CATIE

Canada's source for HIV and hepatitis C information

La source canadienne de renseignements sur le VIH et l'hépatite C

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

CanHepC
Canadian Network on Hepatitis C
Réseau Canadien sur l'Hépatite C

The Kirby Institute
for infection and immunity in society
UNSW MEDICINE

CTAC

Please make sure you access the audio portion:
Toll-free access number: 1-866-500-7712
Access code: 6527797

The webinar will commence shortly.

All participants will be muted until the question period.

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

CMAJ Open 2016.
DOI:10.9778/cmajo.20160008

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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[7]University of Toronto, Toronto, Canada
[8]Vancouver Coastal Health, Vancouver, Canada
[9]BC Centre for Disease Control, Vancouver, Canada
[10]Department of Medicine, Brown University, Providence, United States

Background

- 2nd generation HCV DAAs: (SVR rates >90%),
- min. adverse events, shorter duration
- ↓ Patient-level Tx barriers = ↑ Tx uptake
- List price in Canada is prohibitive

  ~$60,000 for 12 wk. course of LED/SOF

- Universal drug coverage = immense challenges

Background

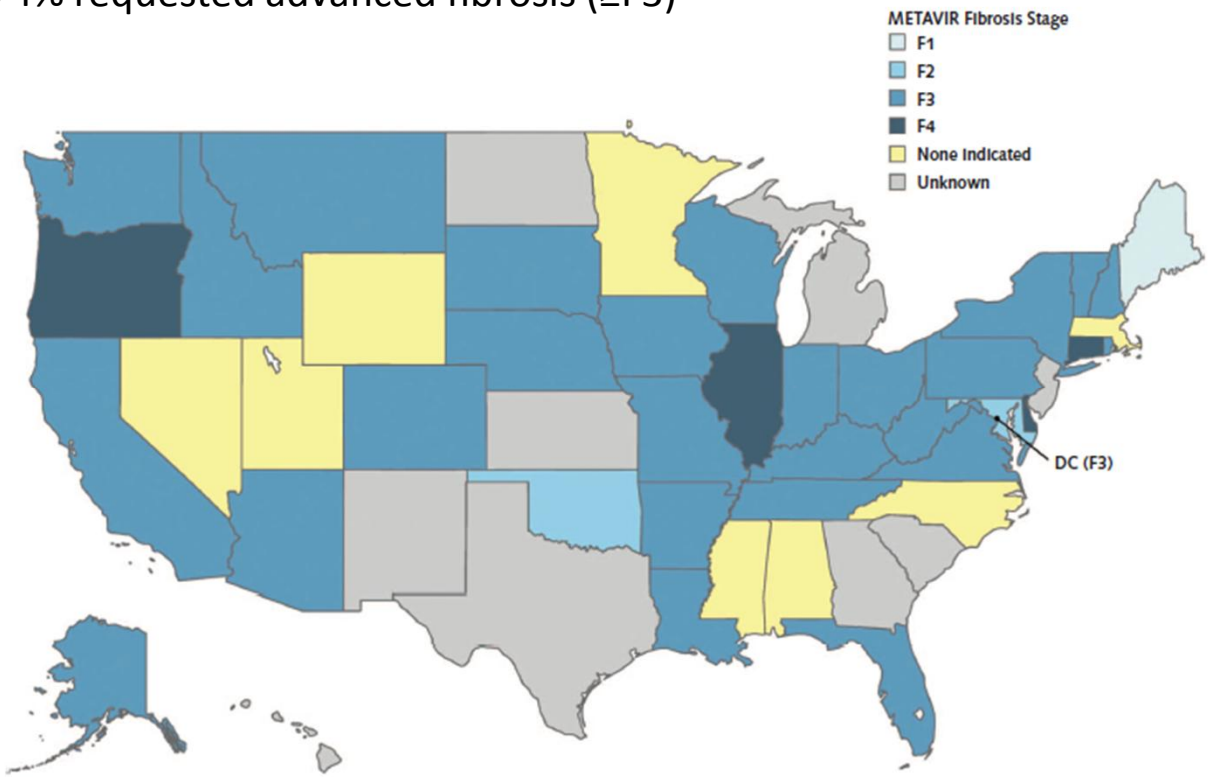
- Barua et al. 2015 – Sofosbuvir Reimbursement Criteria
- Of 42 US states with available Medicaid data:
  - 74% requested advanced fibrosis (≥F3, METAVIR)
  - 88% had drug or alcohol use restrictions
  - 24% required HIV co-infected to be treated with ART or have suppressed HIV viral loads
  - 33% limited prescriber type to specialists

➢ Restrictions do not align with AASLD-IDSA, CASL or EASL guidelines

Barua, S et al. Ann Intern Med. 2015.

