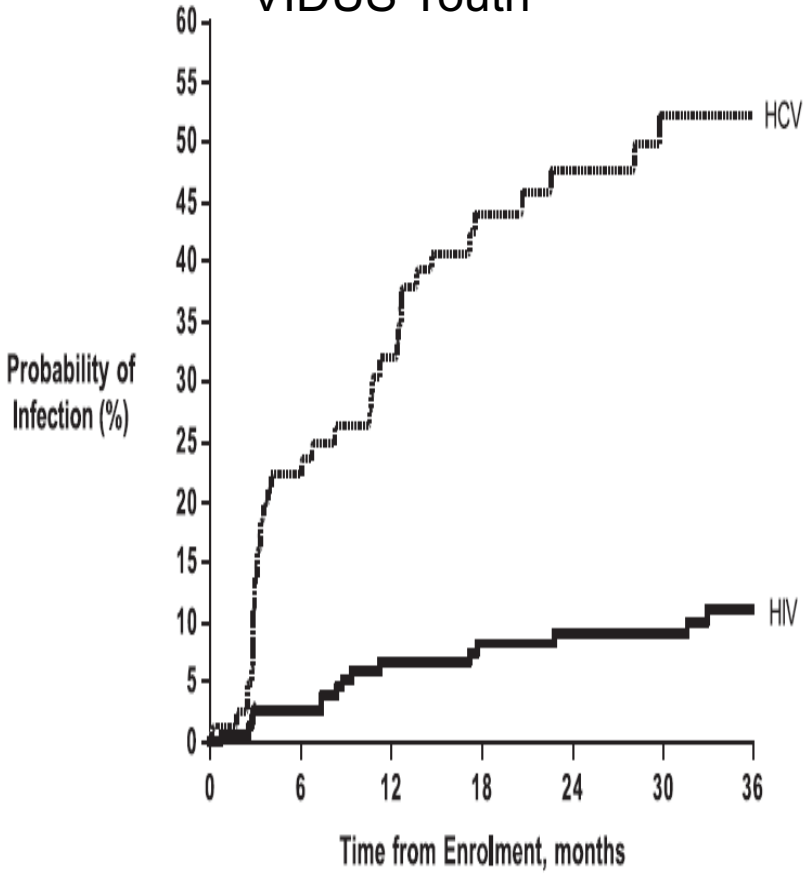
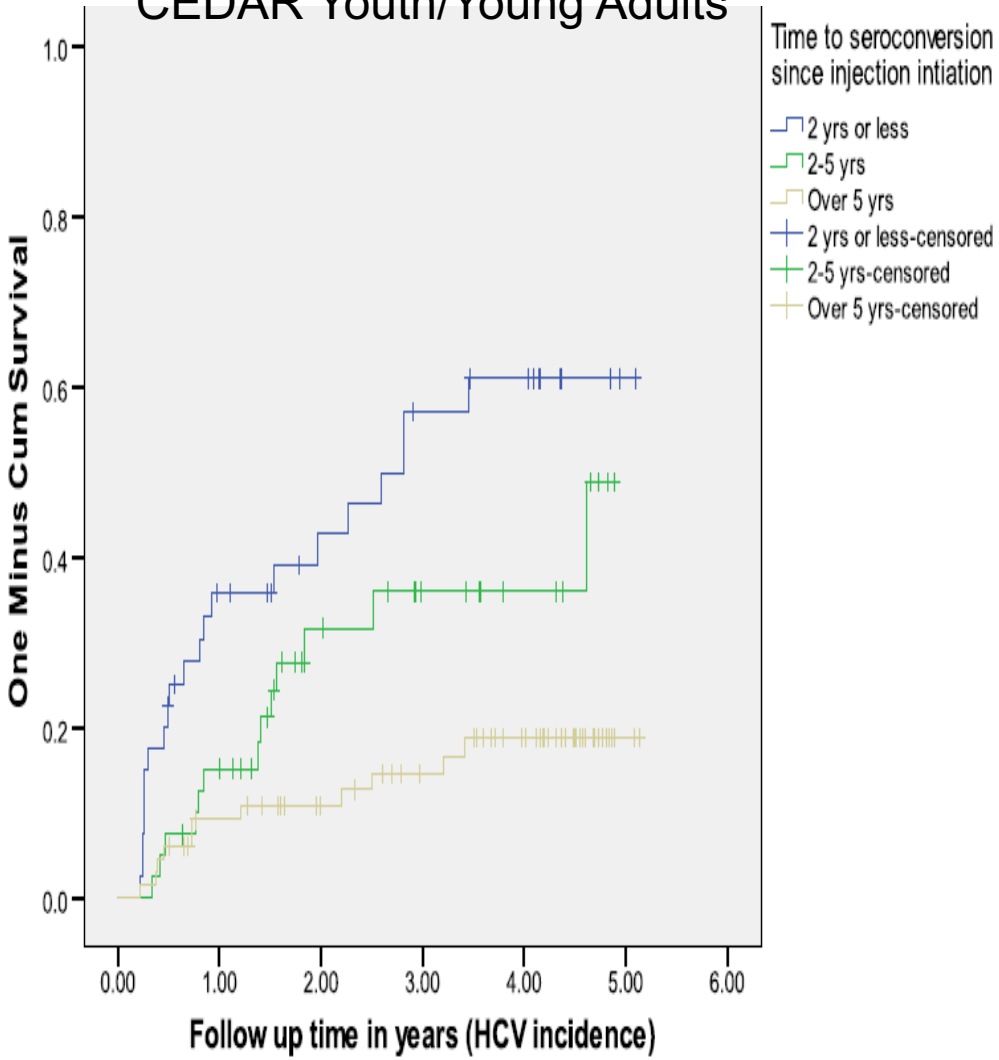


Figure 1. Cumulative HIV and HCV infection rates among IDU ≤24 years of age at baseline

Miller, C. Can J Public Health 2005;96:107

CEDAR Youth/Young Adults



Spittal, P. BMC Public Health 2012;12:632

HCV Natural History

- 75-85% patients exposed to HCV develop chronic infection
- 16- 20% pts develop cirrhosis after 20 years of infection
  Thein, HH et al. Hepatology 2008;48:418.
- Hepatic decompensation after cirrhosis - 3.9% per year risk
  Fattovich, G et al. Gastroenterology 1997;112:463.
  - ascites, variceal bleeds, encephalopathy
  - Hepatocellular carcinoma

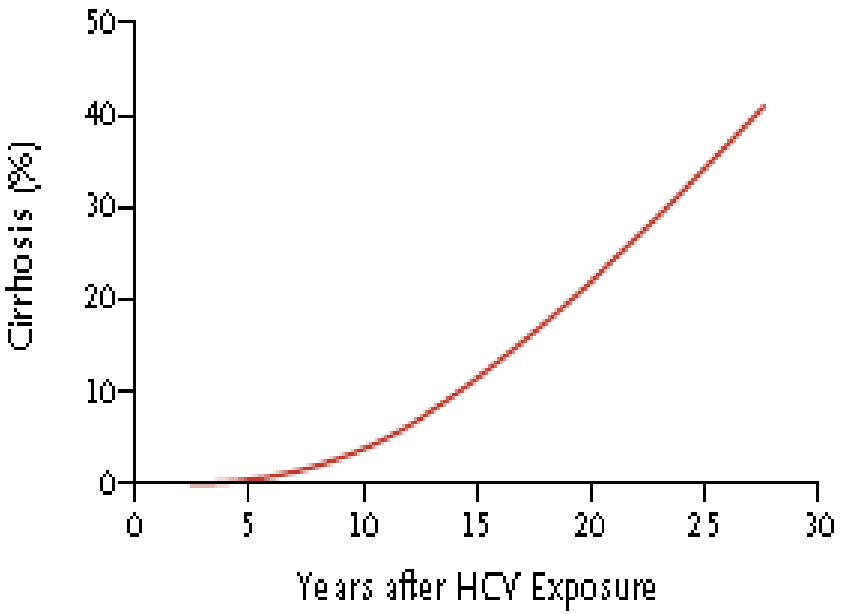
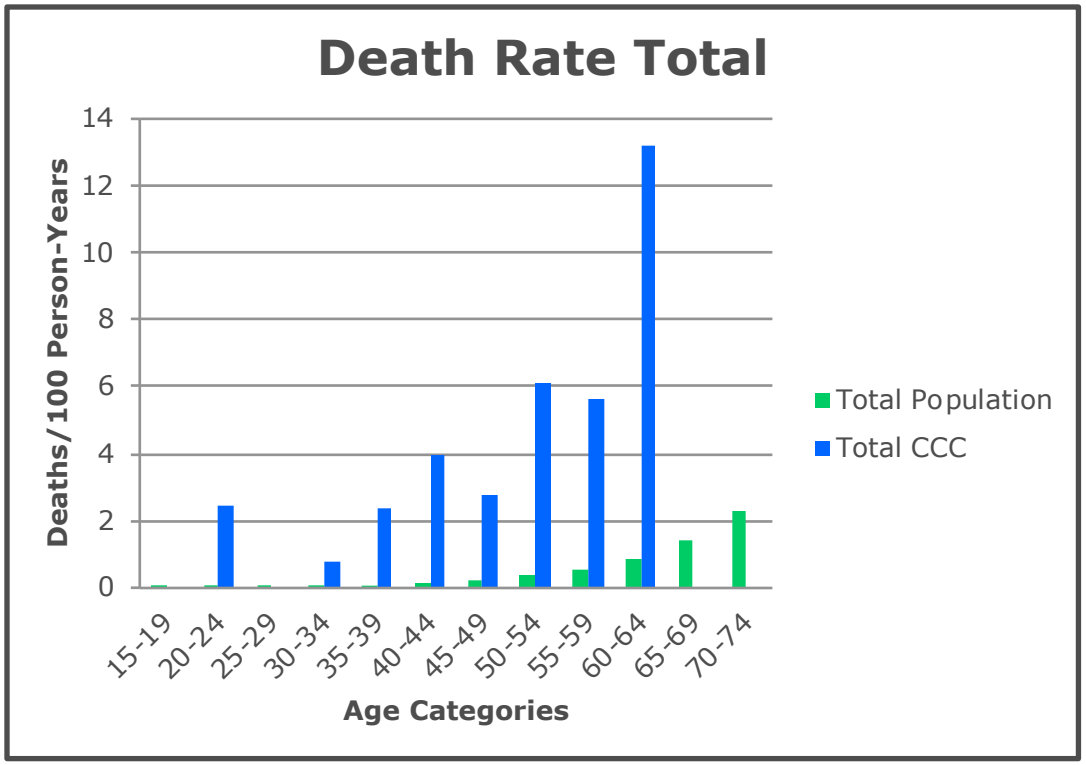


Figure 1. Natural History of Hepatitis C Virus (HCV) Infection.

