Eliminating HCV in vulnerable populations:

advances from the 12th Australasian Viral Hepatitis conference

With the emergence of new therapies that have transformed chronic HCV treatment, public health experts now believe it is possible to eliminate the disease. The 12th Australasian Viral Hepatitis conference, held virtually and at hubs in Brisbane and Sydney from 30 May to 1 June 2021, focused on progress towards hepatitis elimination targets, taking stock and innovating for the future. This article summarises key advances from the conference in eliminating HCV in vulnerable populations, including innovations in screening, enhanced linkage to care and the latest developments in treatment.

The presentations chosen for inclusion in this article were carefully selected by Gilead Sciences and not representative of the broad range of presentations given at the conference. Studies supported by Gilead in this article through the CheckCureControl (CCC) program or via other research programs are identified in the text below.

Check **Cure** **Control**

To find out how Gilead can help support point-of-care testing (POCT) for HCV at your clinic through the CCC program, please contact Medical Affairs for more information (1800 806 112 within Australia or +61 3 9272 4400 outside Australia).

Gilead is committed to creating a healthier world for everyone – no matter the challenges ahead of us. Gilead acknowledges and thanks the people with lived experienced of viral hepatitis who have generously agreed to participate in the research initiatives and community projects discussed in this article.

HCV elimination in Australian prisons

Evaluation of hepatitis C treatment-as-prevention in Australian prisons: the SToP-C study

Behzad Hajarizadeh, The Kirby Institute, UNSW Sydney, NSW

The Surveillance and Treatment of Prisoners with HCV (SToP-C) study is a 5-year project aimed at evaluating the impact of treatment-as-prevention (TasP) on HCV incidence in 4 prisons in NSW that was supported in part by Gilead.[1] SToP-C is the first study of TasP for HCV in the prison setting, and the largest of its kind in any setting.

All participants were tested for HCV at enrolment and classified as HCV infected, HCV previously infected or HCV uninfected. Those infected were referred for treatment and those at risk of infection or reinfection were re-tested every 3 to 6 months.

From 2014 to 2017, participants received interferon treatment for HCV through the prison health service. From 2017 onwards, direct-acting antiviral (DAA) treatment for HCV was scaled up and participants received 12 weeks of sofosbuvir/velpatasvir (SOF/VEL) through the SToP-C study.

A total of 3691 participants were enrolled. There was no follow up after enrolment for approximately 50% of participants, largely due to release from prison or transfer to another prison.

The median age of participants was 33 years, 82% were male, 27% identified as Aboriginal or Torres Strait Islander, 55% had a history of injecting drug use (IDU), 22% had injected in the prison environment in the previous month and 91% had reused injecting equipment after someone else had used it.

Testing at enrolment showed 19% of participants were infected with HCV, 20% were previously infected (at risk of re-infection) and 61% were uninfected (at risk of primary infection).

The number of participants testing positive for HCV decreased significantly compared with the predicted trend over the course of the study, largely due to the scale-up of DAA treatment, particularly in those with primary HCV infection or IDU. This decrease was evident in participants with a primary HCV infection, as well as in those with HCV reinfection. Overall, the incidence of HCV almost halved following the scale-up of DAA, supporting TasP for HCV in this setting.

Injecting drug use was found to be a strong predictor of testing positive for HCV, with a 6-fold higher risk for those with IDU in the previous 6 months compared with those without IDU.

A combination of rapid DAA scale-up and enhanced HCV prevention strategies are likely to provide even greater reductions in HCV transmission given the high risk associated with IDU in the prison setting.

HCV reinfection following direct-acting antiviral treatment in the prison setting: the SToP-C study

Joanne Carson, et al. The Kirby Institute, UNSW Sydney, NSW

In a further analysis of the SToP-C study, participants who tested positive for HCV RNA and received DAA treatment were followed to determine the incidence of reinfection.

Follow up was available for 165 participants, of who 90% were male, 37% identified as Aboriginal or Torres Strait Islander and 44% had IDU in the previous month.

There were 14 cases of reinfection (8%). The only factor associated with reinfection in the adjusted analyses was IDU in the previous month. Regression analyses showed sharing needles or syringes was strongly associated with reinfection.

