Strategies to address reimbursement restrictions for Hepatitis C treatment: Lessons from Australia

The webinar will commence shortly.

All participants will be muted until the question period.

Please make sure you access the audio portion:

Toll-free access number: 1-866-500-7712
Access code: 6527797
Overview

Presentations on the Australian model

- A review of restrictions for reimbursement of direct-acting antiviral treatment for hepatitis C virus infection in Canada, Alison Marshall, PhD Candidate, Kirby Institute, UNSW
- Direct-acting antiviral therapy for HCV: the Australian model, Professor Greg Dore, Head, Viral Hepatitis Clinical Research Program, The Kirby Institute, UNSW Sydney
- Advocacy strategies for universal access to hepatitis C medicines, Helen Tyrrell, Chief Executive Officer, Hepatitis Australia
- Additional factors linked to the development of the Australian model, Professor Greg Dore, Head, Viral Hepatitis Clinical Research Program, The Kirby Institute, UNSW Sydney
- Questions for presenters, Professor Jason Grebely, Associate Professor, Viral Hepatitis Clinical Research Program, The Kirby Institute

Discussion - Reflections for Canada

- Dr. Alexandra King, MD, FRCPC, Lu’ma Medical Centre
- Adam Cook, Policy Researcher, Canadian Treatment Action Council
- Zoe Dodd, Co-Founder, Hepatitis C Program, South Riverdale Community Health Centre

Questions
A review of restrictions for reimbursement of direct-acting antiviral treatment for hepatitis C virus infection in Canada

Alison D. Marshall,1 Sahar Saeed,2 Lisa Barrett,3 Curtis L. Cooper,4 Carla Treloar,5 Julie Bruneau,6 Jordan J. Feld,7 Lesley Gallagher,8 Marina B. Klein,2 Mel Krajden,9 Naglaa H. Shoukry,6 Lynn E. Taylor,10 and Jason Grebely,1 on behalf of the Canadian Network on Hepatitis C (CanHepC)

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Background

- 2nd generation HCV DAAs: (SVR rates >90%),
- min. adverse events, shorter duration
- \(\downarrow\) Patient-level Tx barriers = \(\uparrow\) Tx uptake
- List price in Canada is prohibitive
  \(\sim\$60,000\) for 12 wk. course of LED/SOF
- Universal drug coverage = immense challenges
Background

• Barua et al. 2015 – Sofosbuvir Reimbursement Criteria

• Of 42 US states with available Medicaid data:
  • 74% requested advanced fibrosis (≥F3, METAVIR)
  • 88% had drug or alcohol use restrictions
  • 24% required HIV co-infected to be treated with ART or have suppressed HIV viral loads
  • 33% limited prescriber type to specialists

➢ Restrictions do not align with AASLD-IDSA, CASL or EASL guidelines
Medicaid criteria – Fibrosis stage restrictions

74% requested advanced fibrosis (≥F3)
Medicaid criteria – Drug or alcohol restrictions

88% had drug or alcohol use restrictions

pan-Canadian Pharmaceutical Alliance (pCPA)

• Previously the Pan-Canadian Pricing Alliance and the Generic Value Price Initiative

• Reviews completed by CDR or pCODR are considered

• pCPA holds negotiations with drug manufacturer
  • (led by ON)

• Letter of Intent signed

➢ Health ministry in each province/territory sets its own reimbursement criteria
Aims

• To appraise reimbursement criteria in Canada for:
  • simprevir w/PEG-IFN/RBV
  • sofosbuvir w/PEG-IFN/RBV or RBV ledipasvir-sofosbuvir
  • paritaprevir-ritonavir-ombitasvir plus dasabuvir w/ or w/o RBV

• Criteria for First Nations people and Inuit (NIHB Program) & federal prisoners (CSC) were also reviewed

➢ Hypothesis: Canada would have more consistent criteria across jurisdictions compared to the US
• Minimum fibrosis stage required
  • No restrictions; ≥F2; ≥F3; or F4, METAVIR or equivalent