Rosen, H. NEJM 2011;364:2429.

Mortality in the Canadian Co-infection Cohort Study



Cause of death	N	%
ESLD	18	29
OVERDOSE	15	24
CANCER	6	10
AIDS	3	5
OTHERS (infections/trauma)	9	15
UNKNOWN	11	18
Total	62	100

SMR: 17.08 (95% CI; 12.83, 21.34) for males

SMR: 28.74(95% CI; 14.66, 42.83) females

Klein, M. HIV Medicine 2013; 14: 10-20.

Who to screen for Hepatitis C

- Population-based screening
  - Those born between 1945 – 75 Shah, H. CMAJ 2018;June 4;190:e677 – 87.
- Risk-Based screening
  - Persons who inject drugs (PWID) or history of ever using injection drugs
  - Prior incarceration
  - Remote blood transfusion
  - Immigrants from endemic countries Shah, H. CMAJ 2018;June 4;190:e677 – 87, Ha S. Can Comm Dis Rep 2016;42:57-62.

Assessment for HCV

- 1. Screening Hepatitis C Antibody
  - If positive – perform Hepatitis C RNA PCR to determine active viremia
  - If viremic, order HCV genotype
- 2. Clinical staging for cirrhosis/advanced disease
- 3. Vaccinate as needed for Hepatitis A,B, pneumonia

Staging of Liver Disease - APRI

AST: Platelet Ratio Index

$$\text{APRI} = \frac{\dfrac{\text{AST Level}}{\text{AST (Upper Limit of Normal)}}}{\text{Platelet Count } (10^9/\text{L})} \times 100$$

http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

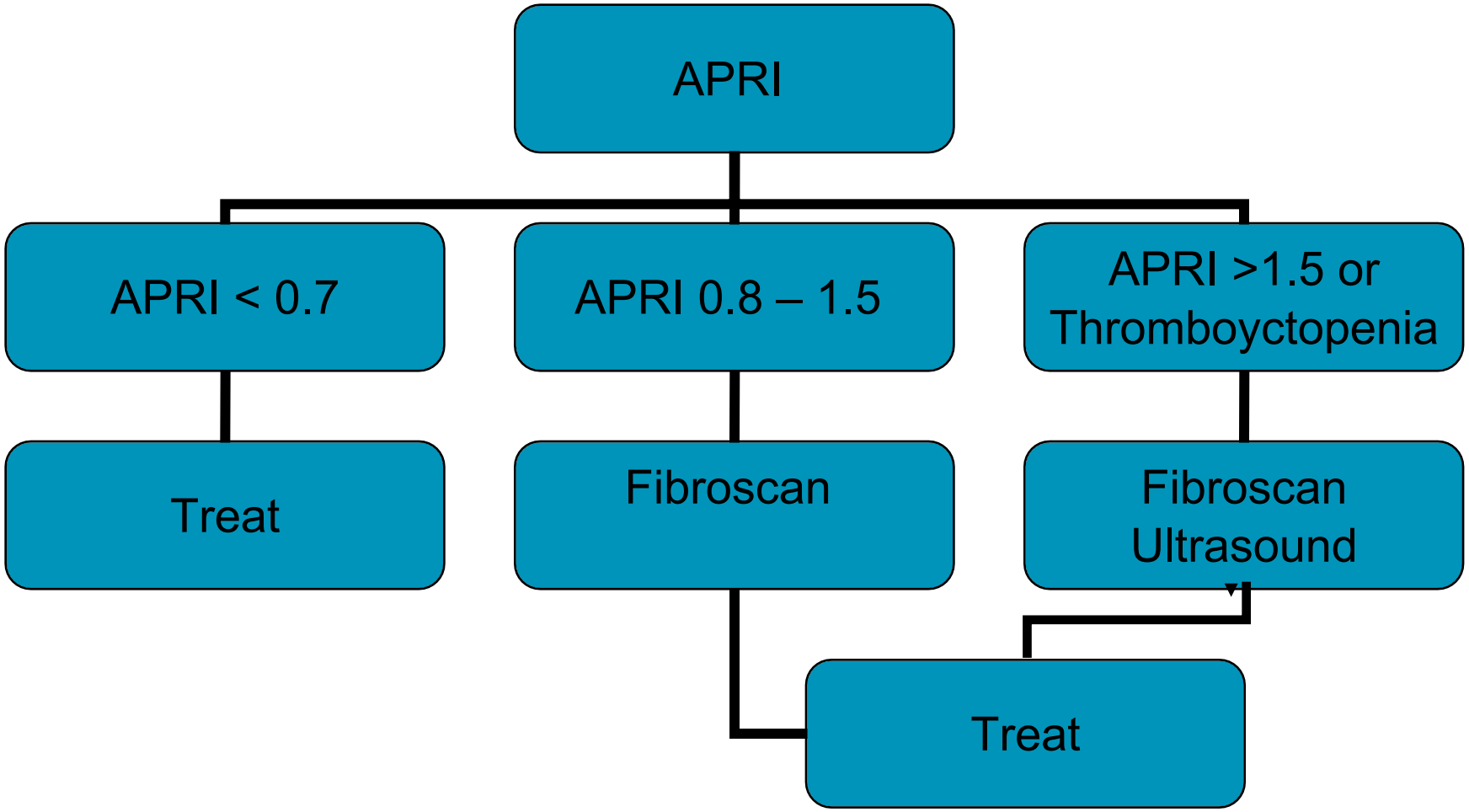
Staging of liver disease

- APRI > 0.7 Sensitivity 77% Specificity 72% for significant fibrosis
- APRI > 2 Sensitivity 46% Specificity 91% for cirrhosis Wai, C. Hepatology 2003;38: 518, Lin Z. Hepatology 2011;53:726
- APRI < 0.7 has high sensitivity to rule out significant liver disease

Staging of liver disease

- Use of non-invasive techniques such as transient elastography (Fibroscan) Stebbing, J et al. J Clin Gastro 2010;44:214.

Staging of liver disease

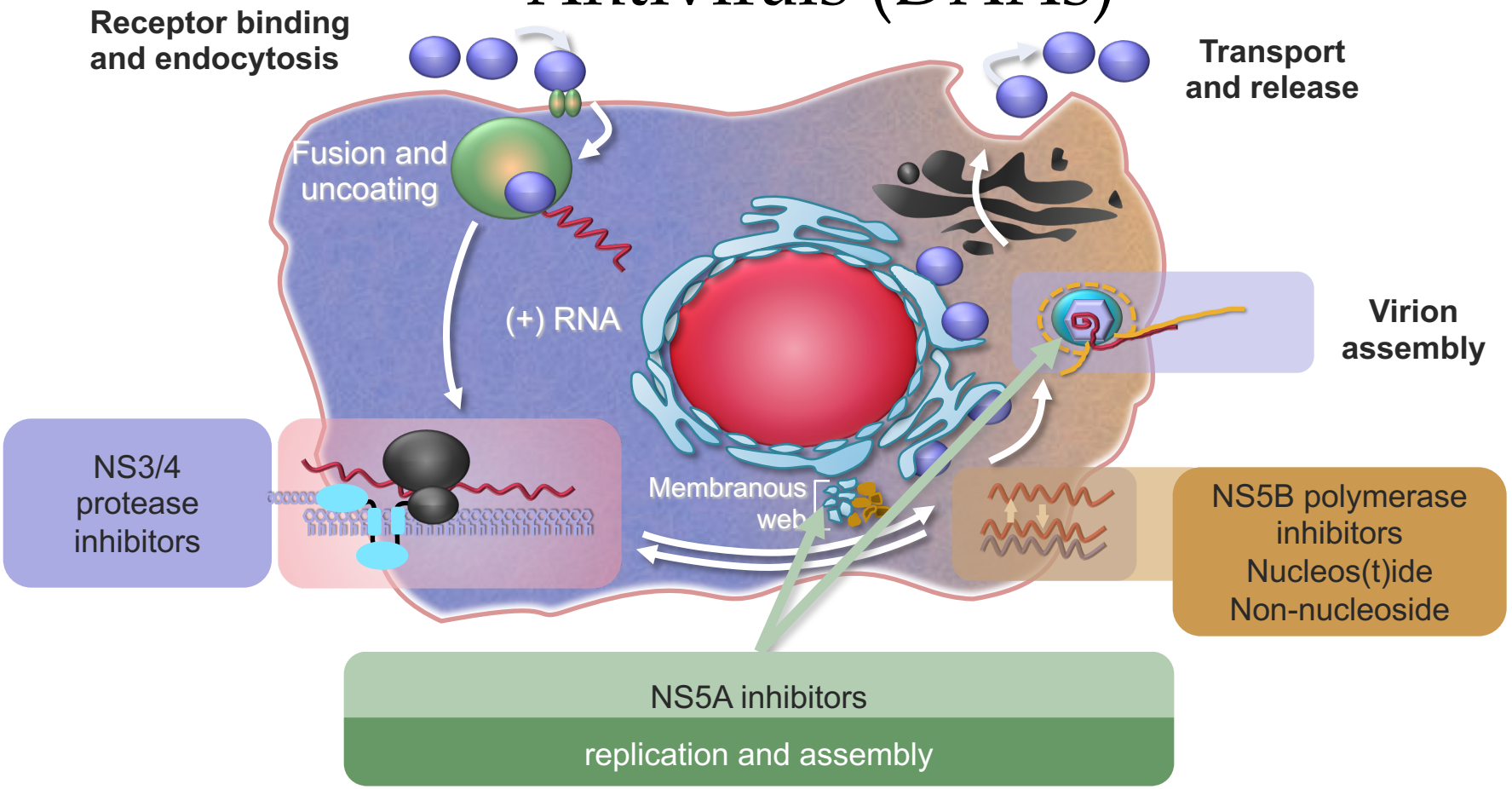


Therapy 2019

- **Who can be treated for Hepatitis C?**

- **Everyone!**
- No restrictions on access to care based on stage of liver disease or genotype
  - Treatment options may differ for those with advanced liver disease
  - Salvage therapy for prior treatment failure now available

