

**BCKD<sub>19</sub>**

**BC KIDNEY DAYS**

**Update on the Use of Hepatitis C Positive Deceased Donor Kidneys in Hepatitis C Negative Recipients**

Matthew Kadatz and Dominique Khoo

## Acknowledgements

- BC Transplant: Dominique Khoo, Tina Robinson, Ed Ferre, David Landsberg
- PHSA: Collen Hart
- BCPRA: Adeera Levin
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- Pathology team: Dr. Mei Lin Bissonnette
- Immunology Team: Paul Keown, Michele Konevecki
- Transplant Clinical Research Group: Jamey Shick
- Members of the DBAAC group responsible for Hep C therapy review and approval at PharmaCare
- Transplant Clinical Team: Physicians, Nurses, Surgeons, Pharmacists
- Dr. Peter Reese/Dr. Deirdre Sawinski – UPenn

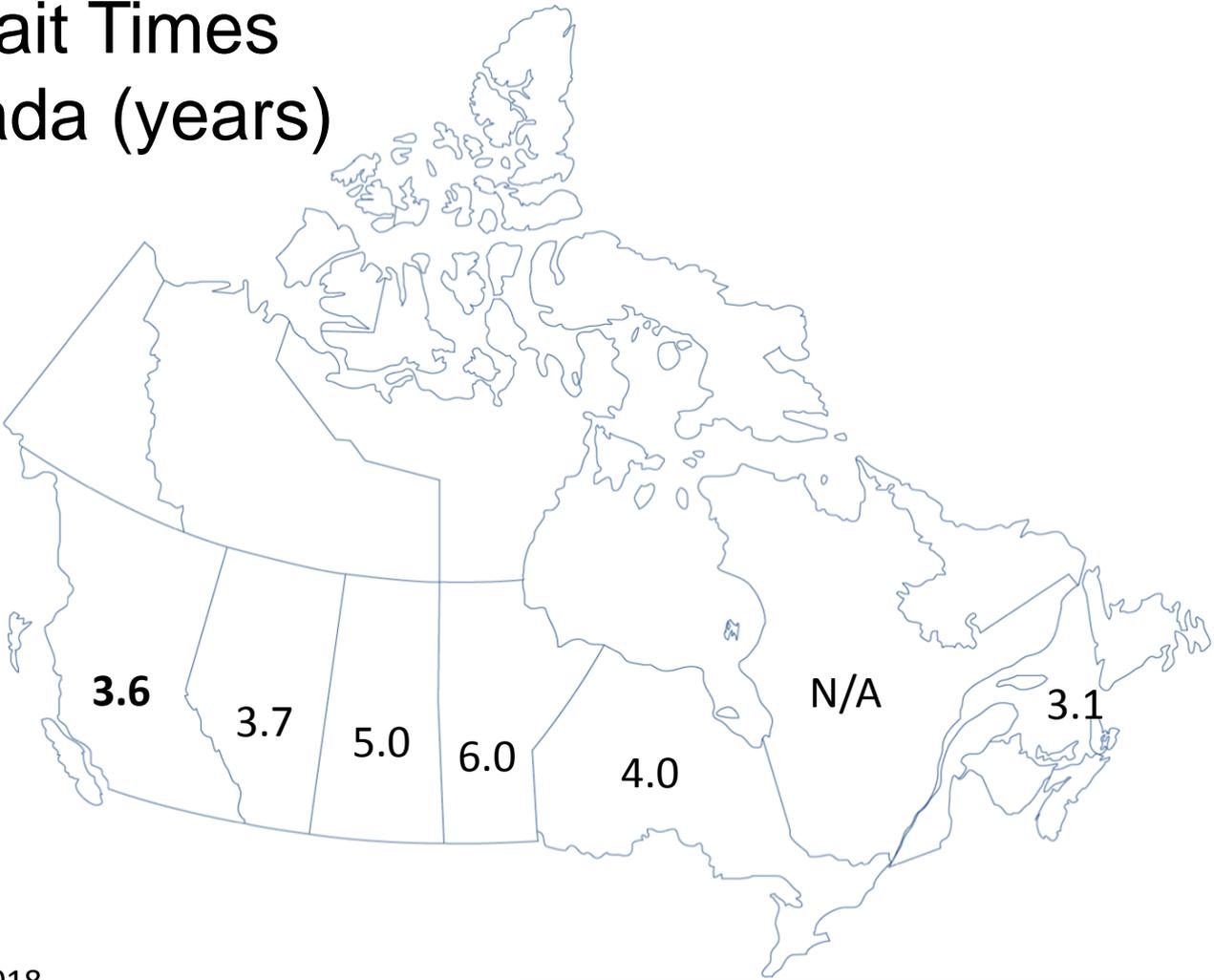
# Objectives

1. Review the available evidence for the use of HCV NAT positive kidneys
2. Description of the HCV Transplant Program in BC
3. Review the role of Pharmacare and treatment of HCV Post Transplant
4. Provide update on HCV Program successes and challenges

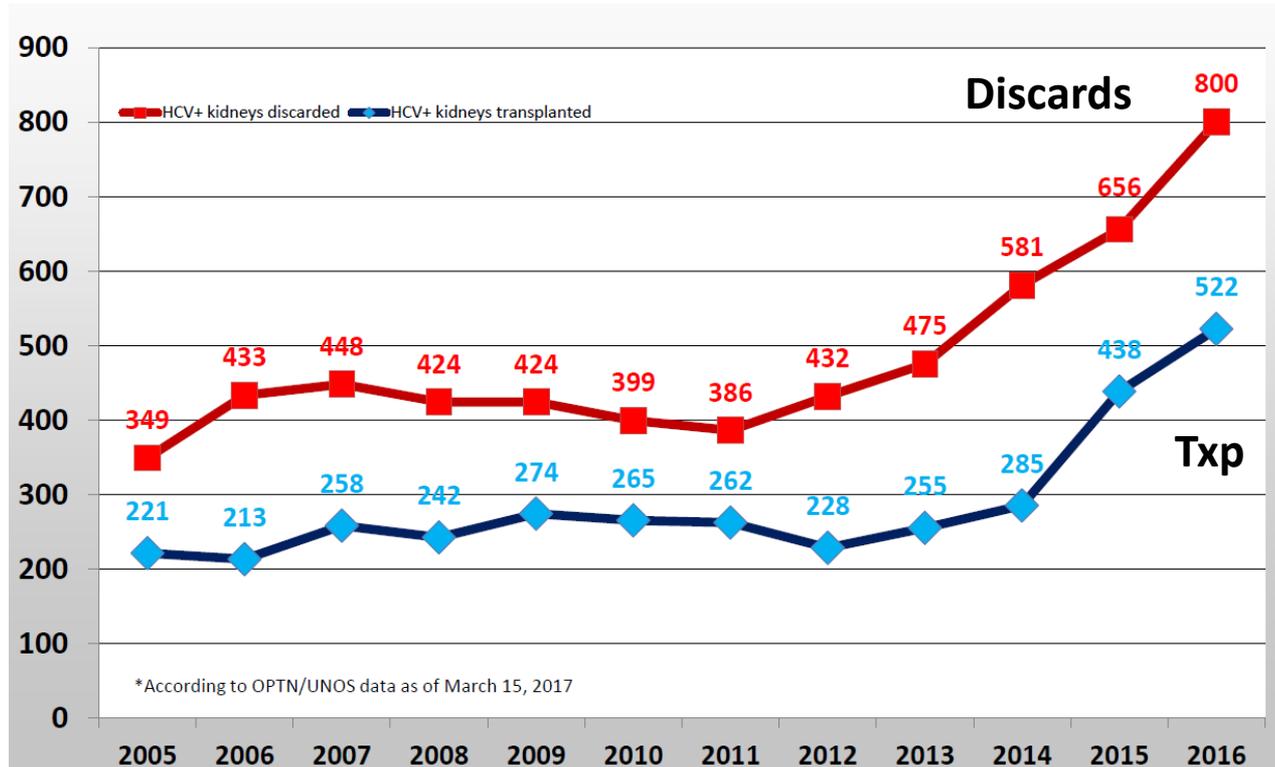
# Introduction

- Kidney transplantation is the treatment of choice for patients with end-stage kidney disease
- Kidney transplantation increases life expectancy and quality of life, while also being less costly than dialysis<sup>1,2</sup>
- Shortage of available organs prohibits universal access to transplantation