This analysis shows HCV reinfection following DAA treatment can reduce the benefits of treatment expansion and highlights the need for increased access to harm reduction support in prisons, including needle and syringe programs (NSPs) and increased coverage of opioid substitution therapy (OST).

Palen Creek prison cures: HCV elimination in a weekend

Mim O'Flynn, Kombi Clinic, QLD

The Palen Creek Correctional Centre is a low security prison approximately 2 hours out of Brisbane with approximately 165 clients. Many of the clients are steroid users, who prefer clean needles, but these are confiscated along with steroids if found by correctional staff. Hence these clients are at high risk of HCV.

The Kombi Clinic conducted a 3-day POCT blitz at the Palen Creek Correctional Centre using 4 GeneXpert systems, which was supported by Gilead through the CCC program. Of 161 tests, 3 clients had HCV and commenced DAA treatment within 3 days. Approximately 34% of those tested had a history of IDU and 6% identified as Aboriginal or Torres Strait Islander.

There was great support from correctional staff during the POCT blitz. Healthcare professionals need to focus on opportunities, rather than barriers, and have a passionate belief that they can enter a setting and eliminate HCV. Unbridled enthusiasm, meticulous planning and adaptability all trump negativity.

Following on from their success at the Palen Creek Correctional Centre, the Kombi Clinic conducted POCT at the Brisbane Women's Correctional Centre and the Helana Jones Centre, and has plans for POCT at other facilities from the far north all the way down the east coast of QLD.

"Healthcare professionals need to focus on opportunities, rather than barriers, and have a passionate belief that they can enter a setting and eliminate HCV."

Point-of-care testing for HCV in the correctional environment

Marian Bloomfield, Justice Health, NSW

Approximately 13,000 people are in custody in NSW and 30,000 people move through the system each year, with 1500 new receptions each month.

The prevalence of HCV is approximately 13% in the correctional environment in NSW. The Ministry of Health aim to conduct 1250 treatments for HCV per year, which requires the testing of approximately 12,000 people.

Looking for clients infected with HCV is like panning for gold and substantially more effort is expended looking for clients than treating them.

To address these challenges, POCT with the GeneXpert system started in January 2021 at the Metropolitan Remand & Reception Centre with support from Gilead through the CCC program.

Over 49 days to date, 379 POCT have been conducted, which is fewer than expected due to disruptions caused by COVID-19 restrictions. However, a benefit of COVID-19 restrictions is that clients are quarantined for 2 weeks, which provides additional opportunity for POCT. The uptake by clients has been great, as no venepuncture is required.

A total of 47 clients had HCV (12%) and 90 clients identified as Aboriginal or Torres Strait Islander, of who 16 (18%) had HCV. Clients who tested positive for HCV were given their result and baseline blood tests were done as part of the HCV treatment pathway.

Keys to success for POCT include testing clients at reception, which reduces the risk of ongoing infection. Furthermore, clients on remand, or who will be released quickly, should be helped to engage in HCV care.

The more clients who are tested for HCV, the more that can be treated. Point-of-care testing is easy, the results are available quickly and multiple clients can be tested within a given timeframe. This allows resources to be better used treating clients rather than looking for them.

Eliminating HCV in correctional setting: testing, treatment and harm reduction. How does policy to practice really work on the inside?

Colette McGrath, Justice Health and Forensic Mental Health Network, NSW

Australia is one of the only countries in the world to provide universal access to DAAs to clients in correctional settings. However, finding clients with HCV in these settings is an ongoing challenge. In response to this challenge, the number of tests for HCV in correctional settings in NSW has increased from 5567 to 13,940 between 2016 and 2020. Furthermore, the number of treatments has increased from 157 to 1236 from 2015 to 2020.

Current testing strategies in correctional settings include conventional venepuncture for those who request a test or are at risk, mass testing via the Hepatitis Prisons Elimination Program, dried blood spot testing, and enlisting the support of primary care nurses and Aboriginal health workers.

A total of 3852 dried blood spot tests have been performed by the Justice Health network, of which 456 were positive for HCV RNA (12%). More recent testing in some prisons has shown this prevalence has decreased to 8%.

Despite the success of dried blood spot testing, there remain challenges to testing and treatment for HCV, such as testing clients who move through the system quickly, clients who are at risk of reinfection but do not want to be treated and a lack of access to OST.