HCV Life Cycle and Targets for Direct-Acting Antivirals (DAAs)



Slide Courtesy Dr Nicholas Wong

Adapted from Manns MP, et al. *Nat Rev Drug Discov*. 2007;6:991-1000.

DAA Agents 2019

Mode of action	Agent
NS3/4A Protease Inhibitors	Grazoprevir Voxilaprevir Glecaprevir
NS5A Inhibitors	Ledipasvir Elbasvir Velpatasvir Pibrentasvir
NS5B Inhibitors	Sofosbuvir

Fixed dose combination DAA's

- Pan-genotypic regimens:
  - glecaprevir/pibrentasvir
  - sofosbuvir/velpatasvir

- Genotype 1 specific regimens:
  - sofosbuvir/ledipasvir
  - elbasvir/grazoprevir

Factors influencing Regimen Choice

- Genotype (pan genotypic agent, or genotype specific?)
- History of prior HCV therapy (treatment failure/relapse?which agents?)
- Presence of cirrhosis
- Co-morbid conditions
  - End-stage renal disease
- Assessment of Drug Interactions

Common Drug Interactions with HCV DAA's

Drug	sofsobuvir/ velpatasvir	glecaprevir/ pibrentasvir	elbasvir/ grazoprevir
PPI	Timing critical	Data for 20mg omeprazole	
Anticonvulsants			
Rifampin			
Certain HIV agents			
Statins	Rosuvastatin	Atorvastatin	

Helpful Hint: Download University of Liverpool HCV Drug Interaction App!! (Liverpool HEP iChart)

ARV	Sofosbuvir/ Ledipasvir	Sofosbuvir/ Velpatasvir	Elbasvir/ Grazoprevir	Glecaprevir/ Pibrentasvir
Raltegravir **Dolutegravir**				
Elvitegravir/ cobicistat	TDF increase	TDF increase		
Efavirenz				
Rilpivirine				
Etravirine		Co-administration not studied		
Atazanavir/r				
Darunvir/r				

Factors affecting regimen choice

	Genotype	HIV PI	PPI	ESRD	Pill burden daily
Sofosbuvir/ Ledipasvir	1				1
Sofosbuvir/ Velpatasvir	1-6				1
Elbasvir/ Grazoprevir	1				1
Glecaprevir/ Pibrentasvir	1-6				3

Therapy for Hepatitis C – Treatment Naïve Individuals

Stage	Duration	DAA
Treatment naïve and no cirrhosis	8 weeks	G-P*
	12 weeks	sofosbuvir/velpatasvir
Treatment naïve and cirrhosis	12 weeks	G-P, sofosbuvir/velpatasvir **

- glecaprevir/pibrentasvir,
- **ribavirin may be added to sof/vel if advanced liver disease

Potential Second-line DAA Regimens

- Sofosbuvir/Velpatasvir/Voxilaprevir
  - Re-treatment of all prior DAA failures
  - Pan-Genotypic
  - 12 weeks
- Glecaprevir/Pibrentasvir
  - Retreatment of genotype 1 and 3 if exposed to certain DAA's in the past
  - 12 weeks (G1) or 16 weeks (G3)

Post Treatment Follow-up

Characteristic	Follow-up
No advanced fibrosis (Metavir stage F0-F2)	• No hepatitis C follow-up
Advanced fibrosis (Metavir stage F3 or F4)	• **Twice-yearly ultrasound surveillance for hepatocellular carcinoma** – If compensated cirrhosis (F4) also refer for endoscopy to assess for varices
Ongoing hepatitis C risk or unexplained hepatic dysfunction	• Test for **reinfection** with quantitative hepatitis C RNA assay

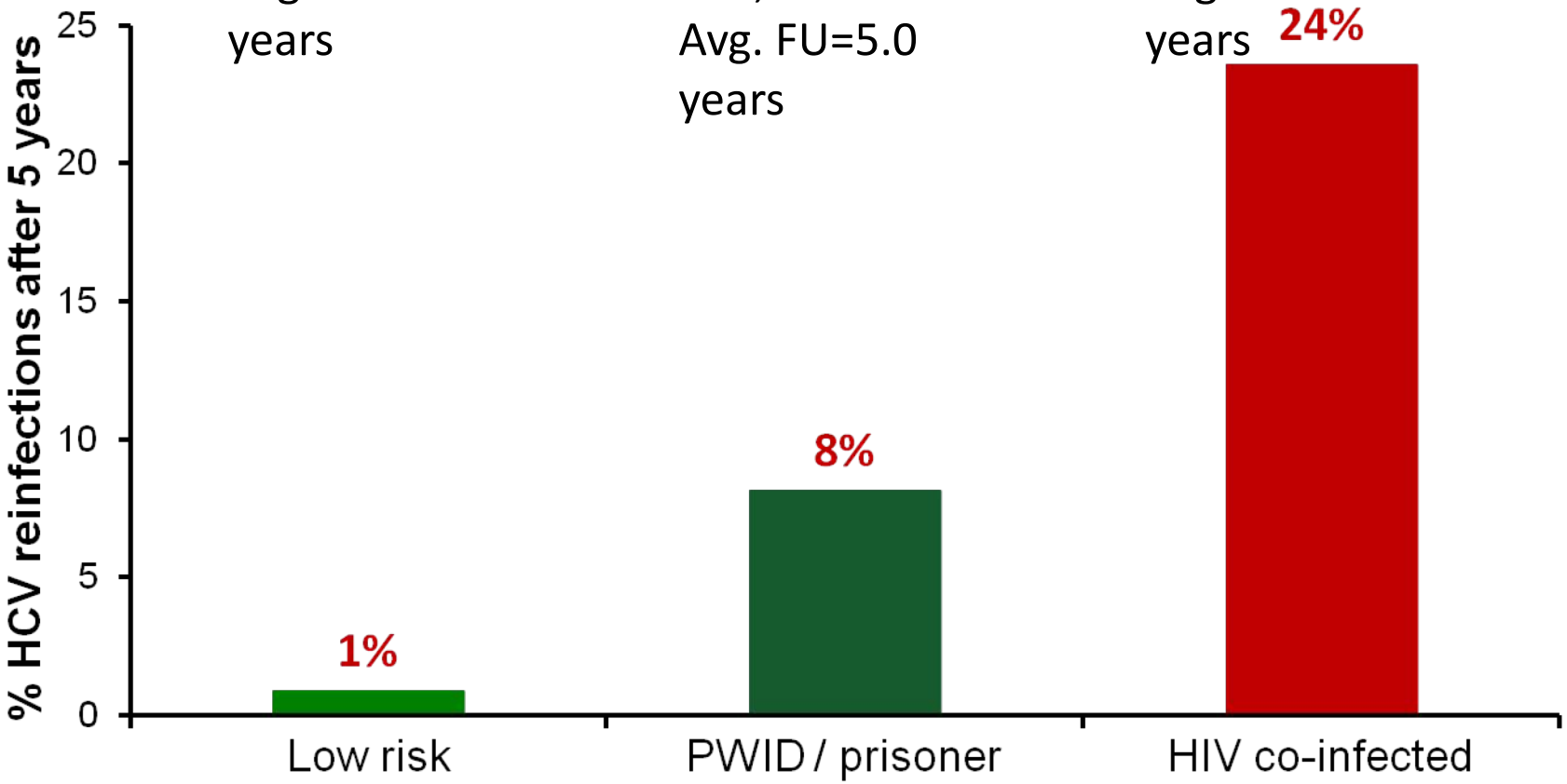
AASLD-IDSA. HCV Guidelines 2016.

Education about reinfection risk is crucial

Low-risk
24 studies
n=6,046
Avg. FU=4.1 years

PWID / prisoners
16 studies
n=1,203
Avg. FU=5.0 years

HIV co-infected
10 studies
n=1,106
Avg. FU=3.1 years



Simmons, B. Clinical Infectious Diseases 2016;62:683.