Medicaid criteria – Fibrosis stage restrictions

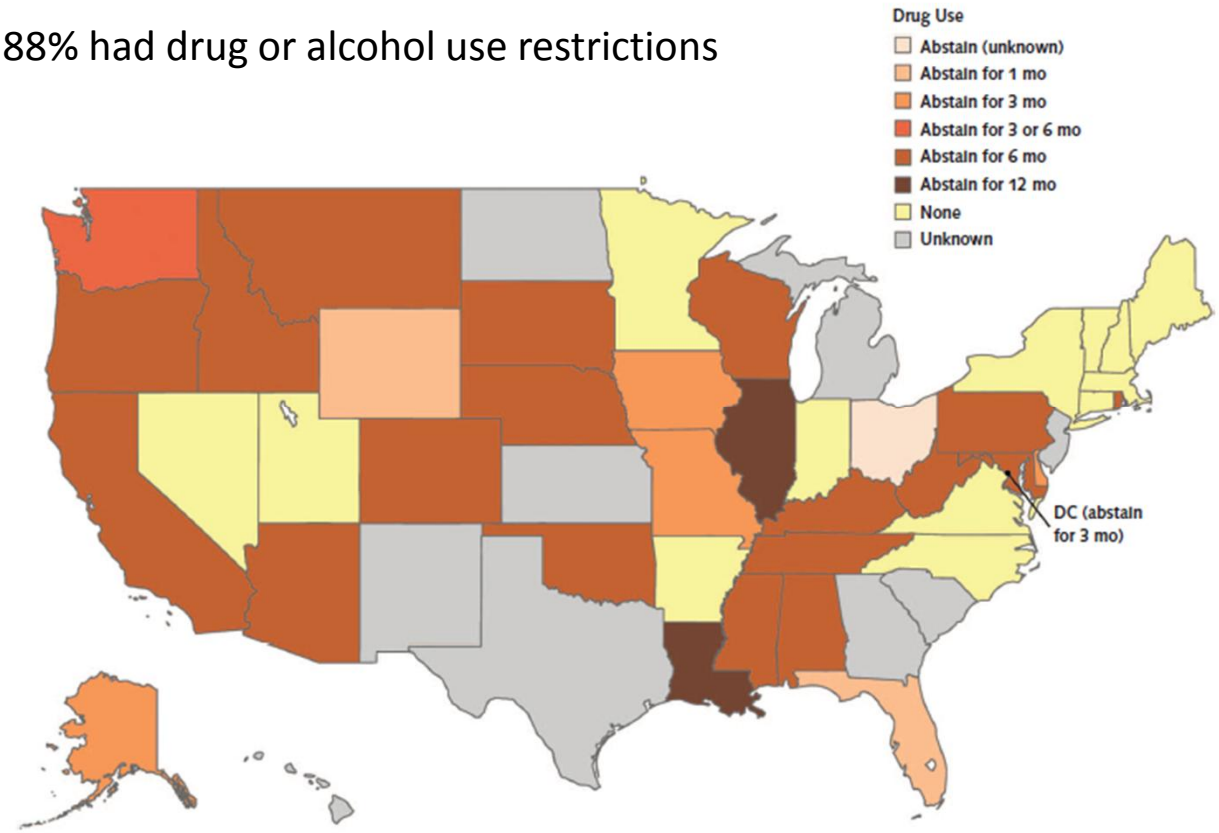
74% requested advanced fibrosis (≥F3)



Barua, S et al. Ann Intern Med. 2015

Medicaid criteria – Drug or alcohol restrictions

88% had drug or alcohol use restrictions



Barua, S et al. Ann Intern Med. 2015.

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

http://canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance

Aims

- To appraise reimbursement criteria in Canada for:
- simeprevir 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

➢ <u>Hypothesis:</u> Canada would have more consistent criteria across jurisdictions compared to the US

Methods – Primary Outcomes

- 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

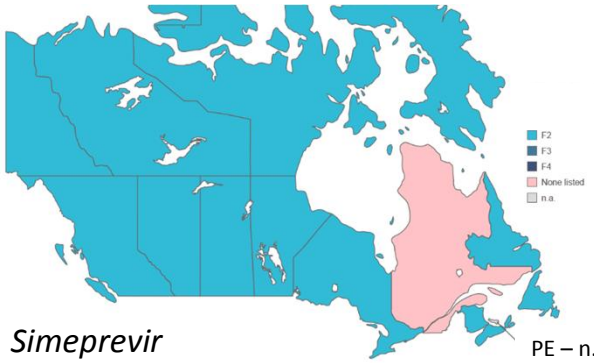
- Two authors collected data; cross-checked the data; inconsistencies resolved through consensus

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

Results

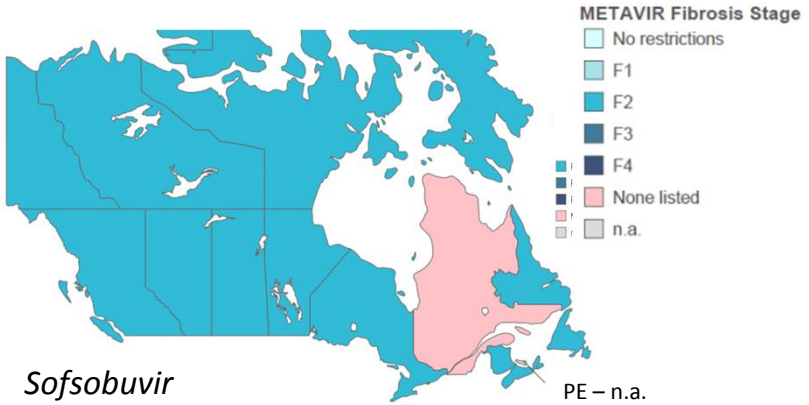
- 82-92% of provinces/territories limit access to persons with moderate fibrosis (≥F2 METAVIR)
- There are no drug and alcohol use restrictions
- Quebec does not reimburse simeprevir or sofosbuvir for HIV co-infected persons; no restrictions in remaining jurisdictions
- Up to half (50%) restrict prescriber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

Minimum fibrosis stage by HCV DAA



Simeprevir

PE – n.a.