The introduction of depot buprenorphine in correctional settings has helped many clients. Since 2020, 1407 clients have initiated treatment with depot buprenorphine, which now accounts for 66% of the network OST program, compared with 90% methadone in 2018/19.

Other initiatives include peer education, enhanced harm minimisation strategies and POCT, which is currently supported by Gilead through the CCC program *(Figure 1)*. Partnerships and systems approaches are vital in these initiatives, and corrective services need to be onboard. To eliminate HCV in prisons, the full suite of interventions need to be agile and innovative to achieve the best outcomes for people in prison and the community.

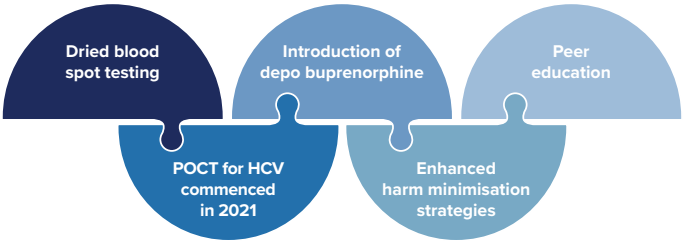

Figure 1. Strategies used by Justice Health for HCV management. Abbreviation: POCT, point-of-care testing. Reprinted with permission from Colette McGrath and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine.

Eliminating HCV in the community

Just a GP, just a finger prick, just an hour

Joss O'Loan, Kombi Clinic & Medeco Inala, QLD

The overarching goal of the Kombi Clinic is to break down barriers to treatment and dispel the myth of the hard-to-reach client. Since 2017, the Kombi Clinic has driven around the greater Brisbane area bringing life-saving information, treatment and a friendly face to those afflicted with HCV.

The new GeneXpert system has been a revolution in HCV management at the clinic as it allows rapid POCT for HCV that is as simple as a blood sugar test. Clients love it, and it avoids the need for venous access, which many clients find very difficult.

The Medeco Inala general practitioner (GP) clinic is located in suburban Brisbane and visited by many clients with IDU. Approximately 220 clients at the clinic are prescribed methadone or suboxone as OST.

From 2017 to 2018, staff worked tirelessly to eliminate HCV from the clinic using traditional testing. They then did a POCT blitz over 4 weeks in November 2020, offering GeneXpert tests to all clients who were at high risk of HCV. Of 157 tests for HCV, 11 were positive, including 6 clients who were previously treated for HCV and reinfected. The 5 new diagnoses were for clients they could not do phlebotomy on and would not have been able to test without the GeneXpert system.

There is a learning curve to using the GeneXpert system and some machine errors were experienced in the beginning. All clients with a positive test result at the clinic commenced treatment for HCV, approximately half within 7 days. Of the negative results, 12 clients did not previously have sustained virologic response (SVR) test results, so the system was useful for obtaining SVR results as well.

The POCT blitz was supported by Gilead Sciences through the CCC program. While the GeneXpert system is approved by the Therapeutic Goods Association, it is not yet reimbursed on the Medicare Benefits Schedule, which will be required to make POCT sustainable.

"Clients love it [rapid point-of-care testing], and it avoids the need for venous access, which many clients find very difficult."

The key benefit of the GeneXpert system is that it is portable and facilitates decentralised testing. In future, primary health networks could share GeneXpert systems with high caseload GP and other clinics. The system could also be used for POCT at mobile outreach clinics, alcohol and other drug clinics, and NSPs, as well as for high-risk clients in emergency departments and mental health services.

Using point-of-care testing in an outreach mobile setting

Kristen McKee, Storr Liver Centre Westmead, NSW

Many clinics have run out of clients to treat for HCV so, to reach HCV elimination targets by 2030, clinics must go out into the community to screen, diagnose and treat those with HCV.

Point-of-care testing with the GeneXpert system, which is supported by Gilead through the CCC program, is easier from the clients' perspective since a simple finger prick blood sample is all that is required. The system is also easy for staff to use and is a keen point of interest from community members as it is a new technology.

In order for POCT to be successful in a mobile outreach setting, staff should practise collecting blood samples before taking blood from clients, which can be a challenge when it is cold or clients' skin integrity is not good. It also helps to learn how to troubleshoot common problems with the GeneXpert system and to time testing appropriately, as the van needs to be packed up at the end of the day and driven away.