# Median Wait Times Across Canada (years)



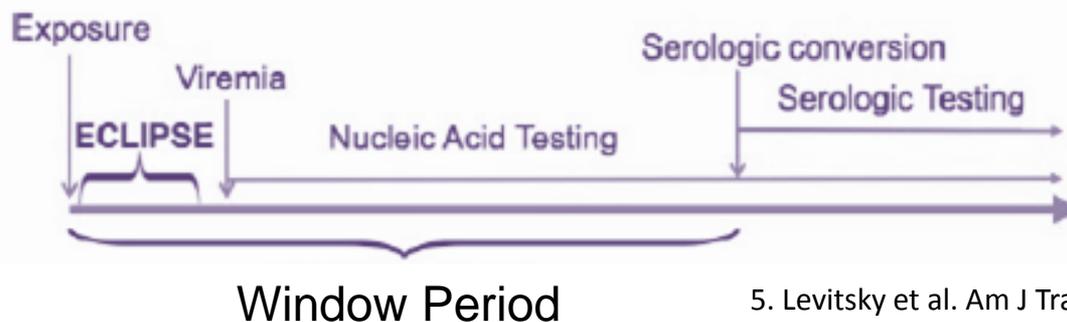
# HCV+ Kidneys are being discarded



4. Goldberg & Reece. Annals Int Med. 2018.

# What is an HCV “Positive” Donor?

HCV Ab	HCV NAT	Interpretation	Risk of Transmission
+	+	Active infection	Yes
+	-	Previously Infected or False Positive	None documented*
-	+	Window Period infection False Positive	Yes



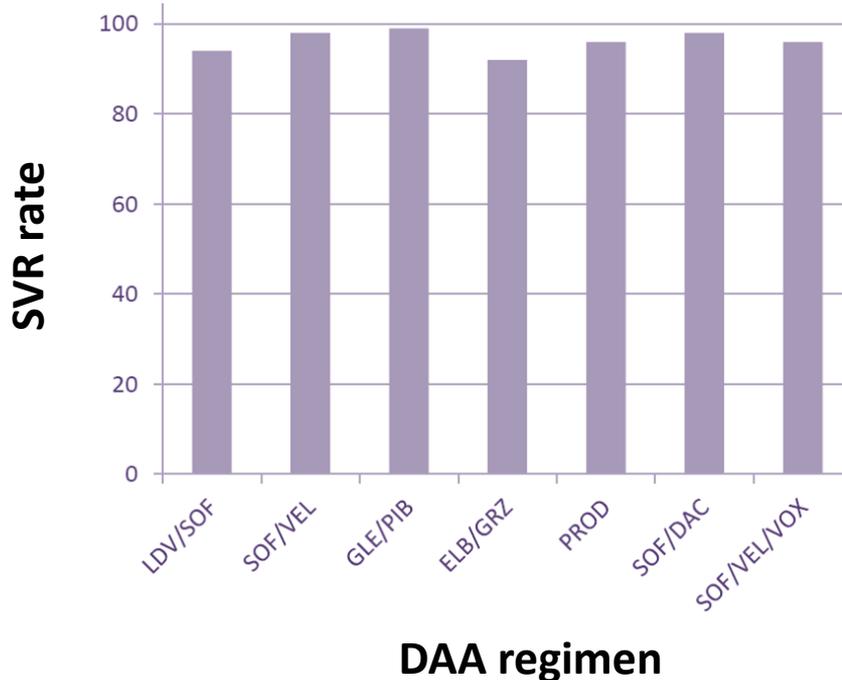
# Direct Acting Antivirals

- Historically, treatment of Hepatitis C was limited to Interferon and ribavirin based regimens
- Neither of these drugs are particularly well tolerated in transplant recipients <sup>5,6</sup>
- The advent of direct acting antivirals has made the treatment of acquired Hepatitis C infection highly effective

6. Weclawiack et al, Nephrol Dial Transplant. 2008

7. Kamar et al. Am J Kidney Dis. 2004

# DAA's make Transplantation Using HCV NAT Positive Kidneys Feasible



- Highly Effective
  - SVR generally >95%
- Interferon free
- Pan-genotypic options
- Options available for any GFR

# Evidence in Kidney Transplantation

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Annals of Internal Medicine

ORIGINAL RESEARCH

## Direct-Acting Antiviral Prophylaxis in Kidney Transplantation From Hepatitis C Virus-Infected Donors to Noninfected Recipients

An Open-Label Nonrandomized Trial

Christine M. Durand, MD; Mary G. Bowring, MPH; Diane M. Brown, MSN; Michael A. Chattergoon, MD, PhD; Guido Massaccesi, BS; Nichole Bair, BSN; Russell Wesson, MBChB; Ashraf Reyad, MBBCh; Fizza F. Naqvi, MD; Darin Ostrander, PhD; Jeremy Sugarman, MD; Dorry L. Segev, MD, PhD; Mark Sulkowski, MD; and Niraj M. Desai, MD