• Drug and alcohol use restrictions
  • Yes/No

• HIV co-infection restrictions
  • Eligible/Ineligible

• Prescriber type restrictions
  • Specialist/GP
Methods – Data Collection & Analysis

- Provincial/territorial health ministerial websites
  - April 2015 to January 2016
  - Special authorization request forms; Drug formularies; Amendments to formularies; Drug Benefit Lists

- Two authors collected data; cross-checked the data; inconsistencies resolved through consensus

- Descriptive statistics used to demonstrate proportion of provinces/territories that restrict drug coverage by outcome
  [Excel; Map imagery with Tableau Software]
Results

- 82-92% of provinces/territories limit access to persons with moderate fibrosis (≥F2 METAVIR)
- There are no drug and alcohol use restrictions
- Quebec does not reimburse simeprevir or sofosbuvir for HIV co-infected persons; no restrictions in remaining jurisdictions
- Up to half (50%) restrict prescriber type to specialists only
- NIHB and CSC similar to remaining jurisdictions
Minimum fibrosis stage by HCV DAA

- **Simeprevir**: PE – n.a.
- **Sofosbuvir**: PE – n.a.
- **Ledipasvir-sofosbuvir**: PE – n.a.
- **Paritaprevir-ritonavir-ombitasvir plus dasabuvir**: PE – no restrictions
Discussion

• Less HCV DAA heterogeneity by jurisdiction than the US

• AASLD-ISDA does not prioritize by disease stage

• Tx across all disease stages is cost effective (CADTH review)

• National HCV Strategy in Canada

• Limitations:
  • Access to information; cannot speak to implementation; additional research
Acknowledgements

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Provincial/Territorial Ministries of Health

Student Scholarships
Direct-Acting Antiviral Therapy for HCV: the Australian model

Professor Greg Dore
Head, Viral Hepatitis Clinical Research Program, The Kirby Institute, UNSW Sydney
Epidemiology of HCV in Australia

230,000
Australians live with chronic HCV infection
bk2  can you verbalize the relative % of HCV patients who are aboriginal vs Western heritage?

Bruce Kreter, 12/1/2016
HCV care cascade in Australia: end 2015

- Living with chronic HCV: 227,310
- Diagnosed living with chronic HCV: 186,760
- Ever received HCV treatment: 50,170
- HCV cured: 32,140

- 82% of those living with chronic HCV were ever treated
- 22% of those ever treated achieved cure
- 14% of those cured
this is a very high diagnosis rate relative to rest of world - how was this accomplished, despite typically low numbers of patients receiving treatment?

Bruce Kreter, 12/1/2016

I will cover reasons for high diagnosis rate when I present.

Greg Dore, 12/2/2016
Chronic HCV liver disease burden

Estimates and projections of DC and HCC in Australia

Sievert W et al. JGH 2014
Key elements of Australian HCV strategy

- Development of National Hepatitis C Strategies since 2000
- Partnership approach, with involvement of government, community, clinical/peak body, and academic representatives
- Funding of national and state-based hepatitis C and drug user community organisations: pivotal voices in advocacy for “access to all”
- General practitioner and addiction medicine clinician education on hepatitis C from early 2000s
- Harm reduction approach for PWID since early 1990s
- Bipartisan support and political leadership
National Strategies and Partnership

Australian HCV strategy and treatment guidelines


Australia one of the first countries to make “access for all” public health policy

March 2015:
PBAC recommends funding of IFN-free DAA regimens ($AUD15,000/ICER)

May 2015:
“Access for all to highly effective HCV treatment a priority”

December 2015:
$AUD1 billion for HCV treatment over 5 years (2016-2020)
“a watershed moment”

Health Minister: Sussan Ley
Key features of Australian DAA Access

- Several DAA regimens subsidised since March 2016 (SOF/LDV, SOF/DCV, PrOD, EBR/GZR) with more to follow in 2017 (SOF/VEL)
- No restrictions based on liver disease stage or drug and alcohol use
- No cap on number of patients treated per year
- Risk-sharing arrangement with pharma, with capped annual expenditure
- Broad practitioner base: gastro/hepatology, ID, other specialists, and GPs; Public hospital (S100) and community pharmacy (S85) dispensed
- Retreatment (including for reinfections) allowed
- Co-payment: $6-36/month
HCV treatment in Australia: 1997-2016

