Delivering HCV care to PWID: We know that DAA therapies are effective, now what?
Associate Professor Jason Grebely
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Disclosures

- Funding and speaker fees from AbbVie, Bristol-Myers Squibb, Cepheid, Gilead Sciences and Merck

- This presentation will include the discussion of the investigative use of medical devices (Xpert HCV Viral Load, Cepheid)
HCV DAA therapy, reinfection, and elimination among PWID

- DAA therapy is safe and effective among PWID, even in the “real-world”
- We need to acknowledge and accept that HCV reinfection will occur
- Testing, diagnosis, and linkage to care will be a major barrier moving forward
- Simplification of models of care and interventions will be crucial to achieve HCV elimination among PWID
- Remaining challenges for HCV elimination in PWID

DAA therapy is safe and effective among PWID, even in the “real-world”
Defining populations of PWID

People receiving OST – phase II/III trials

SVR12 among former/recent PWID

Lost to follow-up post-treatment in the “real-world”
Recent PWID – The SIMPLIFY Study (SOF/VEL)

- 100% injecting in past 6 months, 35% G1a, 58% G1, 9% cirrhosis, DAA-treatment naïve
- No virological failures, no viral relapse, 1 case of reinfection

We need to acknowledge and accept that HCV reinfection will occur
What is the risk of HCV reinfection following therapy?

Specific issues on HCV reinfection for PWID

- **Acknowledgement**: there will be cases of HCV reinfection; if there are no cases, it is not a current PWID population
- **Harm reduction optimisation (NSP, OST access)**: HCV reinfection incidence will reflect HCV incidence in the setting
- **Rapid scale-up**: a slow scale-up will create HCV “susceptible” PWID without reduction in viraemic pool
- **Individual-level strategies**: treatment of injecting partners crucial
- **Access to re-treatment**: without stigma and discrimination
- **Community engagement and partnership**: use of peer workers
Testing, diagnosis, and linkage to care will be a major barrier moving forward

HCV care cascade among PWID (IFN-era)

Advances in diagnostics and point-of-care testing

Rapid diagnostic tests
Dried blood spot testing
Point of care and random access HCV RNA testing

Finger-stick testing for HCV RNA detection

- Relatively easy-to-use point-of-care HCV RNA test – GeneXpert in many LMIC
- Real-world performance for HCV RNA quantification very good
  - Venepuncture HCV Viral Load – Sensitivity 99%, Sensitivity 96%¹
  - Modified finger-stick assay – Sensitivity 98%, Sensitivity 99%²
  - Xpert® HCV Viral Load Fingerstick - Sensitivity 100%, Sensitivity 100%³
- One step closer to a single-visit diagnosis (needs to be more “rapid”)
Moving to a single-visit hepatitis C diagnosis

Simplification of models of care and interventions will be crucial to achieve HCV elimination among PWID
**What is a model of care?**

**WHERE**
- Hospitals

**WHAT**
- Stethoscope

**WHO**
- Practitioner

**HOW**
- Doctor

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**Settings, services, and providers**

**Settings**
- Sexual health
- Drug and alcohol clinics
- Primary health care / GPs
- Prisons

**Services**
- NSP services
- Community health centres

**Providers**
- Task-shifting
  - Specialists
  - Drug and alcohol specialist
  - Primary care providers
  - Nurses
  - Peer support workers
  - Others
### Need to move towards simplified models of HCV care

- Many programs for HCV treatment are built upon interferon-era
- Need to move towards simplification of existing models
- Not at the expense of strengthening foundation for drug user health

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Remaining challenges for HCV elimination in PWID
The burden of HCV among PWID is considerable

- 8.2M (4.7-12.4) PWID are HCV antibody positive (52%)
- 4 countries account for 51% of burden (Russia, United States, China, and Brazil)

Harm reduction services remain inadequate

Reimbursement restrictions must be removed

17% drug/alcohol use  46% >F2 (advanced disease)  94% specialist prescribing

Key features of Australian DAA access

• Several DAA regimens subsidised since March 2016
• 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: $AUS 7-38/month
HCV treatment in Australia: 1997-2017


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IFN-free DAA = 61,085 (26% chronic HCV)

* extrapolated


Australia – Treatment among PWID

Annual Needle Syringe Program Survey (n=2,500):

HCV treatment among chronic HCV (%)

HCV RNA+ (%)

Iversen J, et al. INHSU 2017, New York, United States, September 6-8, 2017
HCV treatment in Australia: Prescriber type

Kirby Institute 2017 (http://kirby.unsw.edu.au/research-programs/vhcrp-newsletters)

Task shifting to community-based non-specialist providers

- Three hour education and training
- Overall SVR12 following sofosbuvir/ledipasvir was 87%
- No difference by provider type: NPs, 90%; PCPs, 88%; and specialists, 85%

Provider | SVR Rate | Patients With SVR/Total Patients, n/W | SVR Rate (95%CI)
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NPs | | | |
NP 1 | 0.77 | 33/43 | |
NP 2 | 1.00 | 12/12 | |
NP 3 | 0.80 | 4/5 | |
NP 4 | 1.00 | 30/30 | |
NP 5 | 0.92 | 55/60 | |
PCPs | | | |
PCP 1 | 0.75 | 24/32 | |
PCP 2 | 1.00 | 19/19 | |
PCP 3 | 0.88 | 43/49 | |
PCP 4 | 0.88 | 21/24 | |
PCP 5 | 0.89 | 32/36 | |
Specialists | | | |
Specialist 1 | 0.77 | 47/61 | |
Specialist 2 | 0.85 | 50/59 | |
Specialist 3 | 0.89 | 34/38 | |
Specialist 4 | 0.76 | 13/17 | |
Specialist 5 | 0.84 | 30/37 | |
Specialist 6 | 0.82 | 64/78 | |

Key populations for HCV elimination efforts

- Former PWID: N=180,000 with chronic HCV
- Current PWID: N=38,000 with chronic HCV
- PWID in OST: N=24,000 with chronic HCV
- Prisoners: N=40,000, Chronic HCV 25%, N=10,000

Remaining challenges for HCV elimination among PWID

- Further work is needed to address drug user health for PWID
- Continue to address stigma, discrimination, and HCV awareness
- Further simplification of testing and treatment
- One size will not fit all – different settings will require different interventions
- Continue to engage people in care other than HCV
Remaining challenges for HCV elimination among PWID

- Need to remove disease-stage reimbursement restrictions (double restriction)
- Task shifting to community-based non-specialist providers
- Education and training of providers and front-line workers
- Reinfection needs to be acknowledged and accepted
- Low and middle-income country setting (cost of testing, treatment, barriers)
- Act regionally, but think globally (micro-elimination)

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