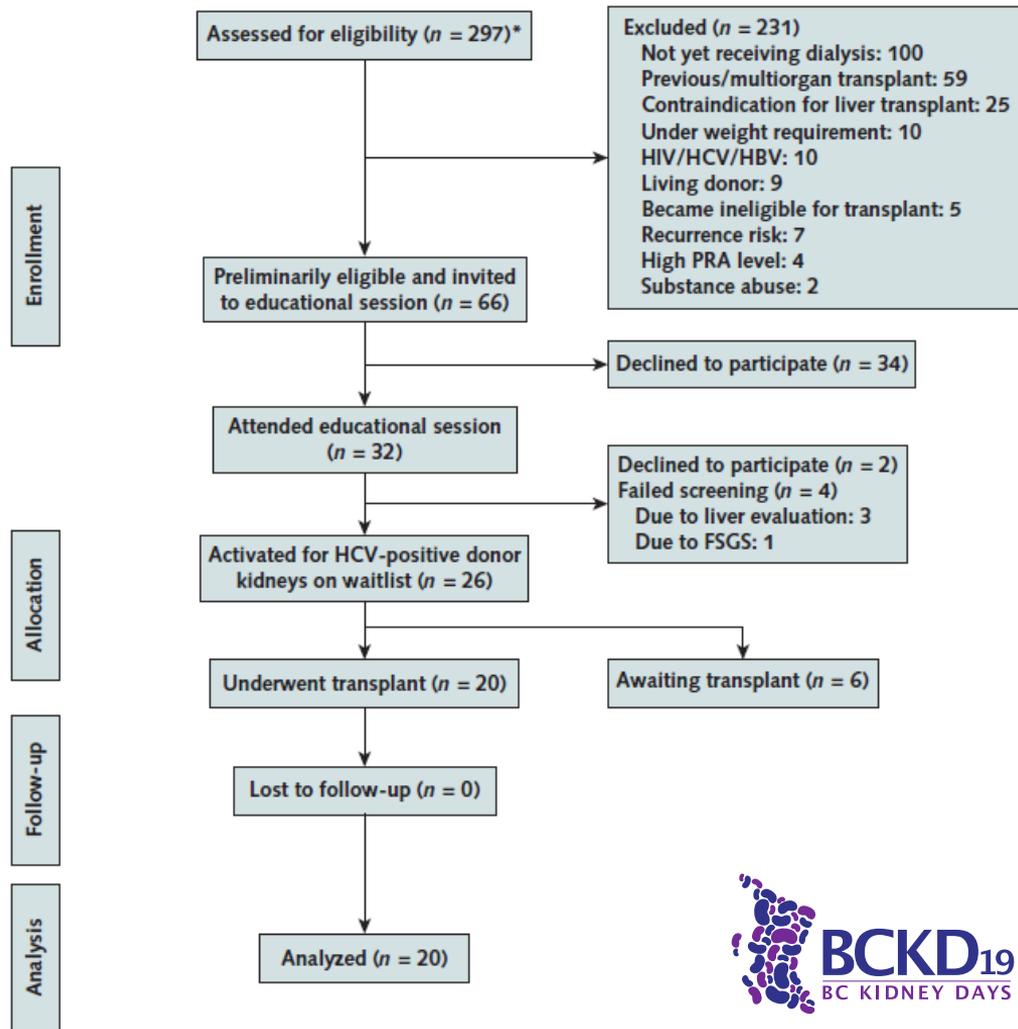
CORRESPONDENCE

## Trial of Transplantation of HCV-Infected Kidneys into Uninfected Recipients

# THINKER-1

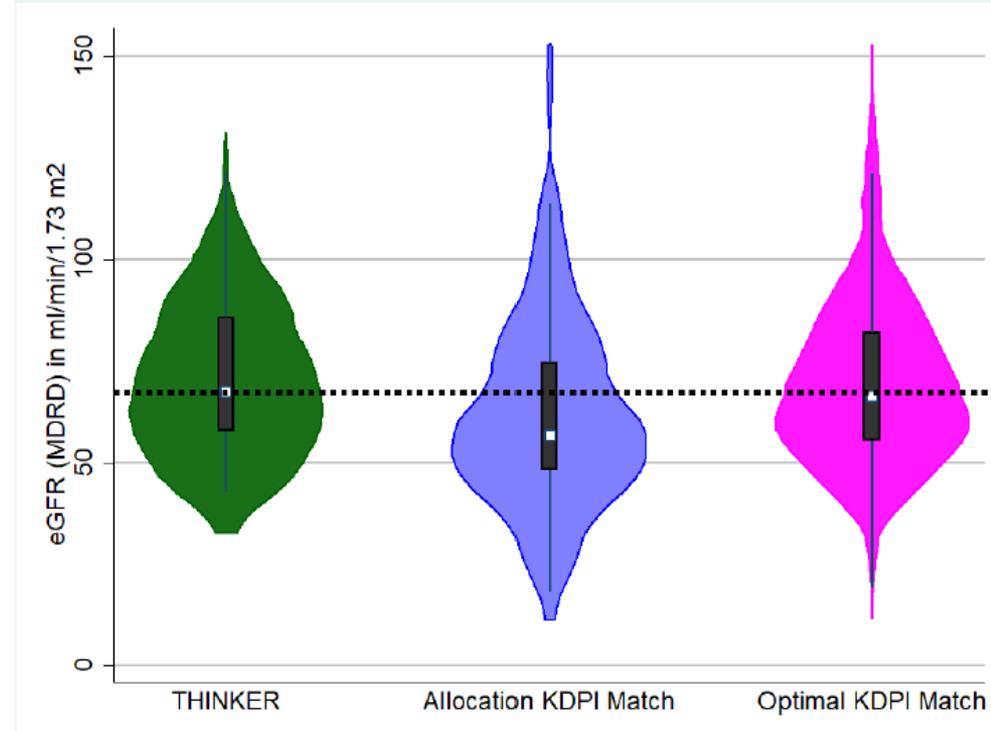
- Donors were all Genotype 1\*
- All recipients received rATG induction
- Day 3 – checked HCV Viral Load
- Patients Treated if HCV Viral Load +

9. Goldberg et al NEJM 2017;  
10. Reese et al Annals Int Med 2018



# THINKER-1

- 100% detectable HCV Viral Load at 3 days
- 100% achieved SVR 12 (cure)
- 25% Delayed Graft Function
- Adverse Events:
  - 25% transient increase in LFTs
  - 1 de novo FSGS
  - *De novo* DSA in 20%
- Median 12 month Scr 96.8  $\mu\text{mol/L}$
- THINKER GFR is better than KDPI matched HCV-



# EXPANDER

Characteristics of EXPANDER Cohort (N=10)	
Median age	71 (65-72)
Female	20%
White	80%
ESRD - PCKD	20%
ESRD –DM/HTN	30%
Median years on dialysis	1.6 (0-2.6)
Median months to Tx	1 (0.7-2)
Median KDPI	45 (41-50)

- 15 patients screened, 10 enrolled and transplanted
- Genotyping – results in 7 days
- DAA started on call to the OR
- HCV VL measured POD#1

# EXPANDER

- 3/10 with detectable HCV RNA on POD#1
- 50% develop anti-HCV Ab
- 100% SVR 12
- 1 patient with transaminitis – resolved
- Median Scr 1.05mg/dL at 12 weeks

# Summary

- Using kidneys from hepatitis C - nucleic acid test–positive donors for transplantation in hepatitis C–negative recipients has been done **successfully and safely**
- Treatment costs of DAA’s can prohibit programs from adopting this strategy to reduce wait-times

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**ORIGINAL ARTICLE**

AJT

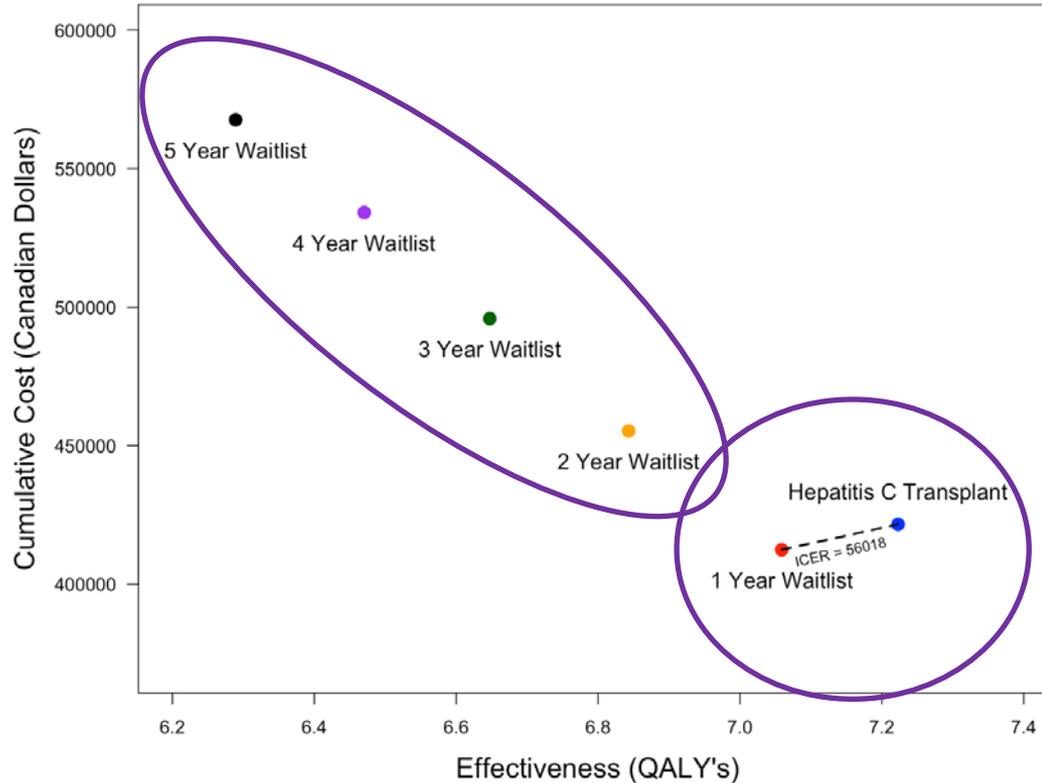
# Cost-effectiveness of using kidneys from hepatitis C nucleic acid test-positive donors for transplantation in hepatitis C-negative recipients