Battery power should be considered, as well as how to safely move the system, and weather, space, staffing and expiry dates of reagents should be thought about. It should be remembered that not all clients will feel positive about POCT or can wait for the result, and in these cases other tests are relevant. Consequently, staff should be experienced making decisions about the right test for the right situation.

There are many benefits to POCT in the mobile outreach setting. There is genuine interest from some community members and the system makes a good talking point for engagement. It is great for clients who decline a venous sample or when a highly skilled phlebotomist is not available. It is also able to provide conclusive test result within an hour, and clients will often bring back friends and neighbours for test.

Despite the benefits of POCT, it can still take time to get clients onto treatment, as they are not in a rush and often need time to process a diagnosis. Hence same day treatment is not always possible.

A collaborative approach is needed for POCT, and peer support workers play a key role. The Storr Liver Centre plan to continue using POCT and, although it is not always the right test for all their clients, it is great for those who want it or for those who have issues giving venous blood.

"A collaborative approach is needed for point-of-care testing, and peer support workers play a key role."

Rapid point of care HCV testing allows high throughput HCV screening and rapid treatment uptake among people with injecting drug use attending a medically supervised injecting room

Michael MacIsaac, St Vincent's Hospital Melbourne, VIC

HCV treatment for people with IDU needs to be scaled up to meet the HCV elimination targets. In VIC alone there are 15,000 to 25,000 people with IDU, of who 50% have chronic HCV, and modelling shows that >1000 people with IDU need to be treated for HCV each year in VIC to meet elimination targets.[2]

The medically supervised injecting room (MSIR) opened in June 2018 in Melbourne and has a safety-first, medical approach focused on harm reduction. Richmond was chosen as the location due to the high number of drug-related deaths in the area.

Clients are registered the first time they use the premises, they undergo a brief assessment, and they must disclose the drug they intend to inject and ensure they have a supply. They are then allocated an injecting booth, provided with sterile injecting equipment, given harm reduction advice and supervised by qualified health staff. After injecting, clients move to an aftercare area where they can stay until they feel comfortable to leave and can be monitored in case they have an overdose.

Staff can engage with clients in the aftercare area to offer health and social support, and refer to an appropriate site service if available. Clients who choose to engage with support move to another area with clinic rooms offering services such as primary care, dental care, housing support and blood borne virus screening.

The MSIR provides an opportunity to screen a large number of people with IDU for HCV. Point-of-care testing with the GeneXpert system is particularly promising as it allows testing and diagnosis within a single visit, it increases testing rates, improves linkage to care and is highly acceptable among people with IDU, most of who do not want venepuncture.

A 9-week prospective pilot study was conducted to evaluate POCT for HCV among people with IDU attending the MSIR. The study was supported by Gilead through the CCC program. A total of 228 participants consented to screening (47% of those approached), which represented an almost 3-fold increase in HCV screening rate compared with the same 9-week period 12 months prior.

The median age of participants was 43 years, 78% were male, 19% identified as Aboriginal or Torres Strait Islander, over 25% were homeless or in temporary accommodation and the drug of choice was heroin for 87%.

Of 228 participants, 64 (28%) tested positive for HCV RNA. Almost two thirds received their result on the same day as testing and 92% of those informed of their result commenced DAA therapy *(Figure 2)*. Almost one quarter commenced treatment on the same day and, for those who did not commence treatment on the same day, the median time to DAA start was 9 days. The most common DAA regimens were SOF/VEL 61% and 8-week glecaprevir/pibrentasvir (35%).

"The MSIR provides an opportunity to screen a large number of people with IDU for HCV."

To date, 17 of 19 (89%) participants who received treatment and had with an available HCV RNA result tested negative for HCV. The remaining 2 participants were not adherent to treatment. A total of 4 of 5 participants with SVR12 results tested negative for HCV, with one client being reinfected.

The clinic plans to continue POCT at the MSIR and will evaluate a nurse and harm reduction worker-led model of care. They also plan to apply this model of care to other settings with high-risk populations of people with IDU.