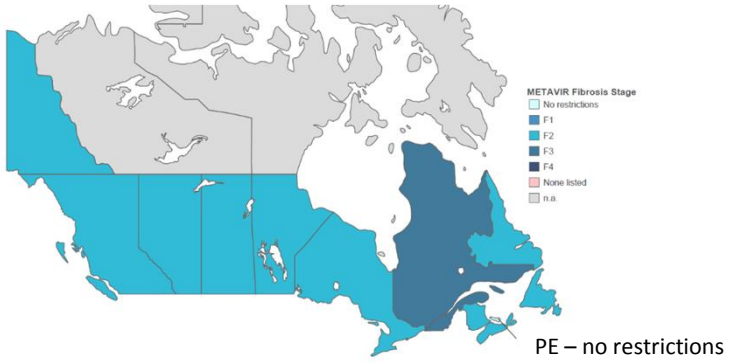


Sofsobuvir

PE – n.a.

PE – n.a.

Ledipasvir-sofsobuvir



PE – no restrictions

Paritaprevir-ritonavir-ombitasvir plus dasabuvir

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

Drugs for Chronic Hepatitis C Infection: Recommendations Report. CADTH Therapeutic Review. November 2015. Available from: https://www.cadth.ca/sites/default/files/pdf/TR0008_HepatitisC_RecsReport_e.pdf

Acknowledgements

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Carla Treloar
Greg Dore

Provincial/Territorial Ministries of Health

Student Scholarships

Direct-Acting Antiviral Therapy for HCV: the Australian model

Professor Greg Dore

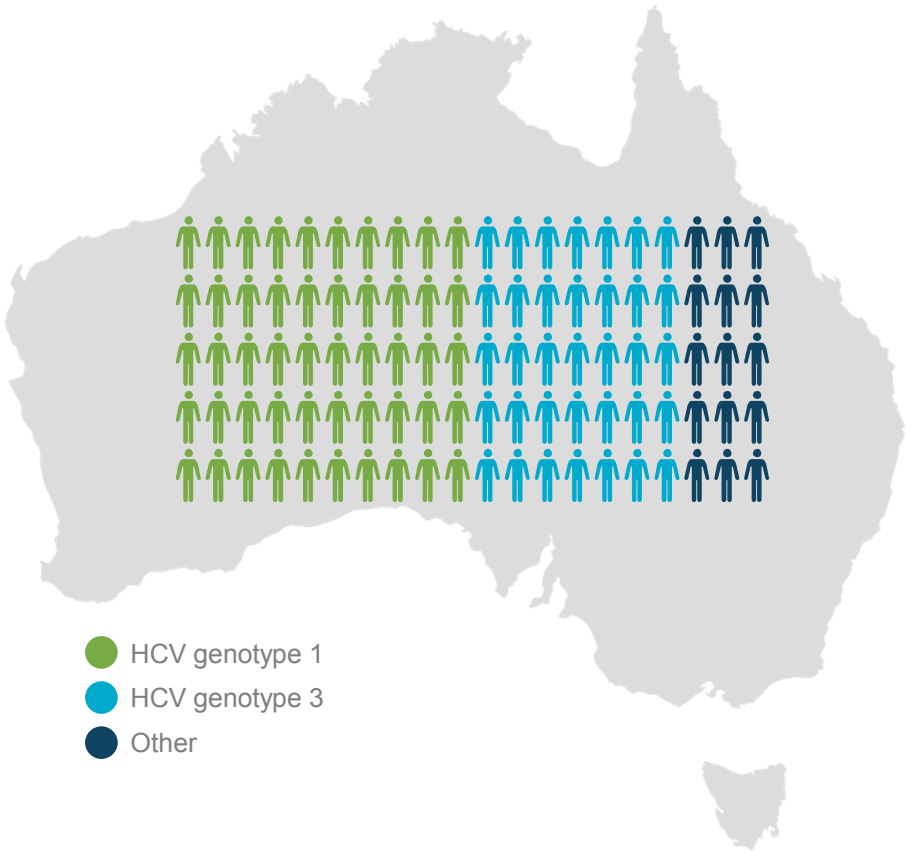
Head, Viral Hepatitis Clinical Research Program,
The Kirby Institute, UNSW Sydney