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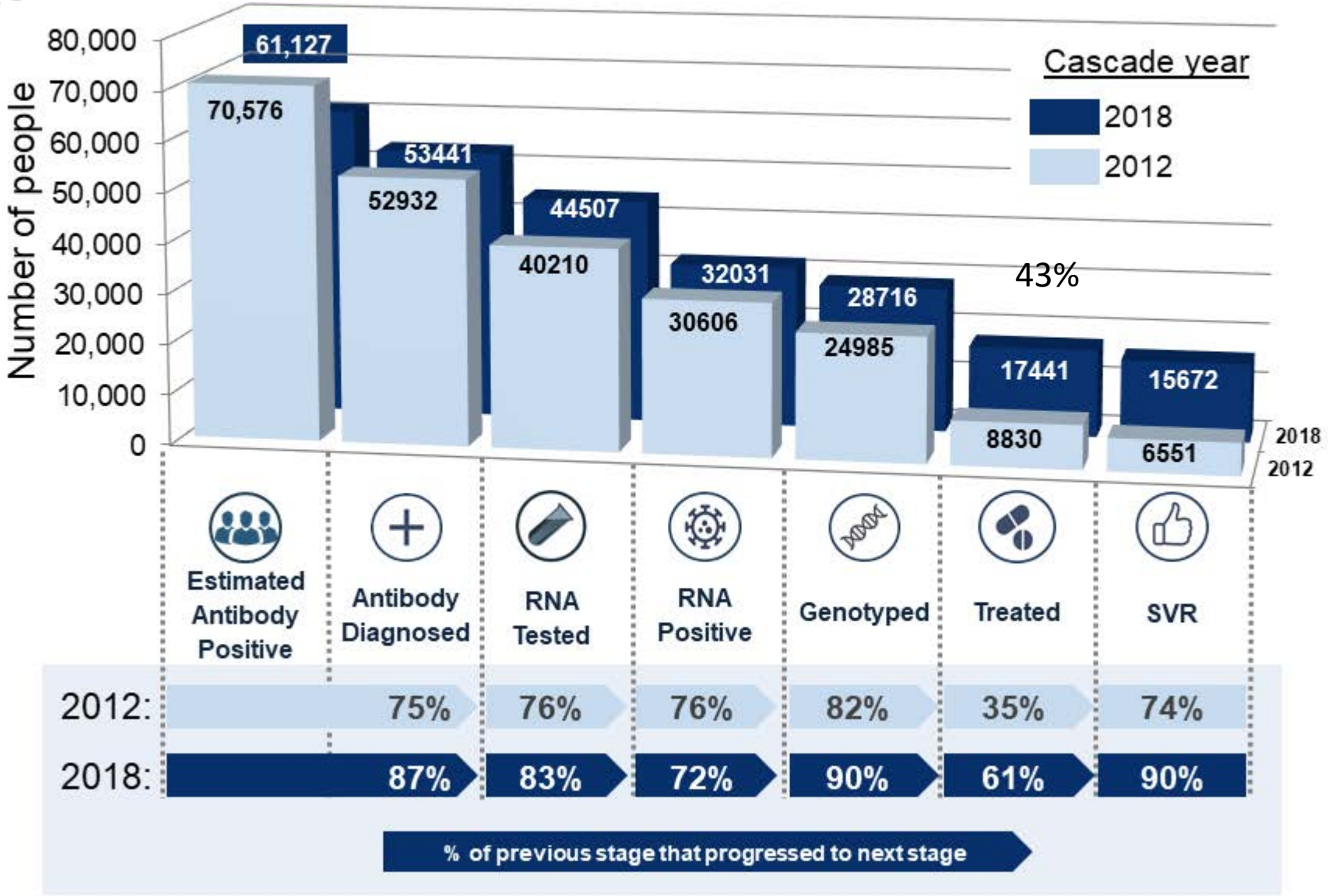
HCV Cascade of Care in BC 2012 vs 2018

Providence HEALTH CARE How you want to be treated.

a place of mind UBC



Bartlett S et al Liver International, 2019, DOI: 10.1111/liv.14227

Slide Dr. N. Janjua

Conclusions

- DAA regimens allow short course therapy for a majority of patients
  - Outcomes >95% SVR with most regimens
  - Outcomes for HIV co-infection equal mono-infection
- Regimens can be individualized based on patient factors
  - Comorbid conditions
  - Other drug interactions
- We must strive for identification of undiagnosed cases, universal therapy and ultimately HCV elimination

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How you want to be treated.

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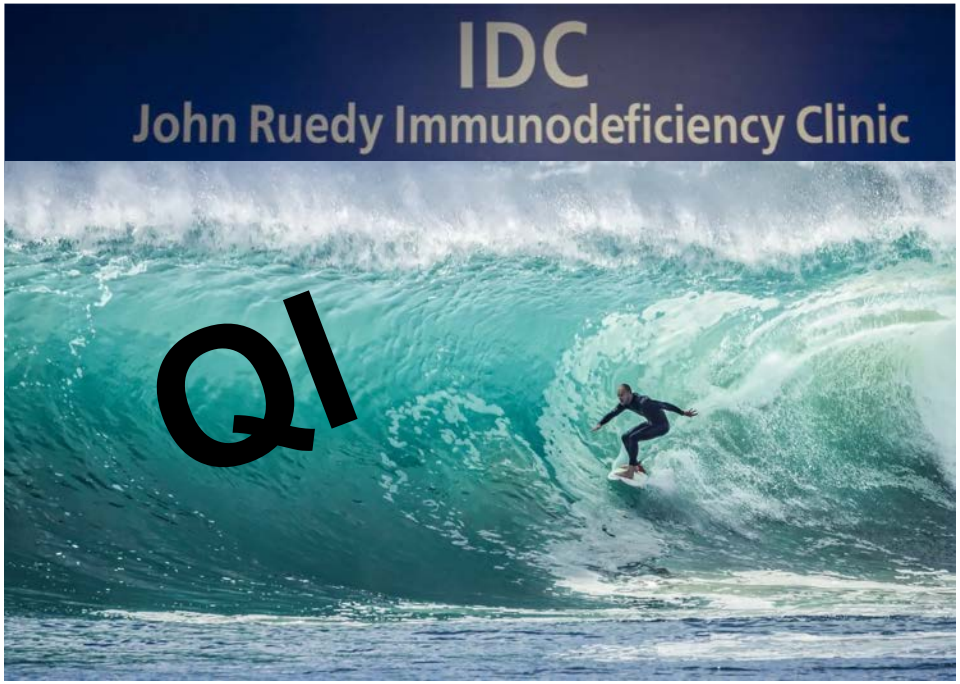
Hepatitis C

Dr. Cole Stanley, MD, CCFP
Innovation and QI Lead
Hope to Health Research and Innovation Clinic

Jan 20, 2020

@bccfe @ccsmd



BC-CfE BOOST
Best-Practices in Oral Opioid agoniSt Therapy Provincial Collaborative

HDC Health Data Coalition

PSP Practice Support Program

Vancouver CoastalHealth
Promoting wellness. Ensuring care.

MSPQI

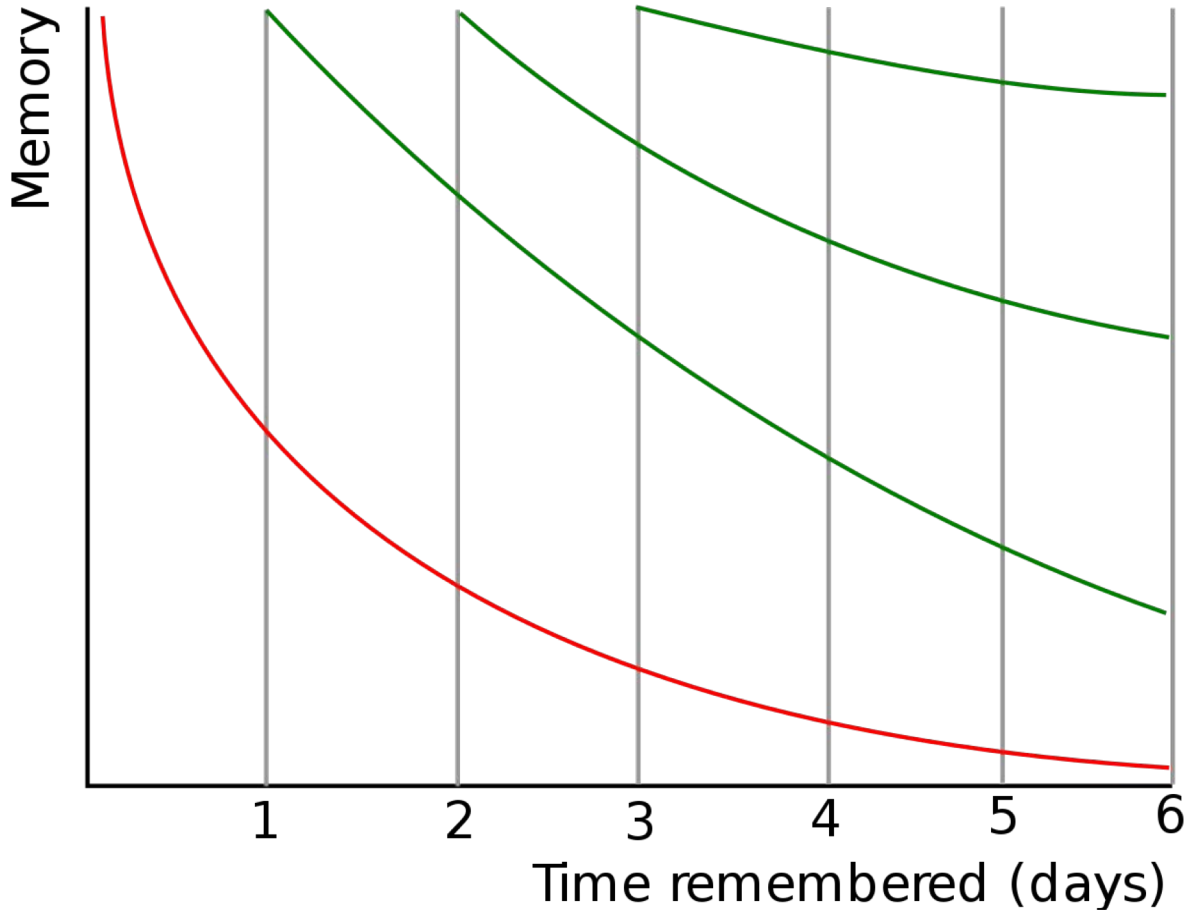
SharedCare
Partners for Patients

SSC
SPECIALIST SERVICES COMMITTEE

Disclosures

- Travel grants received for conference attendance from the following
  - 2019 – Canadian Association for HIV Research (with support from Viiv)
  - 2017 – Gilead Sciences
  - 2016 – Canadian Association for HIV Research (with support from Viiv), Gilead Sciences
- Advisory Board – Viiv Feb 2019
- Mitigating bias
  - **Treatment recommendations based on Canadian Guidelines**

The Forgetting Curve



Mr. L

- 49M, construction worker, long-term girlfriend, patient of JDC for 10 years
- PMHx – HIV dx 2004, hepatitis C dx 2010
- Meds – atazanavir, ritonavir, TDF/FTC
- Habits – heavy etOH (binges), previous IVDU (none since 2010), daily cannabis
- Sexually active with one female partner

Question for the team

What else do you want to know on history?