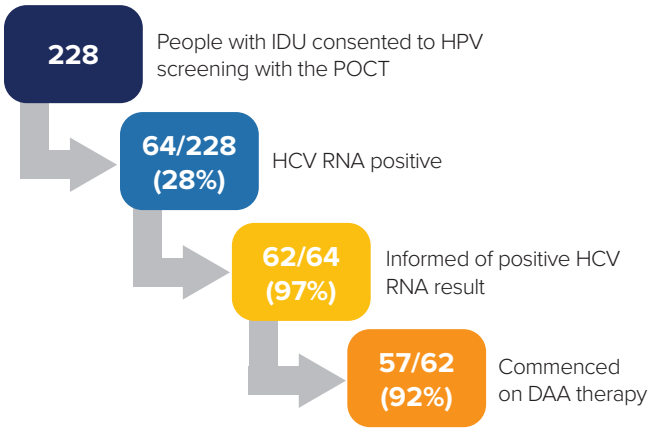

Figure 2. Rapid HCV point-of-care testing results at the medically-supervised injecting room. Abbreviations: DAA, direct-acting antiviral; IDU, injecting drug use; POCT, point-of-care testing; RNA, ribonucleic acid. Reprinted with permission from Michael MacIsaac and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine.

A successful HCV outreach service in a medically supervised injecting room: increased uptake of screening and high rates of treatment initiation

Michael MacIsaac, et al. St Vincent's Hospital Melbourne, VIC

The MSIR in Melbourne provides a unique opportunity to engage and treat a large number of people with IDU and HCV. A retrospective analysis showed there was a high rate of linkage to treatment for clients with chronic HCV.

The study included all clients visiting the MSIR for a 2-year period who underwent screening and/or treatment for HCV. Cases were identified from the MSIR blood borne virus database, St Vincent's Hospital Melbourne HCV database and pharmacy dispensing records, and a search of pathology ordered by integrated hepatitis nurses. The endpoints were the number of clients diagnosed with chronic HCV and the number of DAA prescriptions written.

Of 4649 clients who visited the MSIR during the study period, 321 were engaged in HCV screening and/or treatment. The median age was 43 years, 79% were male, 13% identified as Aboriginal or Torres Strait Islander and 38% were homeless. A total of 143 clients tested positive for HCV RNA (45%) and, of these, 122 commenced DAA therapy (85%), most commonly with SOF/VEL (67%).

HCV testing and treatment in needle and syringe settings

Amanda Kvassay, et al. Queensland Injectors Health Network, QLD

The Queensland Injectors Health Network (QuIHN) is a state-wide, non-government, not for profit charity that provides specialist health and social services related to alcohol and other drug use, as well as mental health. QuIHN aims to make meaningful connections with clients through their harm reduction workforce. They also emphasise quality and value client decisions in testing and treatment, linkage to key service providers and relationships needed to sustain outreach ventures.

The QuIHN HCV Treatment Management Program provides support for DAA treatment to high needs populations. Their case management involves harm reduction, and they assist clients all the way through to SVR. They also provide incentive vouchers for testing and treatment milestones.

The service employs a harm reduction case manager and peer workers, and they have developed a prison transition service for clients. Clients can access HCV treatment via 1) the nurse practitioner in hepatology, 2) QuIHN GPs in Brisbane and 3) external GPs in Townsville. They also run fibroscan outreach clinics, and collaborate with specialists and an expert advisory panel.

QuIHN has purchased 3 GeneXpert systems to offer POCT for HCV to their clients (see below). They also continue to offer onsite venous blood collection for pathology.

From 2016 to 2020, 1329 people from targeted groups were screened for HCV by QuIHN, of who 16% identified as Aboriginal or Torres Strait Islander and 69% were male. Treatment was started in 696 clients and, of those with data available, 454 had SVR confirmed (96% cure rate) *(Figure 3)*.

QuIHN plans to increase their testing rates, expand POCT testing to HIV and syphilis, and integrate telehealth. They also aim to expand their nurse practitioner workforce, continue to engage clients with skilled harm reduction and peer workers through education and support, and maintain evaluation of programs intended to eliminate HCV.