Matthew Kadatz<sup>1,3</sup>  | Scott Klarenbach<sup>2</sup> | Jagbir Gill<sup>3,4</sup> | John S. Gill<sup>3,4</sup>

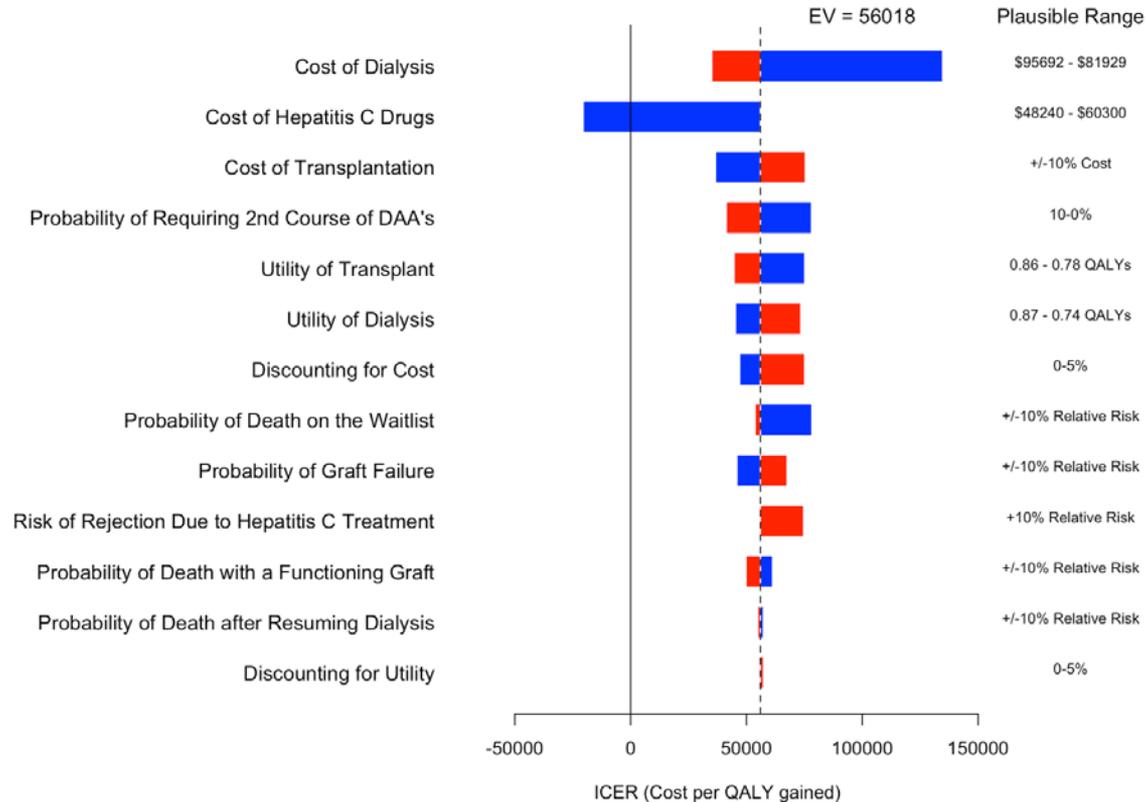
# Base Model Results

- Using a kidney from a HCV NAT-positive kidney donor **dominated** remaining on the waitlist for 2 or more years for a NAT negative kidney
- Using a HCV NAT-positive kidney compared to remaining on the waitlist for 1 additional year for a NAT-negative kidney had an ICER of \$56,018/QALY
  - Incremental cost of \$9,188 CAD
- When modeled from the societal perspective, the ICER for using a HCV NAT-positive kidney donor compared to remaining on the waitlist for 1 year was \$4,647/QALY
  - Incremental cost of \$762 CAD

# Primary Markov Model Outputs: Cumulative Costs and Cumulative Effectiveness



# Tornado Diagram of Univariate Sensitivity Analyses



# Budget Impact

If 20 HCV NAT-positive kidneys were used in patients to shorten their wait-time by 2 to 5 years



Potentially savings to the health-care payer between \$674 000 and \$2.9 million over 10 years

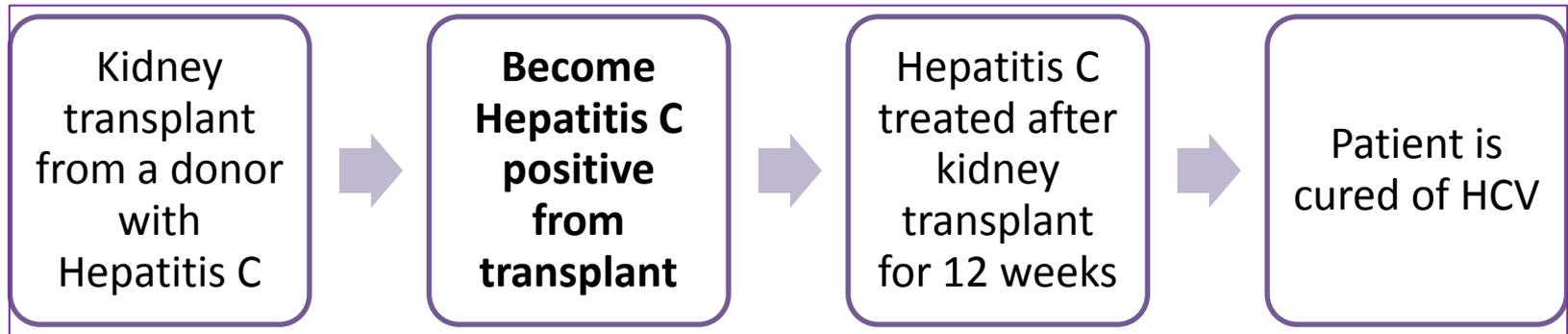
Cumulative Costs Per Patient:	5 Years	10 Years
HCV NAT + Kidney Transplant	\$310,009	\$421,656
Remain on Waitlist: 2 Years	\$343,673	\$455,365
Remain on Waitlist: 3 Years	\$387,322	\$495,872
Remain on Waitlist: 4 Years	\$429,287	\$534,161
Remain on Waitlist: 5 Years	\$469,306	\$567,627

# Cost Effectiveness Conclusions

- Use of kidney's from HCV NAT positive donors in HCV NAT negative recipients is **cost saving** when 2 years of wait-time on dialysis is foregone
- Use of kidney's from HCV NAT positive donors in HCV NAT negative recipients is **cost effective** when 1 year of wait-time on dialysis is foregone

# Program Overview

- Patients on the waiting list who will wait more than 2 years for a transplant
- Consent to be on the wait list for a transplant from a donor with Hepatitis C (HCV) infection
- Anticipate to 10-15 patients will receive an offer for a kidney transplant from a donor with HCV in 2019



# Program Enrollment Process

Patients on the waitlist and new activations to the waitlist are regularly screened for eligibility

Eligible patient are invited to participate in an education session

Following education, patients are offered to consent to participate in the program

# Who can participate?

- ✓ Waiting time of 2 years or greater
- ✓ At least 19 years of age
- ✓ Only listed for a kidney transplant
- ✓ Understand the HCV treatment is provided by PharmaCare and agree to pay costs of applicable deductibles
- ✓ Men and women must use barrier methods to prevent exchange of bodily secretions during sexual activity
- ✓ Women of child-bearing age must agree to standard recommendations to prevent pregnancy after transplant