First visit template

- PMH - «»
- Meds - «»
- Allergies - «»
- Habits
  - tobacco smoking - «»
  - cannabis - «»
  - ups (crystal, crack, cocaine, etc) - «»
  - downs (heroin, opiates, benzos) - «»
  - party drugs (ecstasy, ketamine, GHB, etc) - «»
  - etOH - «»
- SHx - «»
- Sexual Hx - «»
- date of HCV dx - «»
- HCV RFs - «»
- HCV past consultations or treatments - «»
- symptoms of liver disease - «»
- other issues - «»
- Physical exam - «»

Hepatitis C - Issues and Plan

Education - «»

Adherence - «»

Drug-drug interactions - «»

Fibrosis - «»

Hepatitis A and B - «»

HCC screening - «»

Pharmacare application - «»

Observations

2018 Canadian Guidelines: The management of chronic hepatitis C: 2018 guideline update from the Canadian Association for the Study of the Liver

Patient Resources: CATIE - Hepatitis C

- Past medical hx review ☐
- Meds review ☐
- Allergies review ☐
- Habits review ☐
- Social hx review ☐
- HCV risk factors review ☐
- Sexual hx review ☐

Date of HCV dx (approx.): dd-MMM-yyyy

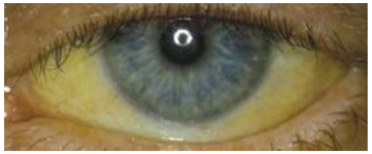
HCV past consultations and treatments:

Symptoms of HCV:

Objective:

Physical exam

- Physical exam – some increased abdominal adiposity, slight **scleral icterus**, otherwise unremarkable



Question for the team

What investigations do we need to order?

Investigations

- HIV VL<40, CD4 700 (22%)
- HCV RNA 5.67 log
- HCV genotype 1a
- Hep b sAb >10, sAg neg, cAb neg
- Bilirubin 55μmol/L, INR 1.0, Alb 45
- Platelets 100, Hgb 140
- Creatinine and Alk Phos WNL
- AST 120, ALT 140
- Fib-4 = 5.0, APRI = 3.0, MELD = 11, Child Class B (7 points)
- Recent abdo ultrasound – no signs of cirrhosis, some increased echogenicity of liver

Hepatitis C Virus Ab				
HCV RNA (qualitative)				
ALT	14	U/L	17-Jan-2020	N
AST	14	U/L	17-Jan-2020	N
Gamma GT	12	U/L	17-Jan-2020	N
Creatinine	70	umol/L	17-Jan-2020	N
Hgb	126	g/L	17-Jan-2020	A
TSH	1.19	mU/L	17-Jan-2020	N
Total Bilirubin	<3	umol/L	17-Jan-2020	N
Hemoglobin A1c	5.7	%	17-Jan-2020	N
Hep B Core antibody (HBcAb)	Non-Reactive		17-Jan-2020	
Hep B Surface antigen (HBsAg)	Non-Reactive		17-Jan-2020	
Hep B Surface antibody (HBsAb)	<2		17-Jan-2020	
Fibroscan score		kPa		
Date of abdo ultrasound	dd-MMM-yyyy			
Issues and Plan				

- Basic education review ☐
- Reasons for treating reviewed ☐
- Patient goals updated ☐
- Adherence strategies ☐
- Fibrosis assessment ☐
- Hepatitis A and B screening ☐
- Secondary screening ☐
- HCC screening ☐
- Varices screening ☐

Drug Interaction Checker Liverpool interactions checker

Question for the team

Which is the most appropriate next step?

a) Apply for treatment with DAA-based regimen

b) Complete Fibroscan and order complete secondary screen with ceruloplasmin, immunoglobulins, ferritin, transferrin saturation

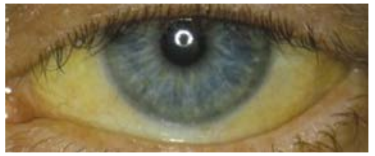
c) Complete Fibroscan only

d) Complete Fibroscan and DAA resistance testing

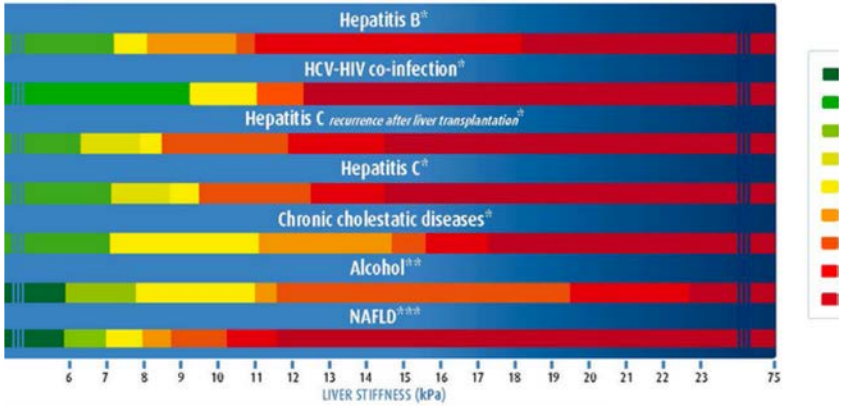
e) Reassess his ARV regimen

ARV switched

- atazanavir changed to darunavir
- bilirubin now WNL
- scleral icterus gone
- Child Pugh and MELD scores drop



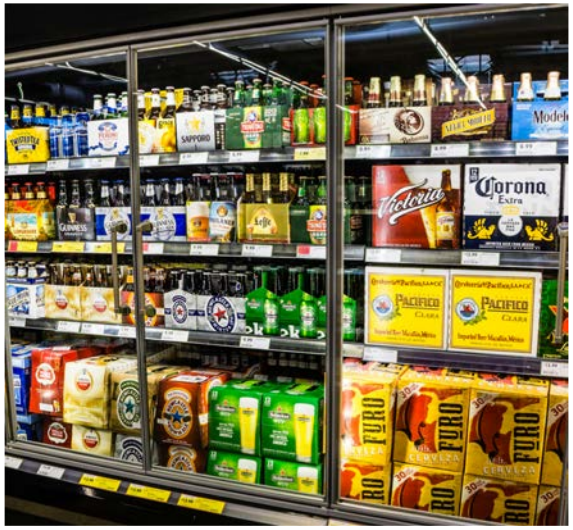
FibroScan®



- Fibroscan result = 13.5kPa (F3 fibrosis)
- Secondary screen – non-contributory

Time to treat

- LDV-SOF x 12 weeks – approved
- But, life gets in the way…



Six months later

- Re-engaged in care, HIV viral load undetectable
- Repeat Fibroscan score = 19kPa (F4 – cirhhosis)
- Now he has compensated cirrhosis, genotype 1a, and has never been treated

Question for audience

Which treatment would be most appropriate from this list?

a) LDV/SOF for 12 weeks

b) LDV/SOF for 16wks with weight-based ribavirin

c) VEL/SOF for 12 weeks

d) SOF/VEL/VOX

e) Detox and abstinence from alcohol before treating

What the guidelines tell us

Regimen	1a
Ledipasvir/sofosbuvir (Harvoni)	12 wk ± ribavirin†
Elbasvir/grazoprevir (Zepatier)	12–16 wk ± ribavirin†
Paritaprevir/ritonavir/ombitasvir + dasabuvir (Holkira Pak)	+ RBV 12 wk
Sofosbuvir + daclatasvir (Sovaldi + Daklinza)	24 wk
Sofosbuvir/velpatasvir (Epclusa)	12 wk
Glecaprevir/pibrentasvir (Maviret)	12 wk
Sofosbuvir/velpatasvir/ voxilaprevir (Vosevi)	NR

GUIDELINE VULNERABLE POPULATIONS CPD

The management of chronic hepatitis C: 2018 guideline update from the Canadian Association for the Study of the Liver

Hemant Shah MD MScCH(HPTE), Marc Bilodeau MD, Kelly W. Burak MD MSc, Curtis Cooper MD, Marina Klein MD MSc, Alnoor Ramji MD, Dan Smyth MD, Jordan J. Feld MD MPH; for the Canadian Association for the Study of the Liver

Cite as: *CMAJ* 2018 June 4;190:E677-87. doi: 10.1503/cmaj.170453

Treatment outcome

- Treated with VEL/SOF for 12 weeks
- End of treatment HCV RNA is **POSITIVE**
- Clients says he missed 2 weeks of therapy due to another alcohol binge

Question for audience

What does this mean?

a) Treatment failed, likely due to non-adherence

b) Treatment failed, likely due to drug resistance

c) Treatment failed, likely because we didn't add ribavirin

d) We need more information

Treatment outcome

- Repeat HCV RNA after 12 weeks is **NEGATIVE**
- Client starts seeing an addictions counsellor and goes on naltrexone, dramatically reduces drinking
- Client starts going to gym more regularly, and watching what he eats – abdominal fat starts shrinking

Discussion questions

- Are we certain that he is "cured" with this SVR12?
- Does he have significant immunity to HCV now?
- When should we re-screen?
- What about HCC screening and esophageal varices screening?
- Should we repeat the Fibroscan?
- What would you retreat with if his initial treatment failed? (ie relapse)
- What would you do if his HCV RNA was positive at 24 weeks after treatment?