Estimated = 14% chronic HCV
HCV treatment in Australia: DAA regimen

SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir; RBV: Ribavirin; PrOD: Parataprevir/ritonavir/Ombitasvir/Dasabuvir
HCV treatment in Australia: March–June 2016

The Kirby Institute 2016
Optimising HCV treatment uptake and impact

- Community awareness + enhanced screening
- PCP education and mentorship
- Enhanced drug and alcohol and prison-based HCV treatment
- Optimisation of OST and NSP coverage
- Access to retreatment for reinfection and virological failure
- Monitoring and evaluation
Monitoring and Evaluation of HCV Elimination

• **DAA scale-up**: Monitoring of DAA uptake, prescriber patterns, geographical coverage, treatment completion, and retreatment

• **REACH-C**: Real-world DAA treatment outcomes through national registry, including tertiary, primary, drug service, and prison clinics

• **Liver Disease burden**: Data linkage (NSW >100,000 HCV diagnoses) with hospitalisation (DC, HCC), cancer registry (HCC), death registry (liver disease and all-cause mortality), PBS (DAAs), and MBS (procedures).

• **Chronic HCV burden**: Annual Needle Syringe Program Survey (ANSPS) of 2,500 current PWID for HCV Ab/RNA; DAA resistance monitoring.

• **HCV transmission**: HCV notifications (acute, younger age); reinfection (ANSPS, post-treatment longitudinal cohort studies in community and prison settings)
do you have a numerical model to measure your progress against disease burden reduction (DCC, HCC, OLT) as modeled in slide #4?
Bruce Kreter, 12/1/2016

Yes, the data linkage project will provide this data, through linkage with hospitalisation datasets, and reimbursed procedural datasets.
Greg Dore, 12/2/2016
ADVOCACY STRATEGIES FOR UNIVERSAL ACCESS TO HEPATITIS C MEDICINES

Helen Tyrrell, CEO, Hepatitis Australia
February 2017
FOUNDATIONS FOR EFFECTIVE ADVOCACY

Longstanding National Partnership Approach:
✓ The hepatitis community sector is a respected and key partner in the national response to viral hepatitis alongside government, clinicians, and research institutes.
✓ Government actively seeks advice and input from Hepatitis Australia and other community organisations
✓ Involved in the formulation of national strategies and all other major national policies

Longstanding Political Engagement:
✓ Parliamentary Liaison Committee
✓ Hepatitis C Parliamentary Inquiry
✓ Individual relationships built with key politicians and their advisors
IN THE BEGINNING

The consensus was that the price was too high to make the hep C medicines available to everyone, everywhere in Australia.

Many people told us we had no hope of achieving universal access - no other country had achieved this.

We were told it was an admirable but unrealistic goal.

We heard many clinicians present arguments for priority treatment access for individual segments of the hep C population.
Universal access is a prerequisite for elimination of hepatitis C

- Eligibility: for everyone with hep C who has a Medicare Card
- Cost: a small co-payment for prescriptions ($38.80 or $6.30)
- Treatment cap: None
- Prescribers
  - Hospital based specialists
  - Community based GPs
CHANGING THE NARRATIVE FROM PRICE TO VALUE

WORLD HEPATITIS DAY
JULY 2014

Presenting the facts and highlighting the need for immediate action to avert a liver disease crisis.

PARLIAMENTARY MEETING
SEPTEMBER 2014

Presenting the case to fund the new hepatitis C medicines to Parliamentarians.
SPEAKING OUT - MOBILISATION
MOBILISATION – USING SOCIAL MEDIA

#TimeForAction
TO INCREASE HEPATITIS TREATMENT RATES
TIME FOR NEW HEP C CURES

It’s a signature moment, Minister!
TIME FOR NEW HEP C CURES

One signature ... thousands of lives changed forever
TIME FOR NEW HEP C CURES

Sign now to make hep C history
TIME FOR NEW HEP C CURES
PARTNERSHIPS - OPEN LETTER TO THE MINISTER

24 September 2018
The Hon. Susan Ley MP
Minister for Health
House of Representatives
Parliament House
Canberra ACT 2600
Dear Minister,

Time for New Cure - Time to list new hepatitis C medicines

It is rare that a government has the power to change the course of an epidemic but that is the historic opportunity available to you and your colleagues.