# Who cannot participate?

- ✗ Past or current Hepatitis B, Hepatitis C or HIV infection
- ✗ Liver disease or any persistent liver abnormality
- ✗ Previous non-kidney transplant
- ✗ Pregnant or nursing (lactating) women
- ✗ Patients with primary FSGS (treatment may increase risk of FSGS recurrence)
- ✗ Unable to remain in Vancouver for 3 months to complete HCV treatment

# Education Sessions

- All sessions are presented by a transplant nephrologist
- Sessions conducted in groups either in person or via telehealth
- Translators available for individuals with language barriers

# Consent Process

- Written consent required prior to participation
  - This ensures patients have had ample opportunity to consider risks and benefits of participation
- Patients may withdraw consent without penalty

# After Consent

- Participate continue to be on the routine kidney transplant waitlist, but also a separate waitlist for HCV NAT positive organs
- Everyone contacted to establish plan for DAA coverage through Pharmacare\*
- Patients may choose accept or decline an HCV NAT positive organ at the time of offer

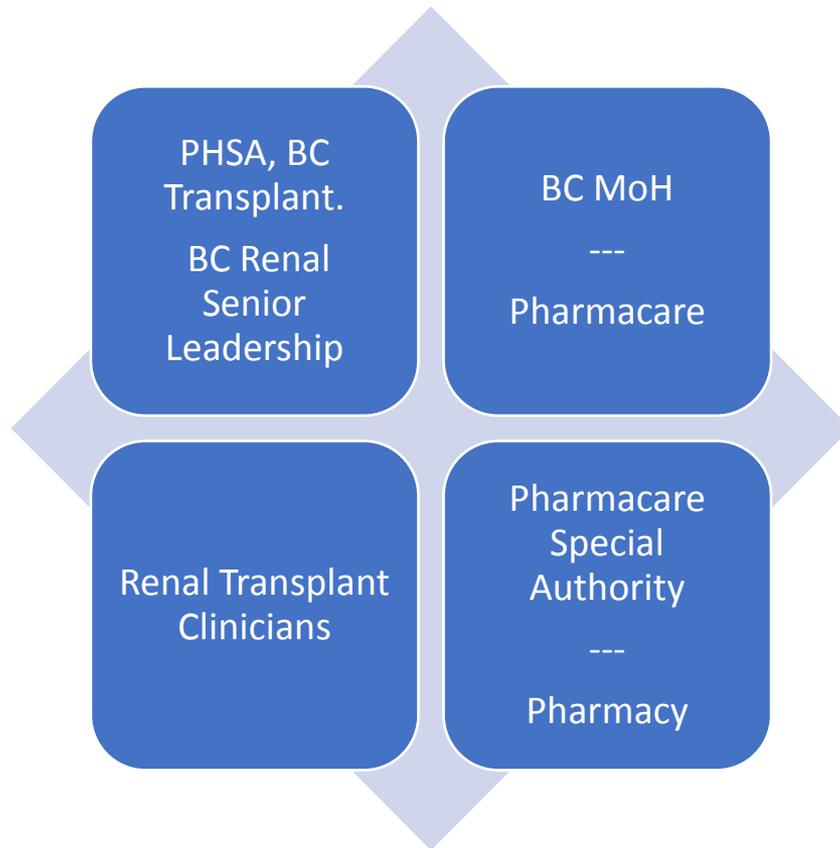
# Donor Selection

- Only donors who are “standard criteria” are used in the program
- Donors must not have had previous treatment with DAA’s
- Once donor approved, virtual crossmatch performed on HCV Waitlist\*

# Post-Transplant Care

- Direct acting antiviral therapy initiated within 1-2 days of transplant surgery
- Treatment continued for 12 weeks
- Extra monitoring of HCV viral loads, liver function and side effects
- Patients followed by Transplant Infectious Disease team

# Implementation Science: Collaboration is key



# GLECAPREVIR PLUS PIBRENTASVIR FOR CHRONIC HEPATITIS C

HLTH 5494 2019/03/15

## URGENT Request for Approval - KIDNEY TRANSPLANT

 For up to date criteria and forms, please check: [www.gov.bc.ca/pharmacarespecialauthority](http://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 <input type="checkbox"/> MAIL CONFIRMATION	
<input type="checkbox"/> COLLEGE ID   OR <input type="checkbox"/> MSP NUMBER    PHONE NUMBER (INCLUDE AREA CODE)	
<b>CRITICAL FOR A TIMELY RESPONSE</b> →	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)
<b>CRITICAL FOR PROCESSING</b> →	PERSONAL HEALTH NUMBER (PHN)

**SECTION 3 – BACKGROUND DIAGNOSTIC INFORMATION**
**GLECAPREVIR + PIBRENTASVIR: 9901-0315**

For the treatment of adult patients with Chronic Hepatitis C genotype 1, 2, 3, 4, 5 or 6 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. For genotype 1, genotype report must be dated May 2012 or later.
- Patient has compensated liver disease (i.e. with no cirrhosis or with compensated cirrhosis). Compensated cirrhosis is defined as cirrhosis with a Child Pugh score = A (5-6).
- 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 \_\_\_\_\_
  - Kidney transplant recipient from a Hepatitis C positive donor (viremic)**
  - 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

PharmaCare may request additional documentation to support this Special Authority request.

Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

**PHARMACARE USE ONLY**

STATUS	EFFECTIVE DATE (YYYY / MM / DD)	DURATION OF APPROVAL
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PATIENT NAME	PHN	DATE (YYYY / MM / DD)
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**SECTION 4: GLECAPREVIR + PIBRENTASVIR (Coverage listed is maximum length - no renewals on all listings.)**

(CHOOSE FROM OPTION A, B OR C)

**A. GENOTYPE 1:**

- 8 weeks coverage**  
Treatment-naïve or treatment-experienced<sup>1</sup> with no cirrhosis.
- OR**
- 12 weeks coverage**  
 Treatment-naïve or treatment-experienced<sup>1</sup> with compensated cirrhosis<sup>2</sup>.  
 Previously treated<sup>3</sup> with an NS3/4A protease inhibitor-containing regimen, but NS5A inhibitor treatment-naïve.
- OR**
- 16 weeks coverage**  
Previously treated<sup>4</sup> with an NS5A inhibitor-containing regimen, but NS3/4A protease inhibitor treatment-naïve.

Refer to Section 5 - Additional Comments

**OR**
**B. GENOTYPE 2, 4, 5 or 6:**

- 8 weeks coverage**  
Treatment-naïve or treatment-experienced<sup>1</sup> with no cirrhosis.
- OR**
- 12 weeks coverage**  
Treatment-naïve or treatment-experienced<sup>1</sup> with compensated cirrhosis<sup>2</sup>.

Refer to Section 5 - Additional Comments

**OR**
**C. GENOTYPE 3:**

- 8 weeks coverage**  
Treatment-naïve with no cirrhosis.
- OR**
- 12 weeks coverage**  
Treatment-naïve with compensated cirrhosis<sup>2</sup>.
- OR**
- 16 weeks coverage**  
Treatment-experienced<sup>3</sup> with no cirrhosis or with compensated cirrhosis<sup>2</sup>.