bk2

Epidemiology of HCV in Australia

230,000

Australians live with chronic HCV infection

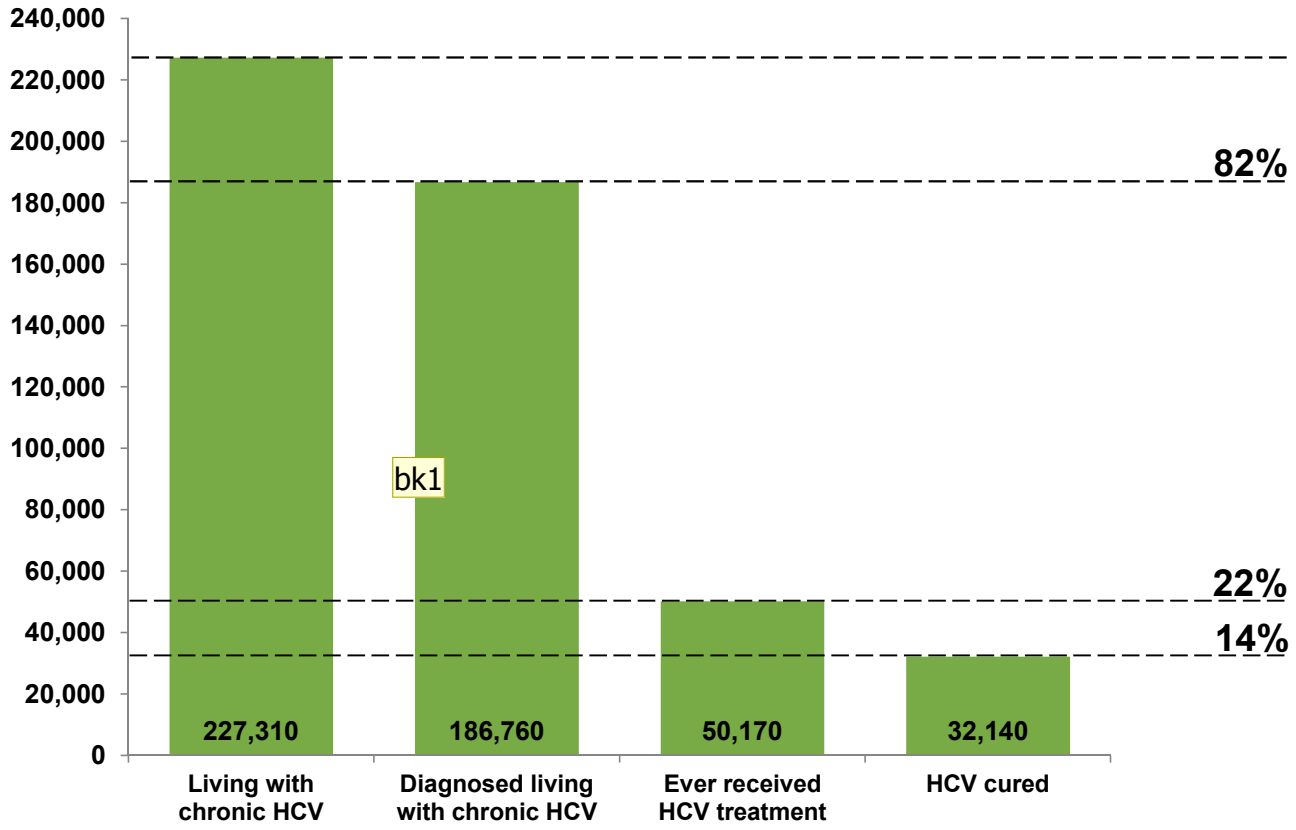


Slide 17

bk2 can you verbalize the relative % of HCV patients who are aboriginal vs Western heritage?
Bruce Kreter, 12/1/2016