Help

Patient Summary

Care Plan HCV intial

Profile

Medical

Status	Onset	Type	Description	Note	Severity	Risk	Updated
	Current		Gastrointestinal	hepatitis C - active (HCV RNA+) (Unconfirmed)		✔	19Jan20
	Current		Gastrointestinal	hepatitis C Ab+ RNA unknown (Unconfirmed)		✔	19Jan20
	Past		Gastrointestinal	Past History of hepatitis C (HCV) - spontaneously cleared		✔	19Jan20
	Past		Gastrointestinal	Past History of hepatitis C (HCV) - treated		✔	19Jan20

Labs

Active Requests

Date	Test Group Name	Description	Observations
19Jan20 01:02 PM	initial HCV assessment	Lab, General Lab, Initial HCV workup, initial HCV assessment	

Investigations

Active Requests

Date	Urgency	Ordering Provider	Facility Type	Description	Reason	Observation Status
19Jan20	Normal	Stanley, Cole	Ultrasound	Investigation, Ultrasound, Ultrasound for HCC screening		

Apply Care Plan Cancel

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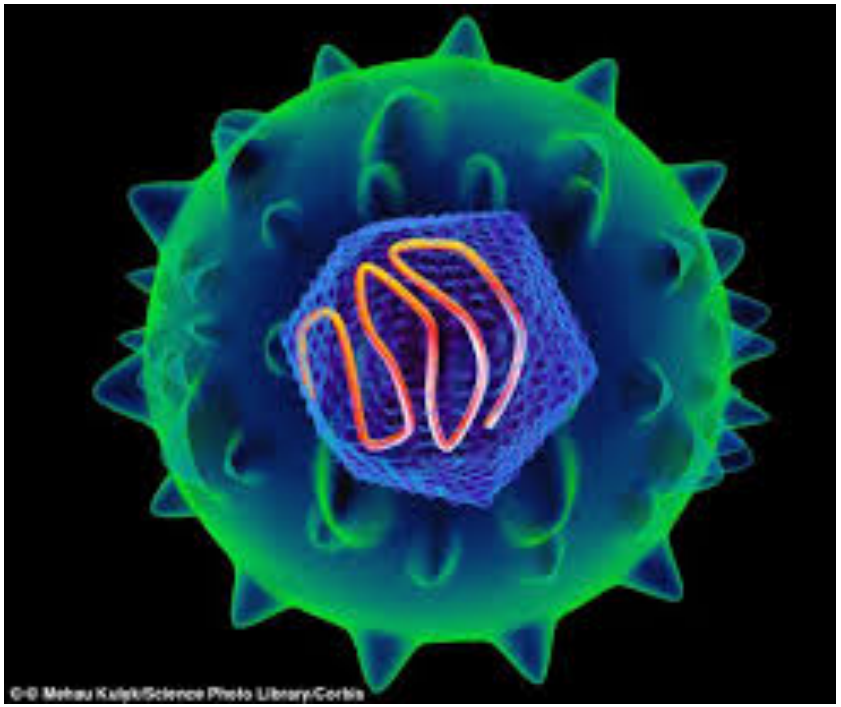
HIV/Hep C Co-Infection Treatment Program
Diagnostic Testing and Assessment

John Ruedy Clinic
St. Paul's Hospital
B512-1081 Burrard St
Vancouver, BC



Clinical Nursing Interventions: Pre-Treatment

- Client engagement
- Assessing for readiness
- Diagnostic testing/serum biomarkers
- Check drug interactions
- Special Authority application
- Client education
- Dispensing/pharmacy considerations
- Treatment monitoring
- EOT follow-up

Client Engagement: Optimizing Success

- 1:1 Engagement→therapeutic rapport
- Case Management:
  - Social Work→Housing
  - SUD Nurse→substance use support
  - Mental Health
  - Pharmacy

Client Engagement: Care Coordination

- Streamline patient care
- Schedule diagnostics (i.e.- blood work, FibroScan) to coincide with Dr's visits
- Anticipate patient attendance at clinic with ORT due dates

Assessing for Readiness

- Are supports in place?
- Adherence to ARV's:
  - VL>40

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Hep C Treatment Checklist

PT INFORMATION	PTS CONTACT INFO	PTS DOCTOR	HCV REFERRAL
Name: **HCV GENO:** **Co infect☐** **Mono☐** **Fibroscan ☐** **ARV's ☐** **HCV MEDICATION REQUESTED:**	Ph#_____ OK to leave message? yes☐ no☐ EMAIL_____ Confidential yes☐ no☐ OTHER CONTACTS FOR PT:	Phone: Fax: Email:	Date received: Referral complete: yes☐ no☐ what is needed: 1 2.
PREFERRED PHARMACY **Phone:** **Fax:** **Email:** **Rx faxed on date:** **Clinic delivery ☐** **Home delivery☐** **Community pharmacy☐**	SPECIAL AUTHORITY COMPLETE ☐ APPROVAL DATES CORRECT ☐ NEED ADJUSTING ☐ DATES ADJUSTED ☐ UPDATED IN CHART☐	TREATMENT START LETTER FAXED TO FAMILY DOCTOR☐ EMR FAXED RE START☐ TX FORM INITIATED ☐ EMR UPDATED RE CARE TEAM☐	BLOOD WORK Pts preferred lab: Ph:_____ Fax:_____ Req's organized☐ Faxed to lab☐ Given to pt☐ Filed with Paul☐
DRUG INTERACTIONS checked ☐ **MEDINET ☐** **LIVERPOOL☐** **OTC medications reviewed ☐**	FINANCIAL COVERAGE DISABILITY☐ PRIVATE COVERAGE☐ MOMENTUM: YES☐ NO☐ ADDITIONAL ASSISTANCE REQUIRED: YES☐ NO☐	PERSCRIPTION RX written ☐ Signed by Dr.☐ Rx faxed ☐ Date faxed:_____	NOTES

Diagnostic Testing: FibroScan

- Determines the level of fibrosis in the liver
- Fibrosis→tough, fibrous scar tissue
- Special Authority requirements: within last 12 months
- No solid food for 3-4 hrs prior; liquids OK

Fibroscan(R) uses low-frequency ultrasound to measure hepatic transient elasticity (stiffness) and fibrosis for the staging of liver injury.

- www.liversupport.com

Assessing Fibrosis Score

- Fibrosis Score: F0-F4

www.slideshare.net/many87/viral-hepatitis-a-b-c-d-e

Serum Biomarkers

- APRI:
  - <0.7 no significant fibrosis; >1.5 significant fibrosis or cirrhosis
- FIB-4:
  - <1.45 no significant fibrosis; >3.25 significant fibrosis or cirrhosis
- University of Washington website:
  - Hepatitisc.uw.edu

$$\text{APRI} = \frac{\dfrac{\text{AST Level}}{\text{AST (Upper Limit of Normal)}}}{\text{Platelet Count } (10^9/\text{L})} \times 100$$

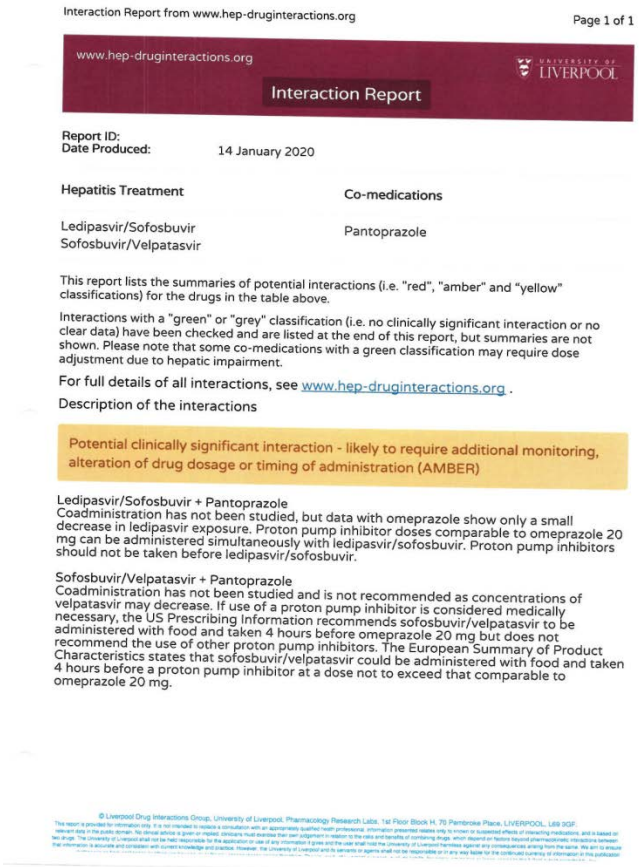
$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST (U/L)}}{\text{Platelet Count } (10^9/\text{L}) \times \sqrt{\text{ALT (U/L)}}}$$

Baseline Blood Work

- Hep C RNA
- Hep C genotype
- Hep A/B Serology
- HIV VL
- CD4
- Hematology panel (CBCD)
- ALT
- AST
- Alkaline Phosphatase
- INR
- Creatinine (GFR)
- Glucose (fasting)
- Insulin (fasting)
- Albumin
- Bilirubin
- Lipids
- Ferritin
- Ceruloplasmin
- Alpha 1 Antitrypsin
- ANA

Drug Interactions

- Liverpool database: www.hep-druginteractions.org
- www.hivclinic.ca



Interaction Report from www.hep-druginteractions.org Page 1 of 1

www.hep-druginteractions.org

University of Liverpool

Interaction Report

Report ID:
Date Produced: 14 January 2020

Hepatitis Treatment	Co-medications
Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir	Pantoprazole

This report lists the summaries of potential interactions (i.e. "red", "amber" and "yellow" classifications) for the drugs in the table above.