Australia is at a crossroads. Down one path lies escalating rates of liver disease and death. Down the other, there is an opportunity to make hepatitis C a rare condition in our lifetime.

The twenty-one organisations which are signatories to this letter acknowledge your commitment to respond to the needs of healthcare consumers and reintroduce new therapies that treat conditions ranging from cancer to eye disease. As such, we urge you to expedite price negotiations and confirm the addition of the new breakthrough hepatitis C medicines on the Pharmaceutical Benefits Scheme without delay.

These new treatments cure hepatitis C and represent a milestone for many people. Yet, despite being recommended by the Pharmaceutical Benefits Advisory Committee six months ago, these medicines are still awaiting consideration by the Federal Cabinet.

With exceptionally high cure rates, shorter treatment duration and fewer side-effects than existing therapies, interferon-free medicines hold the key to preventing liver cirrhosis, liver cancer and liver failure – not to mention halting the rising death toll associated with untreated hepatitis C.

As you know, treatment rates remain lamentably low. Only one per cent of the 220,000 Australians living with hepatitis C are treated each year. This puts thousands at risk of progressing to serious liver disease.

Of further concern are reports by liver clinics that hepatitis C treatment rates have plummeted again as more and more people find themselves in a treatment trap.

Sadly, Australia can no longer regard itself the “lucky country” – not when people with hepatitis C are being cured around the globe. From the United States and Great Britain to Spain and Italy, increasingly desperate Australians are being forced to travel overseas, or take the risky course of importing medicines because these new therapies remain unaffordable in Australia.

Minister, it’s time for action. It’s time for you to intervene and bring the Department, the pharmaceutical companies and the Cabinet together to deliver the cure for which so many Australians are desperately waiting.

We implore you to embrace a new treatment era, to confirm a PBS listing date and make 2018 a watershed year in the fight against hepatitis C.

Yours faithfully,

Melan Syme - CEO, Hepatitis Australia

On behalf of the twenty-one organisations listed below.

- Aboriginal Skills Group
- Anglicare - Tasmania
- Australian Federation of AIDS organisations
- Australian Hepatitis Association
- Australian Liver Foundation
- Cancer Council
- Centre for Infectious Diseases
- Centre for Social Research in Health
- Countermeasures Society of Australia
- Hepatitis Education Program
- Hepatitis Foundation Australia
- Hepatitis Australia
- Hepatitis ACT
- Hepatitis NSW
- Hepatitis Queensland
- Hepatitis SA
- Hepatitis Vic
- Hepatitis WA
- National Aboriginal Community Controlled Health Organisation
- National Association of People with HIV Australia
- Northern Territory AIDS and Hepatitis Council
- Penrith Institute
- Peter Doherty Institute for Infection and Immunity
- Singles SA
- South Australian Council on AIDS, Hepatitis and Related Diseases
- Uniting Care Wesley - Port Adelaide
- Uniting Communities

C.c. Senator the Hon. Peta Rona, Minister for Rural Health
Senator the Hon. Ken Wyatt, Assistant Minister for Health

hepatitis
australia
MEDIA - SNAPSHOT JULY TO DECEMBER 2015

• Time for Action to prevent lives lost to viral hepatitis - July
• Recommendations alone will not avert a liver disease epidemic - August
• Tragic cost of delaying access to new cures revealed - September
• Government’s proud record of subsidising medicines must apply to new hep C cures - September
• New medicines ‘pay for themselves’ but too many Aussies denied access – new analysis – November
• Innovation, Prime Minister, Yes Please! - December
Innovation, Prime Minister? Yes Please!

“Today should have been the day when Australia listed four of the most innovative medicines ever developed for the benefit of Australians living with hepatitis C. But despite PBAC recommendations that date back to March a timeframe for their listing remains entirely unknown…..”