GD1

HCV care cascade in Australia: end 2015



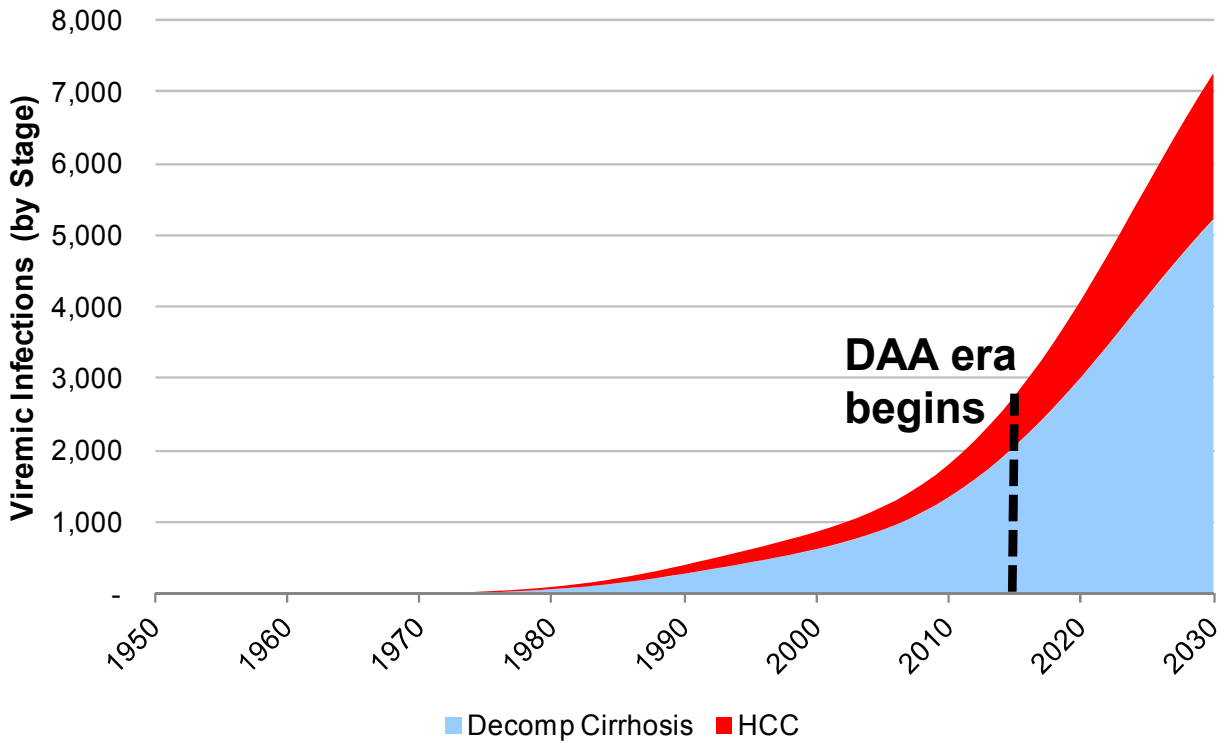
Slide 18

bk1 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

GD1 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



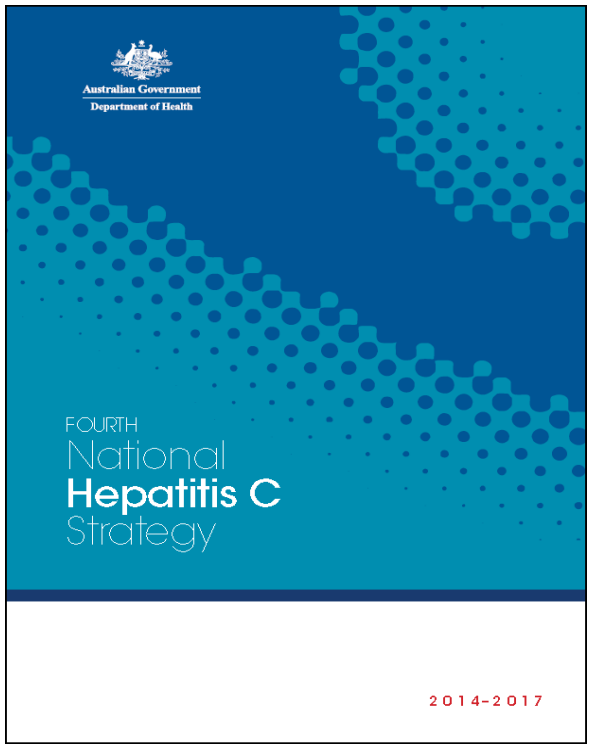
Sievert W et al. JGH 2014

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



http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-hepc (Accessed July 2016)

https://www.asid.net.au/documents/item/1208 (Accessed July 2016)

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

Health Minister: Sussan Ley

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

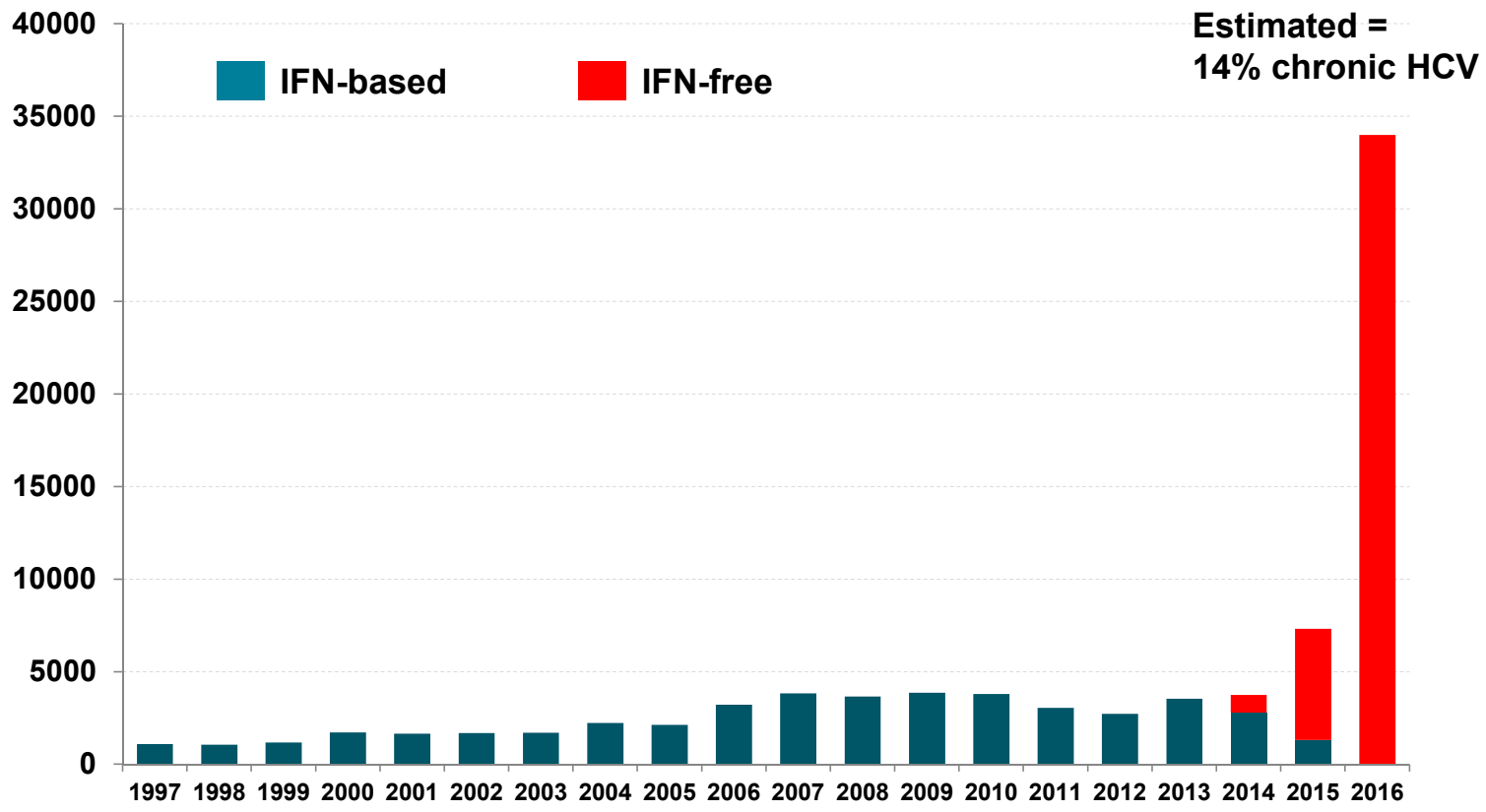
May 2015:
"Access for all to highly effective HCV treatment a priority"