Refer to Section 5 - Additional Comments

**NOTES:**

1. Treatment-experienced is defined as a patient who has been previously treated with **interferon, peginterferon-ribavirin (PR), ribavirin (RBV), and/or sofosbuvir (SOF) (PR, SOF + PR, SOF + RBV)**, but **no prior treatment experience with an HCV NS3/4A protease inhibitor or NS5A inhibitor**, and who has relapsed or not responded to treatment.
2. Compensated cirrhosis is defined as cirrhosis with a Child Pugh score = A (5-6)
3. Patient has been previously treated with simeprevir + sofosbuvir or simeprevir + PR or boceprevir/telaprevir + PR, and who has relapsed or not responded to treatment.
4. Patient has been previously treated with ledipasvir + sofosbuvir or daclatasvir + PR or daclatasvir + sofosbuvir, and who has relapsed or not responded to treatment.

**SECTION 5 – ADDITIONAL COMMENTS**

Exceptional Criteria: URGENT request for a kidney transplant patient who received an organ from a Hepatitis C positive donor (viremic) (Coverage is up to a maximum of 12 weeks. No renewals)

Donor Log Number: \_\_\_\_\_ Donor Viral Load: \_\_\_\_\_

Clinical notes:

Personal information on this form is collected, used and disclosed under the authority of, and in accordance with, the British Columbia Pharmaceutical Services Act and Freedom of Information and Protection of Privacy Act. It will not be disclosed to any persons without the patient's consent. The information you provide will be relevant to and used solely to (a) provide PharmaCare benefits for the medication requested, (b) to implement, monitor and evaluate this and other Ministry programs, and (c) to manage and plan for the health system generally. If you have any questions about the collection or use of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Prescriber's Signature (Mandatory)

# Fair PharmaCare Plan



- Fair PharmaCare helps B.C. families pay for [eligible](#) prescription drugs, dispensing fees and some medical supplies. Fair PharmaCare is income-based; **the less a family earns, the more help they get (ie the lower the deductible).**
- BC Residents with active [Medical Services Plan \(MSP\)](#) coverage, and grant PharmaCare permission to check their (family) income with the Canada Revenue Agency (Income is from two years prior.)

## Assistance Levels:

Reach Family Deductible:  
70% coverage

Reach Family  
Maximum: 100%  
coverage

Reset Jan 1<sup>st</sup>

Family Net Income Range		Family Deductible	Family Maximum	
\$0.00	\$1,875.00	\$0.00	\$0.00	
\$1,875.01	\$3,125.00	\$0.00	\$0.00	
\$3,125.01	\$4,375.00	\$0.00	\$0.00	
\$4,375.01	\$6,250.00	\$0.00	\$0.00	
\$6,250.01	\$8,750.00	\$0.00	\$0.00	
\$8,750.01	\$11,250.00	\$0.00	\$0.00	
\$11,250.01	\$13,750.00	\$0.00	\$0.00	1
\$13,750.01	\$15,000.00	\$0.00	\$100.00	
\$15,000.01	\$16,250.00	\$0.00	\$200.00	
\$16,250.01	\$18,750.00	\$0.00	\$300.00	
\$18,750.01	\$21,250.00	\$0.00	\$400.00	
\$21,250.01	\$23,750.00	\$0.00	\$500.00	
\$23,750.01	\$26,250.00	\$0.00	\$600.00	
\$26,250.01	\$28,750.00	\$0.00	\$700.00	
\$28,750.01	\$30,000.00	\$0.00	\$800.00	2
\$30,000.01	\$31,667.00	\$650.00	\$900.00	
\$31,667.01	\$35,000.00	\$800.00	\$1,150.00	
\$35,000.01	\$38,333.00	\$950.00	\$1,350.00	
\$38,333.01	\$41,667.00	\$1,100.00	\$1,500.00	
\$41,667.01	\$45,000.00	\$1,300.00	\$1,700.00	
\$45,000.01	\$48,333.00	\$1,400.00	\$1,875.00	
\$48,333.01	\$51,667.00	\$1,500.00	\$2,000.00	
\$51,667.01	\$55,000.00	\$1,600.00	\$2,150.00	
\$55,000.01	\$58,333.00	\$1,700.00	\$2,275.00	
\$58,333.01	\$61,667.00	\$1,800.00	\$2,400.00	
\$61,667.01	\$65,000.00	\$1,900.00	\$2,550.00	
\$65,000.01	\$70,833.00	\$2,000.00	\$2,675.00	3
\$70,833.01	\$79,167.00	\$2,250.00	\$3,000.00	
\$79,167.01	\$87,500.00	\$2,500.00	\$3,350.00	

# If patient is not registered for Fair PharmaCare

Family Net Income Range		Family Deductible	Family Maximum
\$87,500.01	\$95,833.00	\$2,750.00	\$3,675.00
\$95,833.01	\$108,333.00	\$3,000.00	\$4,000.00
\$108,333.01	\$125,000.00	\$3,500.00	\$4,675.00
\$125,000.01	\$141,667.00	\$4,000.00	\$5,350.00
\$141,667.01	\$158,333.00	\$4,500.00	\$6,000.00
\$158,333.01	\$183,333.00	\$5,000.00	\$6,675.00
\$183,333.01	\$216,667.00	\$6,000.00	\$8,000.00
\$216,667.01	\$250,000.00	\$7,000.00	\$9,350.00
\$250,000.01	\$283,333.00	\$8,000.00	\$10,000.00
\$283,333.01	\$316,667.00	\$9,000.00	\$10,000.00
\$316,667.01	\$999,999,999.00	\$10,000.00	\$10,000.00

4

# Increased Assistance and Payment Options

- Adjustments of decreased family income of 10% or more
- Families with at least 1 spouse born before 1940
- Divorce or Separation/Child Custody
- Spouse Living in Residential Care Facility
- Death of Spouse
  
- Monthly Deductible Payment Option



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# Example

- Family Net Income \$70,0000
- Fair PharmaCare deductible is \$2000  
Maximum of \$2675
- They do not have 3<sup>rd</sup> party Insurance

Family Net Income Range		Family Deductible	Family Maximum
\$0.00	\$1,875.00	\$0.00	\$0.00
\$1,875.01	\$3,125.00	\$0.00	\$0.00
\$3,125.01	\$4,375.00	\$0.00	\$0.00
\$4,375.01	\$6,250.00	\$0.00	\$0.00
\$6,250.01	\$8,750.00	\$0.00	\$0.00
\$8750.01	\$11,250.00	\$0.00	\$0.00
\$11,250.01	\$13,750.00	\$0.00	\$0.00
\$13,750.01	\$15,000.00	\$0.00	\$100.00
\$15,000.01	\$16,250.00	\$0.00	\$200.00
\$16,250.01	\$18,750.00	\$0.00	\$300.00
\$18,750.01	\$21,250.00	\$0.00	\$400.00
\$21,250.01	\$23,750.00	\$0.00	\$500.00
\$23,750.01	\$26,250.00	\$0.00	\$600.00
\$26,250.01	\$28,750.00	\$0.00	\$700.00
\$28,750.01	\$30,000.00	\$0.00	\$800.00
\$30,000.01	\$31,667.00	\$650.00	\$900.00
\$31,667.01	\$35,000.00	\$800.00	\$1,150.00
\$35,000.01	\$38,333.00	\$950.00	\$1,350.00
\$38,333.01	\$41,667.00	\$1,100.00	\$1,500.00
\$41,667.01	\$45,000.00	\$1,300.00	\$1,700.00
\$45,000.01	\$48,333.00	\$1,400.00	\$1,875.00
\$48,333.01	\$51,667.00	\$1,500.00	\$2,000.00
\$51,667.01	\$55,000.00	\$1,600.00	\$2,150.00
\$55,000.01	\$58,333.00	\$1,700.00	\$2,275.00
\$58,333.01	\$61,667.00	\$1,800.00	\$2,400.00
\$61,667.01	\$65,000.00	\$1,900.00	\$2,550.00
\$65,000.01	\$70,833.00	\$2,000.00	\$2,675.00
\$70,833.01	\$79,167.00	\$2,250.00	\$3,000.00
\$79,167.01	\$87,500.00	\$2,500.00	\$3,350.00