“We have no doubt that the Prime Minister and Federal Health Minister believe in innovation and are committed to improving the health of Australians. The Prime Minister has met with one of his own constituents who is living with hepatitis C, so he understands the desperate need for access to a cure…….”
ANNOUNCEMENT - 20 DECEMBER 2015

A One Billion Dollar Investment
in Hepatitis C Treatment over 5 Years!

Health Minister
Hon. Sussan Ley MP

Prime Minister
Hon. Malcolm Turnbull
## UNIVERSAL (BUT LATE) ACCESS

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Availability in Australia</th>
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<tr>
<td><strong>Sovaldi</strong> (sofosbuvir)</td>
<td>27 Months after FDA approval in December 2013 to PBS listing in March 16</td>
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<tr>
<td><strong>Harvoni</strong> (ledipasvir + sofosbuvir)</td>
<td>17 months after FDA approval in October 2014 to PBS listing in March 2016</td>
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<tr>
<td><strong>Daklinza</strong> (daclatasvir)</td>
<td>7 months after FDA approval in July 2015 to PBS approval in March 2016</td>
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<tr>
<td><strong>VieKira Pak (+/- RBV)</strong> (paritaprevir/ritonavir/ombitasvir, and dasabuvir)</td>
<td>17 months after FDA approval in December 2014 to PBS listing in May 2016</td>
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“We have made a $1 billion investment to fund revolutionary new treatments to cure Hepatitis C, which have been available on the PBS since the start of March. Australia is one of the first countries in the world to publicly subsidise these medicines for the nation’s entire population of Hepatitis C sufferers, no matter what their condition or how they contracted it, with broad access through both specialists and primary care”.
Minister Ley 15 March 2016
ALIGNMENT OF THE STARS?

- Set your expectations high
- Convincing stats and facts
- Community voices
- Collaborations
- Media engagement
- Timing
- Politicians willing to listen and act
ADDITIONAL FACTORS LINKED TO THE DEVELOPMENT OF THE AUSTRALIAN MODEL

Professor Greg Dore
Head, Viral Hepatitis Clinical Research Program, The Kirby Institute, UNSW Sydney
QUESTIONs FOR PRESENTERS

Professor Jason Grebely
Associate Professor, Viral Hepatitis Clinical Research Program, Kirby Institute
Discussion: Reflections for Canada

Dr. Alexandra King
MD, FRCPC
Lu’ma Medical Centre

Adam Cook
Policy Researcher, Canadian Treatment Action Council

Zoe Dodd
Co-Founder
Hepatitis C Program,
South Riverdale Community Health Centre
TRC Calls to Action – December 2015

“We will, in partnership with Indigenous communities, the provinces, territories, and other vital partners, fully implement the Calls to Action of the Truth and Reconciliation Commission, starting with the implementation of the United Nations Declaration on the Rights of Indigenous Peoples.”

PM Trudeau
UN Declaration on the Rights of Indigenous Peoples

Article 24:

- Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, all social and health services.

- Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health. States shall take the necessary steps, with a view to achieving progressively the full realization of this right.
We call upon the federal government, in consultation with Aboriginal peoples, to establish measurable goals to identify and close the gaps in health outcomes between Aboriginal and non-Aboriginal communities, and to publish annual progress reports and assess long-term trends. Such efforts would focus on indicators such as: infant mortality, maternal health, suicide, mental health, addictions, life expectancy, birth rates, infant and child health issues, chronic diseases, illness and injury incidence, and the availability of appropriate health services.
22. We call upon those who can effect change within the Canadian health-care system to recognize the value of Aboriginal healing practices and use them in the treatment of Aboriginal patients in collaboration with Aboriginal healers and Elders where requested by Aboriginal patients.

23. We call upon all levels of government to:
   i. Increase the number of Aboriginal professionals working in the health-care field.
   ii. Ensure the retention of Aboriginal health-care providers in Aboriginal communities.
   iii. Provide cultural competency training for all health-care professionals.
Other Questions
Please evaluate this webinar.

Thank you!