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

Key features of Australian DAA Access

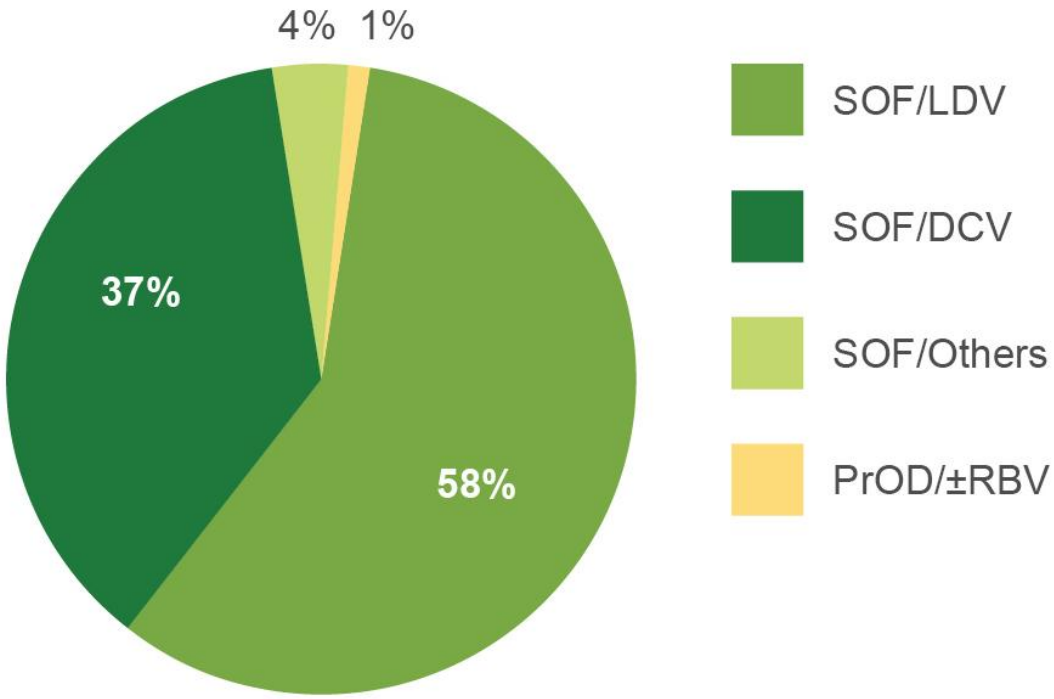
- Several DAA regimens subsidised since March 2016 (SOF/LDV, SOF/DCV, PrOD, EBR/GZR) with more to follow in 2017 (SOF/VEL)
- No restrictions based on liver disease stage or drug and alcohol use
- No cap on number of patients treated per year
- Risk-sharing arrangement with pharma, with capped annual 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



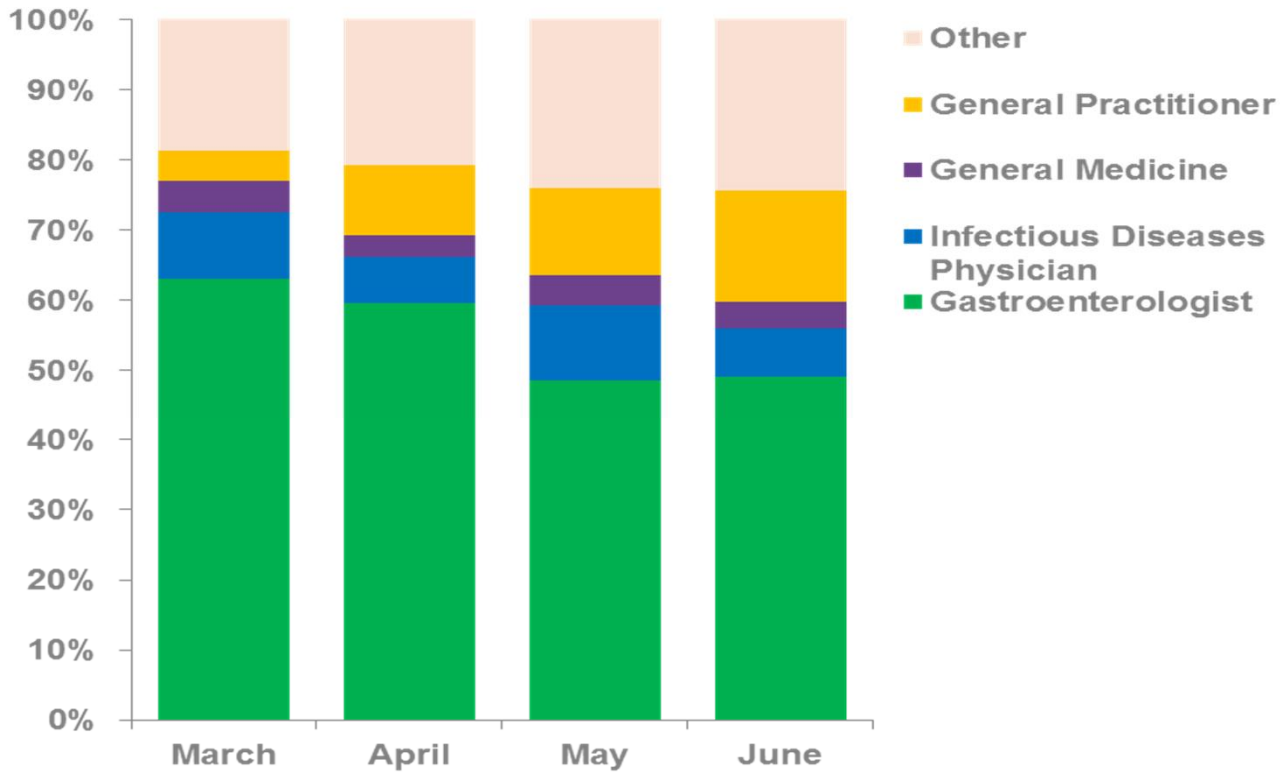
Hajarizadeh B, et al. J Gastro Hepatol 2016 [updated]