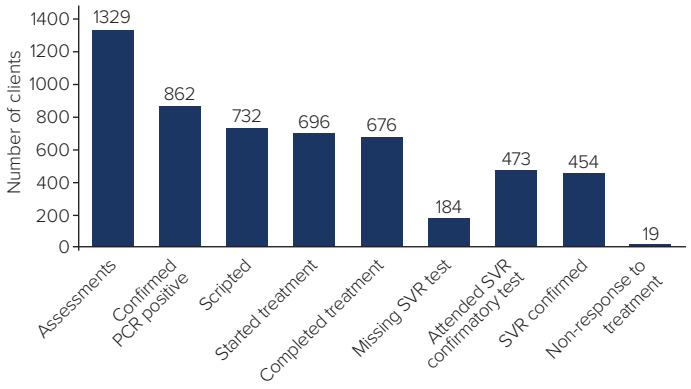

Figure 3. HCV treatment outcomes at the QuIHN HCV Treatment Management Program from January 2016 to December 2020. Abbreviations: PCR, polymerase chain reaction; SVR, sustained virologic response. Reprinted with permission from Amanda Kvassay and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine.

HCV point-of-care testing: implementation, learnings and early results

Amanda Kvassay, et al. Queensland Injectors Health Network, QLD

QuIHN began the process of establishing POCT, which was supported by Gilead through the CCC program, by developing policies and procedures across their 5 NSP sites in QLD, as well as their outreach clinics. Staff were then trained and processes applied to govern how the HCV and SVR results would be provided to clients.

Quality assurance and internal audits are integral to POCT and were also implemented. Furthermore, early issues such as finger prick techniques and machine errors were addressed through training and consultation.

Since November 2021, 343 POCT HCV tests have been conducted on 324 clients. Of these, 267 test results were valid, and the system error rate continues to decrease as experience increases, with the goal of achieving a <5% error rate. Approximately 21% of valid tests were positive for HCV, and POCT continues to enable increased testing rates across QuIHN NSP sites.

When establishing POCT, there are many considerations to work through, which takes time. Staff should practice finger prick sampling, and an internal auditing process can help with this. Furthermore, harm reduction workers can be encouraged to do the testing, as clients appreciate harm reduction workers conducting the test and providing the result.

"Point-of-care testing continues to enable increased testing rates across QuIHN NSP sites."

Advances in treatments for HCV in vulnerable populations

Effectiveness of sofosbuvir/velpatasvir in patients with chronic HCV infection and mental health disorders: real-world care management from 8 countries

Mary Fenech, et al. Queensland Injectors Health Network, Better Access Medical Clinic, QLD

This real-world analysis showed high SVR rates with SOF/VEL for 12 weeks in participants with mental health disorders previously considered difficult to engage in care. Only 2% of participants did not reach SVR12/24 due to a virological failure. Furthermore, high cure rates were observed when SOF/VEL was started rapidly after diagnosis.

The study was sponsored by Gilead and included participants diagnosed with at least 1 mental health condition from 29 cohorts in 8 countries, including Australia, who received SOF/VEL for 12 weeks as part of their care. The endpoints of the study included SVR12/24, treatment adherence and the time between diagnosis and treatment.

A total of 1422 participants were included in the study. The mean age of participants was 52 years, 64% were male, 51% had previous or current IDU, 8% were in prison and 7% were homeless. The most common mental health disorders at baseline were cognitive or psychiatric disorders, depression and anxiety. Of those with a valid SVR12/24 result, 98% achieved SVR12/24, and only 2% experienced virologic failure. At least 95% of participants achieved SVR12/24, regardless of genotype, fibrosis stage, mental health disorder, IDU or antipsychotic drug use. Sustained virologic response rates were 100% for participants treated within 1 week, supporting a test-and-treat approach. Adherence was ≥90% in 97% of participants with adherence information, of who 99% achieved SVR.

HCV elimination in active participants with IDU: sofosbuvir/velpatasvir as a simple tool to implement a test-and-treat approach in this vulnerable population

Joss O'Loan, et al. Kombi Clinic & Medeco Inala, QLD

This real-world study showed high SVR rates with SOF/VEL for 12 weeks in participants with IDU, and that a test-and-treat approach with SOF/VEL resulted in high cure rates.

The study was sponsored by Gilead and included participants with IDU from 25 cohorts in 7 countries who received SOF/VEL for 12 weeks as part of their care. The endpoints of the study included SVR12/24, treatment adherence and the time between diagnosis and treatment.