## Example:

- 1 Jan to 3 Aug - has bought \$2000 of medication
- 14 Aug - a new prescription costs \$100
  - **Pharmacare pays \$70; family pays \$30**
- 29 Nov - have paid \$2675 of medications
- Dec 10, new prescription for \$500
  - **Pharmacare pays \$500; family pays \$0**
- 1 Jan - deductible levels resets again



## Direct-acting antivirals for Hep C (DAAs)

### NS3/4A PROTEASE INHIBITORS

Glecaprevir ★

Grazoprevir

Paritaprevir

Simeprevir

Voxilaprevir ★

### NS5A INHIBITORS

Daclatasvir

Elbasvir

Ledipasvir

Ombitasvir

Pibrentasvir ★

Velpatasvir ★

### NS5B RNA-DEPENDENT RNA POLYMERASE INHIBITORS

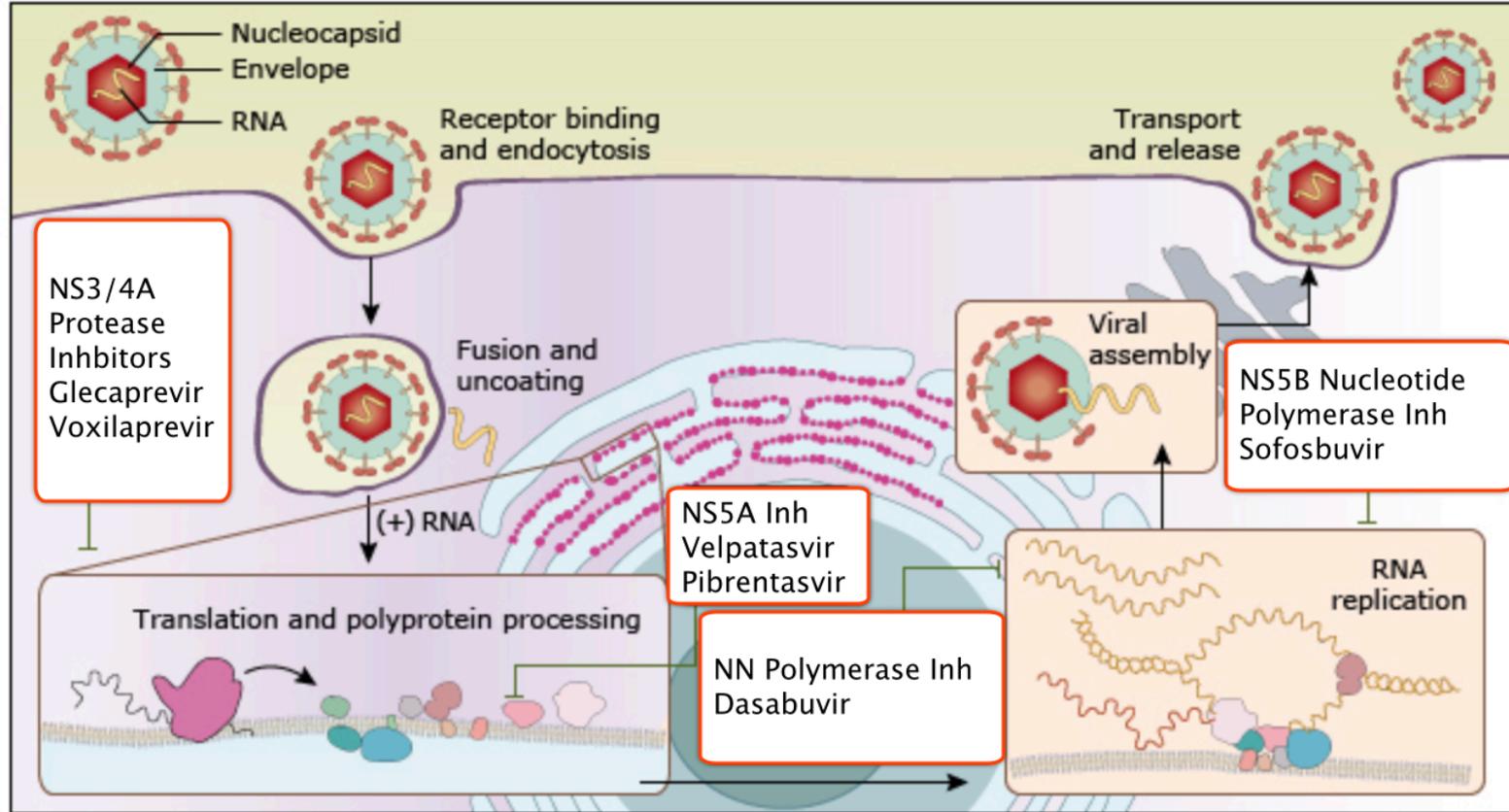
Nucleot(s)ide polymerase inhibitors (NPIs)

- Sofosbuvir ★

Non-nucleoside polymerase inhibitors (NNPIs)

- Dasabuvir

# Mechanism of action of direct acting antivirals for hepatitis C virus



NS5A: nonstructural protein 5A; NS5B: nonstructural protein 5B; NNPI: non-nucleoside polymerase inhibitor.

Brand name (generic name)	Image	Dosage schedule	Food requirements	Weeks of treatment
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### Treatments for all genotypes (1, 2, 3, 4, 5, 6)

<b>Epclusa</b> (velpatasvir + sofosbuvir)				<b>12</b>
with or without ribavirin*				
<b>Harvoni</b> (ledipasvir + sofosbuvir)				<b>8, 12 or 24</b>
with or without ribavirin*				
recommended use depends on genotype				
<b>Maviret</b> (glecaprevir + pibrentasvir)				<b>8, 12 or 16</b>
<b>Vosevi</b> (sofosbuvir + velpatasvir + voxilaprevir)				<b>12</b>

[www.catie.ca](http://www.catie.ca)