HCV treatment in Australia: DAA regimen



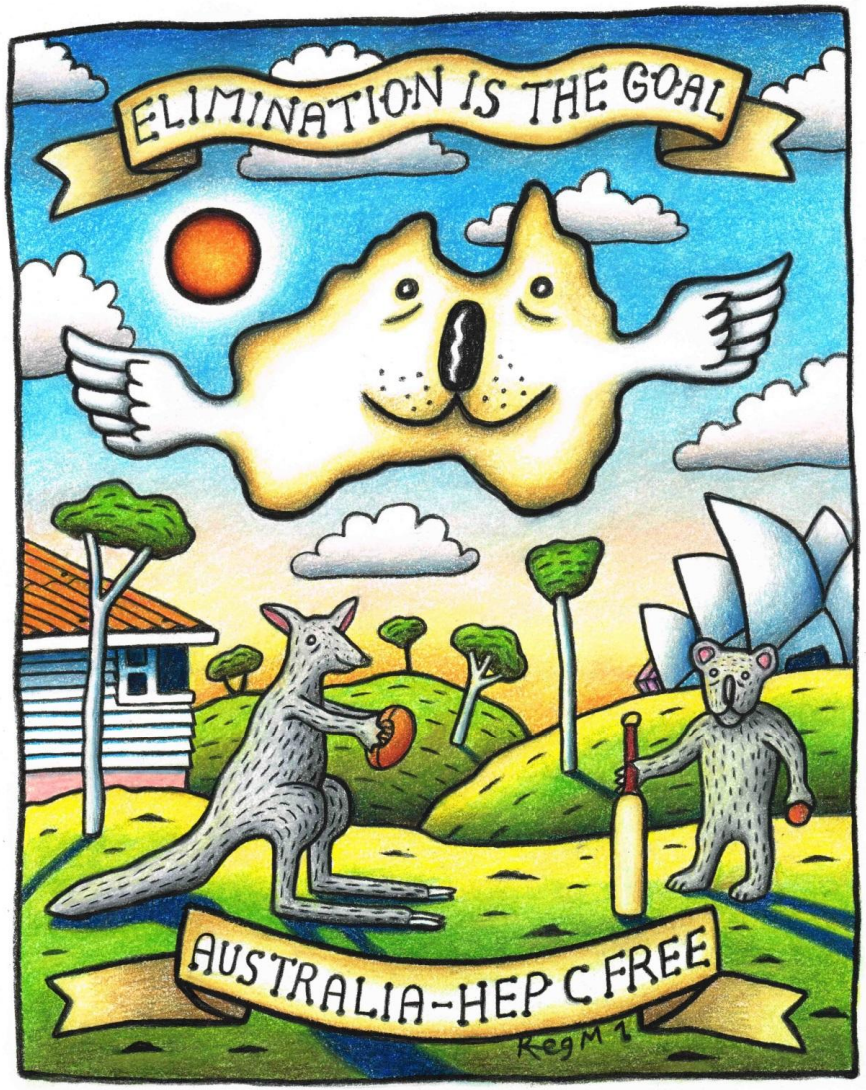
SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir; RBV: Ribavirin; PrOD: Parataprevir/ritonavir/Ombitasvir/Dasabuvir

HCV treatment in Australia: March–June 2016



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


ELIMINATION IS THE GOAL
AUSTRALIA-HEP C FREE
RegM 1

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)

Slide 29

bk6 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

GD4 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

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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.

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SETTING THE ADVOCACY GOAL – BEGINNING WITH THE END IN MIND

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

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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.

liver danger zone

PARLIAMENTARY MEETING
SEPTEMBER 2014

Presenting the case
to fund the new hepatitis C
medicines to Parliamentarians.

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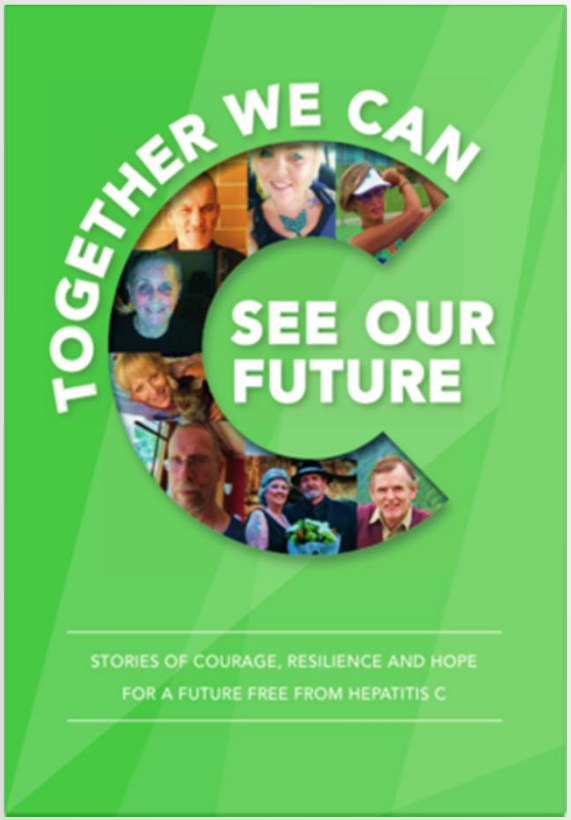
SPEAKING OUT - MOBILISATION