Interactions with a "green" or "grey" classification (i.e. no clinically significant interaction or no clear data) have been checked and are listed at the end of this report, but summaries are not shown. Please note that some co-medications with a green classification may require dose adjustment due to hepatic impairment.

For full details of all interactions, see www.hep-druginteractions.org .

Description of the interactions

Potential clinically significant interaction - likely to require additional monitoring, alteration of drug dosage or timing of administration (AMBER)

Ledipasvir/Sofosbuvir + Pantoprazole
Coadministration has not been studied, but data with omeprazole show only a small decrease in ledipasvir exposure. Proton pump inhibitor doses comparable to omeprazole 20 mg can be administered simultaneously with ledipasvir/sofosbuvir. Proton pump inhibitors should not be taken before ledipasvir/sofosbuvir.

Sofosbuvir/Velpatasvir + Pantoprazole
Coadministration has not been studied and is not recommended as concentrations of velpatasvir may decrease. If use of a proton pump inhibitor is considered medically necessary, the US Prescribing Information recommends sofosbuvir/velpatasvir to be administered with food and taken 4 hours before omeprazole 20 mg but does not recommend the use of other proton pump inhibitors. The European Summary of Product Characteristics states that sofosbuvir/velpatasvir could be administered with food and taken 4 hours before a proton pump inhibitor at a dose not to exceed that comparable to omeprazole 20 mg.

Special Authority Application

- Submit with supporting blood work results/FibroScan report

BRITISH COLUMBIA | Ministry of Health

SPECIAL AUTHORITY REQUEST

VELPATASVIR PLUS SOFOSBUVIR WITH OR WITHOUT RIBAVIRIN (RBV) FOR CHRONIC HEPATITIS C

HLTH 5476 Rev. 2018/03/02

For up to date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1 800 609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

Restricted to:

☐ **Gastroenterologist** ☐ **Infectious Disease Specialist** ☐ **Other physician experienced with treating chronic Hepatitis C**

SECTION 1 – PRESCRIBER INFORMATION

NAME AND MAILING ADDRESS ☐ MAIL CONFIRMATION

☐ COLLEGE ID OR ☐ MSP NUMBER | PHONE NUMBER (INCLUDE AREA CODE)

CRITICAL FOR A TIMELY RESPONSE → PRESCRIBER'S FAX NUMBER

SECTION 2 – PATIENT INFORMATION

PATIENT (FAMILY) NAME

PATIENT (GIVEN) NAME(S)

DATE OF BIRTH (YYYY / MM / DD) | DATE OF APPLICATION (YYYY / MM / DD)

CRITICAL FOR PROCESSING → PERSONAL HEALTH NUMBER (PHN)

SECTION 3 – BACKGROUND DIAGNOSTIC INFORMATION

For the treatment of patients with Chronic Hepatitis C genotype 1,2,3,4,5,6 or mixed genotype who meet all the following criteria:

- ☐ Genotype has been confirmed and a copy of the genotype report is attached. For treatment-experienced patients, genotype must be from post-treatment course.
- ☐ Detectable levels of hepatitis C virus (HCV RNA) in the last twelve months and a copy of the quantitative HCV RNA report is attached.
- ☐ Stage of fibrosis has been evaluated within ONE year by one of the following methods:
  - ☐ Transient elastography (kPa) _____
  - ☐ APRI score _____
  - ☐ Liver biopsy confirmed
- ☐ Copy of most recent bloodwork (i.e. CBC, AST, ALT, bilirubin, albumin) and report confirming fibrosis stage (if applicable) is attached.

Not eligible for coverage:

1. **Patients who are at high risk for non-compliance.**
2. **Patients who are currently being treated with another HCV direct-acting antiviral agent**

Drug Coverage

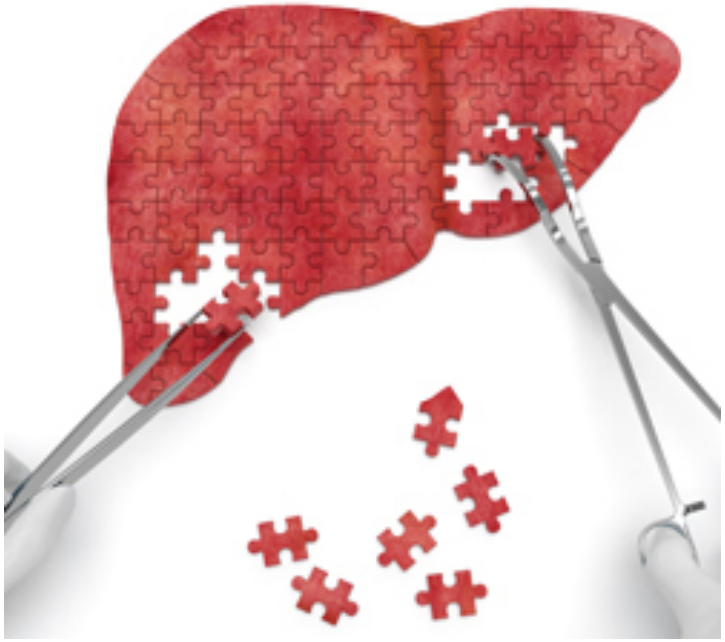
- Pt on disability→ covered through PharmaCare
- If not on disability→may need to apply for Fair PharmaCare
- Extended Health Benefits:
  - Gilead: Momentum Support Program
  - AbbVie: AbbVie Care Support Program

Client Education: DAA's (Direct Acting Antivirals)

- DAA's:
  - Minimal side effects
  - >95% cure rate
- Importance of Adherence
- Drug Administration:
  - With food: Maviret, Vosevi
  - PO once daily→ discuss adherence strategies
  - Missed doses:
    - <18 hrs: take immediately (take next dose at same time)
    - >18 hrs: wait until next dose (add missed pill to EOT)
- Check with Rx/RN before starting any new prescription or OTC meds
- Discuss drug interactions (i.e. Epclusa/Harvoni -avoid OTC antacids)

Client Education: Other Considerations

- Blood work schedule (determine outpatient lab→fax requisitions)
- Hep C infection does not confer immunity
- *Harm reduction/Prevention of Reinfection*
- Provide informational handout
- Contact number for phone support



Pharmacy Considerations

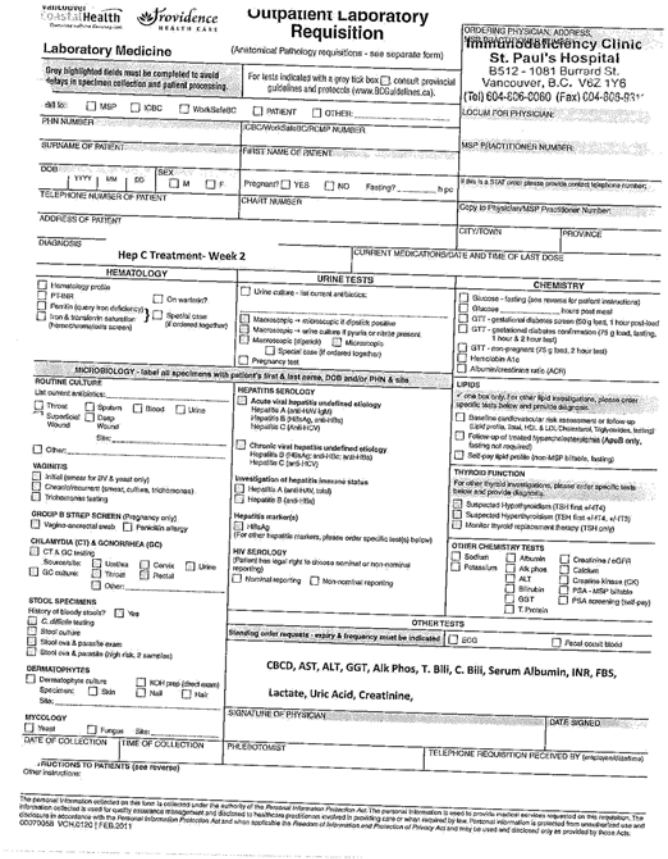
- What pharmacy does the client currently use?
- Dispensing options:
  - Daily dispense
  - Weekly blister pack
  - Delivery to clinic
  - Med support program
- Connect with pharmacist
- Bioscript Pharmacy: www.bioscript.ca
- Once pt starts tx: call/fax Special Authority to update start date

Treatment Monitoring

- Check in phone calls/clinic visit:
  - Adherence
  - Side effects
  - Any major changes in clients life?
- Monitoring adherence:
  - Weekly pharmanet checks
- Monitoring blood work:
  - Week 2, 4, 8, 12/EOT
  - SVR 4, 12, 24
- Utilize community supports (DPC, STOP, community mental health team)

Blood Work Monitoring Weeks 2/4/8

- CBCD, AST, ALT, GGT, Alk Phos, Bilirubin, Albumin, INR, Fasting blood sugar, lactate, uric acid, creatinine



Providence HEALTH

Outpatient Laboratory Requisition

(Anatomical Pathology requisitions - see separate form)

Laboratory Medicine

Grey highlighted fields must be completed to avoid delays in specimen collection and patient processing.