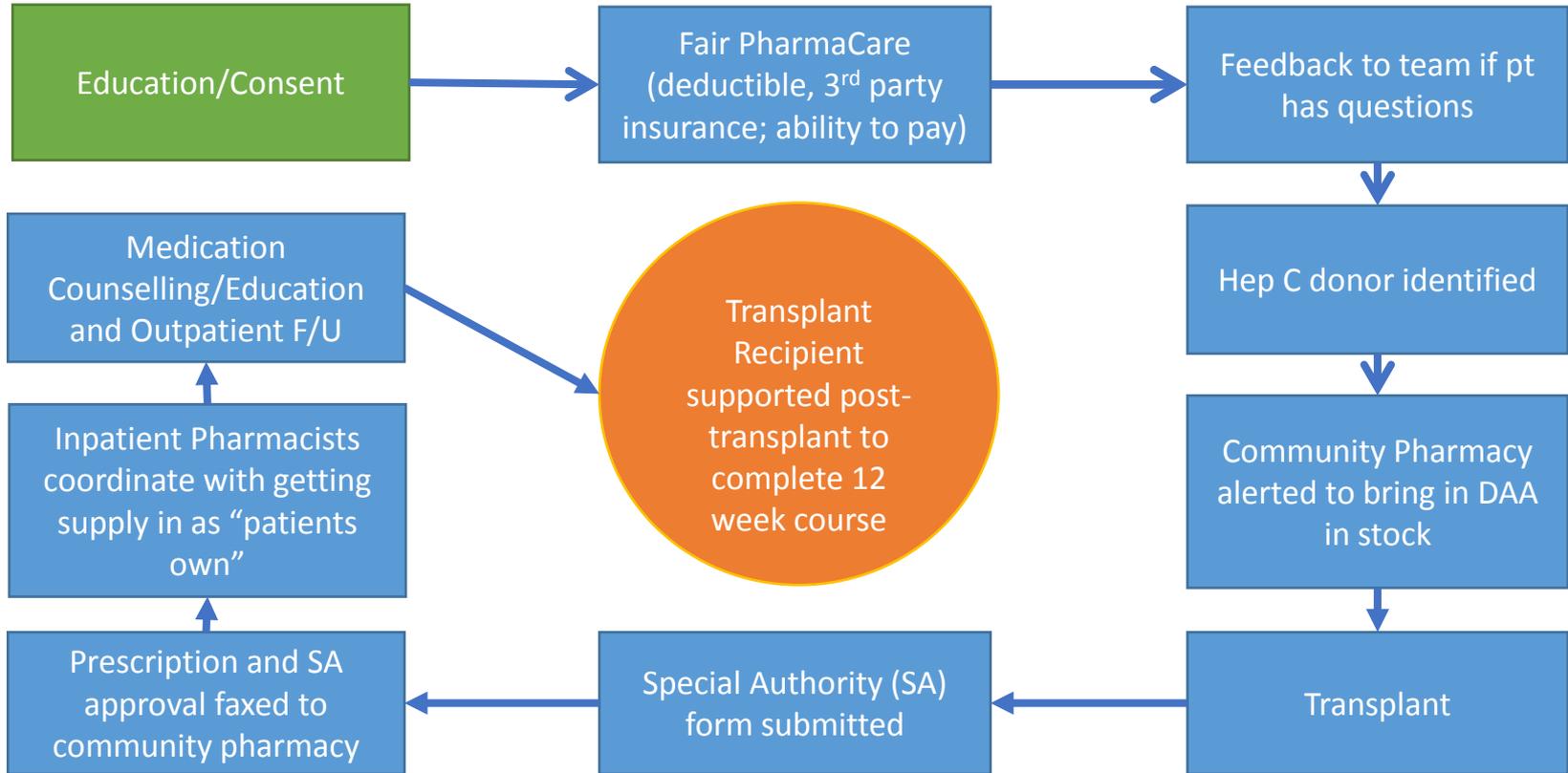
# Maviret

(glecaprevir/  
pibrentasvir)

- Pan-genotypic activity
- Avoids sofosbuvir which has an inactive metabolite (007) that is renally cleared
- Potential drugs interactions with:
  - tacrolimus, statin, carbamazepine, St. John's Wort, boosted HAART



# Pharmacy Support



# Program Progress

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First education session Dec 2, 2018

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First patient consented Dec 2, 2018

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Program went live January 1, 2019

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So far more than 500 patients have been screened  
Over 20 education sessions have been completed

# Timeline



# Waitlist Characteristics

- 41 Patients currently consented and active on the HCV Waitlist
- Mean PRA 71% (20 HSP)
- Majority Blood Group O - 67%
- 2 have withdrawn consent since program initiated

# HCV + Transplants So Far

- Less Hepatitis C positive donors have become available than anticipated
- 4 HCV positive donors in BC since January 2019
- Only 2 / 4 went on to donate
- 5 kidney transplants performed\*

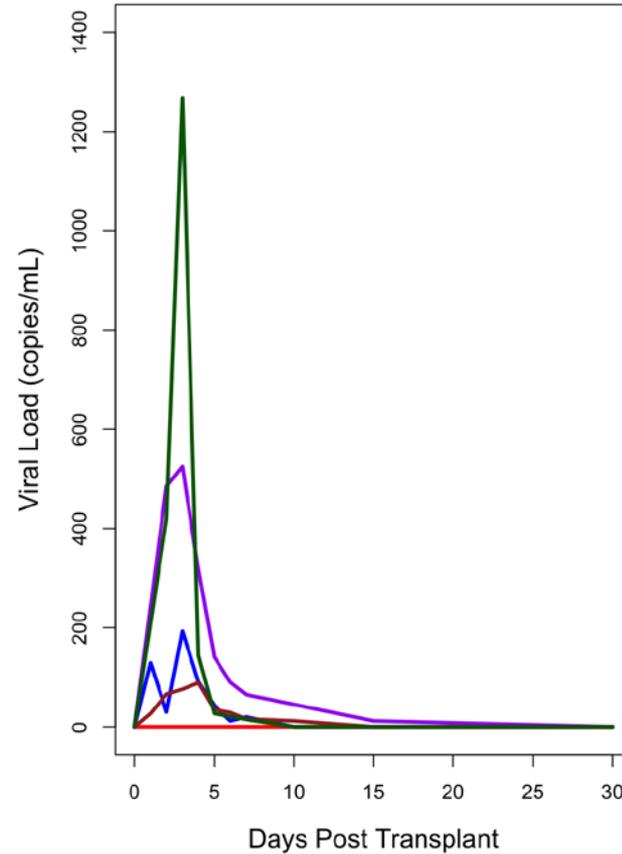
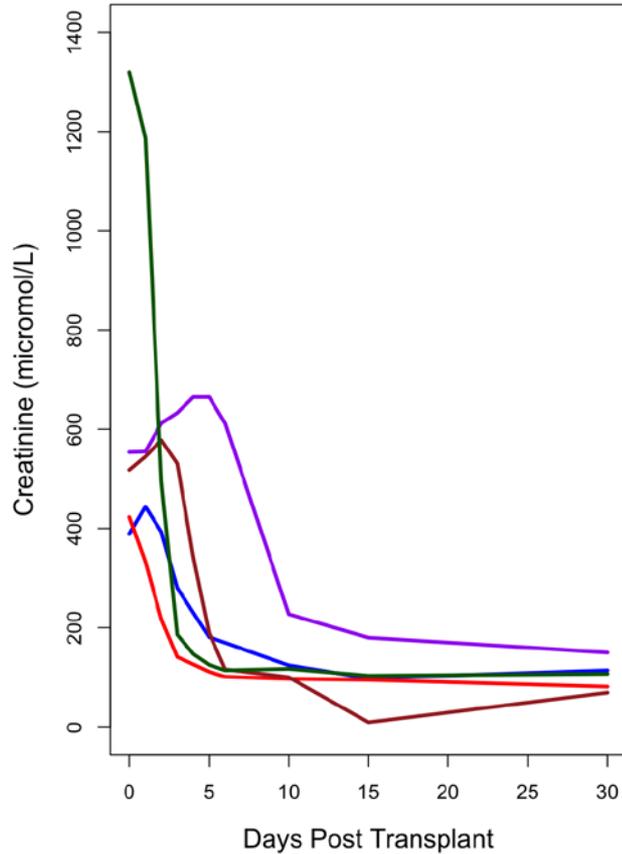
# Donor Characteristics

- Donor 1: Blood Group B, SCD
  - Viral Load 159,788, Genotype 3a
- Donor 2: Blood Group B, SCD
  - Viral Load 818216 copies/mL, Genotype 1a
- Donor 3: Blood Group A, SCD (Import)\*
  - Viral Load 515, Genotype 1a

# Recipient Characteristics

	1	2	3	4	5
Age (years)	65	67	64	64	60
Sex	F	F	M	F	M
Blood Group	B	A	B	B	B
PRA (%)	0	41	0	77	89
Duration of Dialysis Pre-Transplant (years)	2.0	1.2	3.9	3.2	5.2

# Patient Outcomes



# Adverse Events

- One patient experienced dramatic rise in bilirubin
  - Attributed to medication side-effect from Maverit
- One patient experienced a post-operative hematoma
- One patient experienced significant reflux which resolved on completion of DAA therapy

# Future Directions

- Ongoing research directed towards ideal duration of DAA's post-transplant
- Impact on quality of life unknown
- Other organ groups expanding the use of HCV NAT positive organs



Questions or  
Comments?