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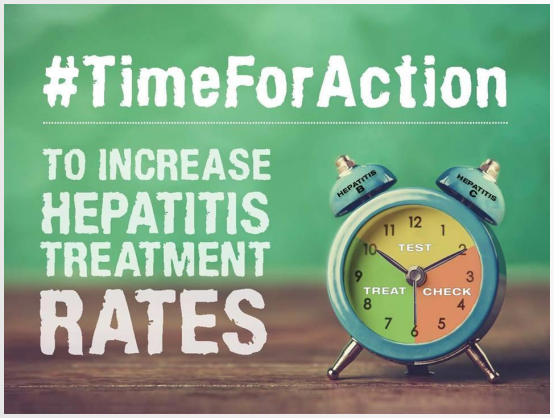
MOBILISATION – USING SOCIAL MEDIA



PARTNERSHIPS - OPEN LETTER TO THE MINISTER

24 September 2015

The Hon. Sussan Ley MP
Minister for Health
House of Representatives
Parliament House
Canberra ACT 2600

Dear Minister,

Time for New Cures – 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-seven organisations which are signatories to this letter acknowledge your commitment to respond to the needs of healthcare consumers and reimburse 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 lifeline 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 230,500 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 clinic staff that hepatitis C treatment rates have plummeted again as more and more people find themselves in a treatment limbo.

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 Egypt and India. 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 cures 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 2015 a watershed year in the fight against hepatitis C.

Yours faithfully,

Helen Tyrrell - CEO Hepatitis Australia

On behalf of the twenty-seven organisations listed below.

- Aboriginal Sobriety Group
- Anglicare – Tasmania
- Australian Federation of AIDS organisations.
- Australian Hepatology Association
- Australian Injecting & Illicit Drug Users League (AIVL)
- Australian Research Centre in Sex Health & Society
- Australasian Society for Infectious Diseases
- Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
- Centre for Social Research in Health
- Gastroenterological Society of Australia including the Australian Liver Association
- Haemophilia Foundation Australia
- Hepatitis Australia
- Hepatitis ACT
- Hepatitis NSW
- Hepatitis Queensland
- Hepatitis SA
- Hepatitis Victoria
- Hepatitis WA
- National Aboriginal Community Controlled Health Organisation
- National Association of People with HIV Australia.
- Northern Territory AIDS and Hepatitis Council
- Penington Institute
- Peter Doherty Institute for Infection and Immunity
- SHine SA
- Tasmanian Council on AIDS, Hepatitis and Related Diseases
- Uniting Care Wesley – Port Adelaide
- Uniting Communities

c.c.
Senator the Hon Fiona Nash, Minister for Rural Health
Senator the Hon Ken Wyatt, Assistant Minister for Health

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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**

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OPINION EDITORIAL - 1 DECEMBER 2015

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……"

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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

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UNIVERSAL (BUT LATE) ACCESS

Medicine	Availability in Australia
Sovaldi (sofosbuvir)	**27 Months** after FDA approval in December 2013 to PBS listing in March 16
Harvoni (ledipasvir+ + sofosbuvir)	**17 months** after FDA approval in October 2014 to PBS listing in March 2016
Daklinza (daclatasvir)	**7 months** after FDA approval in July 2015 to PBS approval in March 2016
VieKira Pak (+/- RBV) (paritaprevir/ritonavir /ombitasvir, and dasabuvir)	**17 months** after FDA approval in December 2014 to PBS listing in May 2016

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TREATMENT ACCESS – SINCE 1 MARCH 2016

OLD TREATMENT IN 2014	NEW TREATMENT IN 2016
2,790 people treated **For the whole year (1%)**	Est **26,360** people initiated on DAA treatment **March to July 2016 (12%)**

"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

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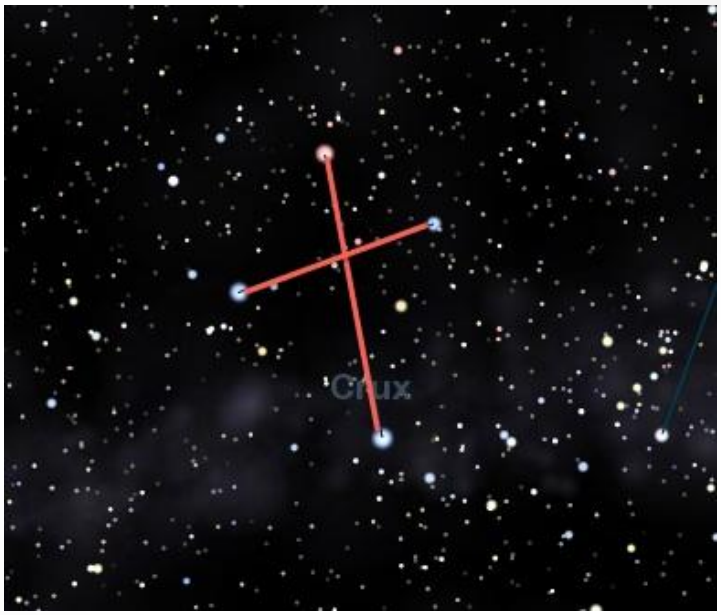
ALIGNMENT OF THE STARS?

- Set your expectations high
- Convincing stats and facts
- Community voices
- Collaborations
- Media engagement
- Timing
- Politicians willing to listen and act



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ADDITIONAL FACTORS LINKED TO THE DEVELOPMENT OF THE AUSTRALIAN MODEL

Professor Greg Dore

Head, Viral Hepatitis Clinical Research Program, The Kirby Institute, UNSW Sydney

Kirby Institute

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.

TRC Calls to Action #19

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.

TRC Calls to Action

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!

CATIE