A total of 371 participants were included in the study. The mean age was 44 years, 77% were male, 19% were in prison and 25% were homeless. At least 94% of participants achieved SVR12/24 regardless of genotype, fibrosis stage and complicating baseline characteristics, such as homelessness and incarceration. Sustained virologic response rates were 100% for those treated within 1 week of HCV diagnosis, supporting a test-and-treat approach in this population. Adherence was ≥90% in 96% of participants with adherence information available, of who 98% achieved SVR.

The value of sofosbuvir/velpatasvir as a pangenotypic and panfibrotic HCV treatment in implementing a test-and-treat strategy in prisons: real-world care management from 6 countries

Joss O'Loan, et al. Kombi Clinic & Medeco Inala, QLD

This real-world study showed cure with SOF/VEL for 12 weeks was possible in incarcerated people traditionally considered difficult to engage in care, and that SVR rates with SOF/VEL were high when treatment was started within 1 day or 1 week.

The study was sponsored by Gilead and included incarcerated participants from 20 cohorts in 6 countries who received SOF/VEL for 12 weeks as part of their care. The endpoints of the study included SVR12/24, treatment adherence and the time between diagnosis and treatment.

A total of 526 participants were included in the study. The mean age was 44 years, 91% were male and 56% were former or current drug users. At least 95% of participants achieved SVR12/24 regardless of genotype, fibrosis stage and complicating baseline characteristics, such as active IDU or antipsychotic drug use. Sustained virologic response rates were 98% for those treated within 1 week of HCV diagnosis, supporting a test-and-treat approach in this population. Adherence was ≥90% in 99% of participants with adherence information available, of who almost 100% achieved SVR.

Please review full Product Information before prescribing. Product Information is available from Gilead Sciences Pty Ltd at www.ebs.tga.gov.au or on 1800 806 112.

EPCLUSA PBS Information: EPCLUSA is PBS listed for the treatment of chronic genotype 1-6 hepatitis C infection. Dual General Schedule and S100 (HSD) listing. Authority required. Refer to PBS Schedule for full authority information.

Minimum Product Information – EPCLUSA®

EPCLUSA (sofosbuvir/velpatasvir) 400/100 mg tablets. INDICATIONS – Chronic Hepatitis C (CHC) infection in adults and paediatric patients ≥ 12 years of age and weighing ≥ 30 kg. **DOSAGE AND ADMINISTRATION** – One tablet daily, orally for 12 weeks. Coadministration with ribavirin for patients with decompensated cirrhosis. **CONTRAINDICATIONS** – Hypersensitivity, concurrent use with other medicinal products containing any of the same active components. **PRECAUTIONS** – Serious symptomatic bradycardia when coadministered with amiodarone, (coadministration is not recommended). Hepatitis B virus reactivation. Use with moderate P-gp inducers and/or moderate to strong CYP inducers. Pregnancy (Category B1 – EPCLUSA, Category X – Use with ribavirin). If ribavirin is coadministered with EPCLUSA, the contraindications regarding use of ribavirin apply (refer to ribavirin PI). **DRUG INTERACTIONS** – acid reducing agents, antiarrhythmics (amiodarone), anticonvulsants, antimycobacterials, antiretrovirals, St John's wort, HMG-CoA reductase inhibitors. **ADVERSE EFFECTS** – Headache, fatigue, nausea, and nasopharyngitis. **This is not a full list; please refer to the full Product Information for more details. Full Product Information is available from Gilead Sciences Pty Ltd Medical Information (1800 806 112) and should be reviewed before prescribing EPCLUSA.** 14 April 2021.

References:
1. Hajarizadeh B, et al. Lancet Gastroenterol Hepatol 2021;6:533-46.
2. Scott N, et al. Gut 2017;66:1507-15.

The content in this publication is based on the 12th Annual Viral Hepatitis conference, held virtually and at hubs in Brisbane and Sydney 30 May to 1 June 2021. This publication is sponsored by Gilead Sciences Pty Ltd, Level 6, 417 St Kilda Road, Melbourne, VIC 3004, Australia. Date of preparation: July 2021. AU-EPC-0095.

GILEAD