For tests indicated with a grey tick box ☐ consult provincial guidelines and protocols (www.BCGuidelines.ca).

bill to: ☐ MSP ☐ ICBC ☐ WorkSafeBC ☐ PATIENT ☐ OTHER:

PHN NUMBER | ICBC/WorkSafeBC/RCMP NUMBER

SURNAME OF PATIENT | FIRST NAME OF PATIENT

DOB YYYY MM DD | SEX ☐ M ☐ F | Pregnant? ☐ YES ☐ NO Fasting? ____ h pc

TELEPHONE NUMBER OF PATIENT | CHART NUMBER

ADDRESS OF PATIENT

DIAGNOSIS

Hep C Treatment- Week 2

CURRENT MEDICATIONS/DATE AND TIME OF LAST DOSE

ORDERING PHYSICIAN: ADDRESS

Immunodeficiency Clinic
St. Paul's Hospital
B512 - 1081 Burrard St.
Vancouver, B.C. V6Z 1Y6
(Tel) 604-806-8060 (Fax) 604-806-8[illegible]

LOCUM FOR PHYSICIAN

MSP P/ACTITIONER NUMBER

If this is a STAT order please provide contact telephone number:

Copy to Physician/MSP Practitioner Number:

CITY/TOWN | PROVINCE

HEMATOLOGY

☐ Hematology profile
☐ PT/INR
☐ Ferritin (query iron deficiency) ☐ On warfarin?
☐ Iron & transferrin saturation (hemochromatosis screen) } ☐ Special case (if ordered together)

URINE TESTS

☐ Urine culture - list current antibiotics:
☐ Macroscopic → microscopic if dipstick positive
☐ Macroscopic → urine culture if pyuria or nitrite present
☐ Microscopic (dipstick) ☐ Microscopic
☐ Special case (if ordered together)
☐ Pregnancy test

CHEMISTRY

☐ Glucose - fasting (see reverse for patient instructions)
☐ Glucose ____ hours post meal
☐ GTT - gestational diabetes screen (50 g test, 1 hour post-load
☐ GTT - gestational diabetes confirmation (75 g load, fasting, 1 hour & 2 hour test)
☐ GTT - non-pregnant (75 g load, 2 hour test)
☐ Hemoglobin A1c
☐ Albumin/creatinine ratio (ACR)

MICROBIOLOGY - label all specimens with patient's first & last name, DOB and/or PHN & site

ROUTINE CULTURE

List current antibiotics:
☐ Throat ☐ Sputum ☐ Blood ☐ Urine
☐ Superficial ☐ Deep Wound
Site:
☐ Other:

VAGINITIS

☐ Initial (smear for BV & yeast only)
☐ Check/treatment (smear, culture, trichomonas)
☐ Trichomonas testing

GROUP B STREP SCREEN (Pregnancy only)

☐ Vagino-anorectal swab ☐ Penicillin allergy

CHLAMYDIA (CT) & GONORRHEA (GC)

☐ CT & GC testing
Source(s): ☐ Urethra ☐ Cervix ☐ Urine
☐ GC culture: ☐ Throat ☐ Rectal
☐ Other:

STOOL SPECIMENS

History of Bloody stools? ☐ Yes
☐ C. difficile testing
☐ Stool culture
☐ Stool ova & parasite exam
☐ Stool ova & parasite (high risk, 2 samples)

DERMATOPHYTES

☐ Dermatophyte culture ☐ KOH prep (direct exam)
Specimen: ☐ Skin ☐ Nail ☐ Hair
Site:

MYCOLOGY

☐ Yeast ☐ Fungus Site:

HEPATITIS SEROLOGY

☐ Acute viral hepatitis undefined etiology
Hepatitis A (anti-HAV IgM)
Hepatitis B (HBsAg, anti-HBc)
Hepatitis C (Anti-HCV)

☐ Chronic viral hepatitis undefined etiology
Hepatitis B (HBsAg anti-HBc, anti-HBs)
Hepatitis C (anti-HCV)

Investigation of hepatitis immune status
☐ Hepatitis A (anti-HAV, total)
☐ Hepatitis B (anti-HBs)

Hepatitis marker(s)
☐ HBsAg
(For other hepatitis markers, please order specific test(s) below)

HIV SEROLOGY

(Patient has legal right to choose nominal or non-nominal reporting)
☐ Nominal reporting ☐ Non-nominal reporting

LIPIDS

✓ one box only. For other lipid investigations, please order specific tests below and provide diagnosis.
☐ Baseline cardiovascular risk assessment or follow-up (Lipid profile, Total, HDL & LDL Cholesterol, Triglycerides, fasting)
☐ Follow-up of treated hypercholesterolemias (ApoB only, fasting not required)
☐ Self-pay lipid profile (non-MSP billable, fasting)

THYROID FUNCTION

For other thyroid investigations, please order specific tests below and provide diagnosis.
☐ Suspected Hypothyroidism (TSH first +/-FT4)
☐ Suspected Hyperthyroidism (TSH first +/-FT4, +/-T3)
☐ Monitor thyroid replacement therapy (TSH only)

OTHER CHEMISTRY TESTS

☐ Sodium ☐ Albumin ☐ Creatinine / eGFR
☐ Potassium ☐ Alk phos ☐ Calcium
☐ ALT ☐ Creatine Kinase (CK)
☐ Bilirubin ☐ PSA - MSP billable
☐ GGT ☐ PSA screening (self-pay)
☐ T. Protein

OTHER TESTS

Standing order requests - expiry & frequency must be indicated ☐ ECG ☐ Fecal occult blood

CBCD, AST, ALT, GGT, Alk Phos, T. Bili, C. Bili, Serum Albumin, INR, FBS,

Lactate, Uric Acid, Creatinine,

SIGNATURE OF PHYSICIAN | DATE SIGNED

DATE OF COLLECTION | TIME OF COLLECTION | PHLEBOTOMIST | TELEPHONE REQUISITION RECEIVED BY (employee/initials)

INSTRUCTIONS TO PATIENTS (see reverse)
Other instructions:

The personal information collected on this form is collected under the authority of the *Personal Information Protection Act*. The personal information is used to provide medical services requested on this requisition. The information collected is used for quality assurance management and disclosed to healthcare practitioners involved in providing care or when required by law. Personal information is protected from unauthorized use and disclosure in accordance with the *Personal Information Protection Act* and when applicable the *Freedom of Information and Protection of Privacy Act* and may be used and disclosed only as provided by those Acts.

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End of Treatment (EOT)

- HCV RNA obtained
- Review results with client
- *Discuss Harm reduction/prevention of reinfection
- Hep C EOT form for client chart
- SVR blood work: SVR 4, 12, 24
  - SVR 4: CBCD, ALT/AST, HCV RNA
  - SVR 12/24: integrate with routine HIV blood work
    - Add HCV RNA

EOT: Follow-Up

- Follow-up appt with MRP/ID Specialist
- If F3 or greater:
  - F3: >11.1 kPa
  - Abdo U/S Q6monthly to monitor for HCC

BRITISH COLUMBIA
CENTRE *for* EXCELLENCE
in HIV/AIDS

Providence HEALTH CARE
How you want to be treated.

a place of mind
UBC

IMMUNODEFICIENCY CLINIC: HIV/HCV C0-INFECTION TREATMENT PROGRAM

Treatment Summary Form

Dear Dr _____

Re: _____ **DOB** __/____/____ (dd/mm/yy)

Your Patient has completed Hepatitis C therapy through the JRC Hepatitis Program. The following is a summary for your records:

Genotype (check all that apply): ☐ 1a/1b ☐ 2 ☐ 3 ☐ 4 ☐ 6

Fibrosis Stage: F__/ 4 (Fibroscan Score _____ kPa) Cirrhosis ☐ Yes ☐ No

Treatment Regimen:

☐ Sofosbuvir ☐ Sofosbuvir/Ledipasvir

☐ Sofosbuvir/Velpatasvir ☐ Sofosbuvir/Daclatasvir

☐ Holkira Pak/Technivie ☐ Elbasvir/Grazoprevir

☐ Ribavirin ☐ Other

Treatment Dates:

Treatment started on (dd/mm/yy): _____

Treatment completed/stopped on (dd/mm/yy): _____

Week at Treatment end: Week ___/of____Weeks

Treatment Outcome:

End of Treatment Response: ☐ Yes / ☐ No / ☐ Not Obtained
SVR 12: ☐ Yes / ☐ No / ☐ Not Obtained
SVR 24: ☐ Yes / ☐ No / ☐ Not Obtained

Additional Follow-up Recommendations for Primary Care Physician:

☐ Arrange ultrasound monitoring for HCC q6months for 3 years
*Imaging post-3 years to be done at the discretion of the MRP

☐ Other_____

For more information…

- www.catie.ca

CATIE
Canada's source for HIV and hepatitis C information

- www.liver.ca

liver.ca
Canadian Liver Foundation
Fondation canadienne du foie
Bringing liver research to life
Donner vie à la recherche sur le foie

References

- www.epclusa.com
- www.harvoni.com
- www.zepatier.com
- www.abbvie.ca
- www.hepatitisc.uw.edu
- www.hep-druginteractions.org
- www.hivclinic.ca
- www.catie.ca
- www.slideshare.net/many87/viral-hepatitis-a-b-c-d-e
- www.liversupport.com
- https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/specia

Post-Learning Reflections

Reflect on the following pre-learning questions and whether you would be able to effectively answer them now based on what you learned in the Hepatitis C: Diagnosis and Management presentation:

- Why is it important to learn about Hepatitis C treatment in 2020?
- What are the current recommendations for screening for Hepatitis C?
- What is the baseline work up for Hepatitis C treatment?
- What are the main treatment options for Hepatitis C in 2020?

WE'D LOVE TO HEAR FROM YOU!

IF YOU HAVE ANY QUESTIONS OR COMMENTS PLEASE EMAIL BC-CFE'S EDUCATION AND TRAINING TEAM AT:

EDUCATION@CFENET.UBC.CA