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Supporting the HIV, Viral Hepatitis and Sexual Health Workforce

Poor access to pharmacotherapy will jeopardise eliminating hepatitis C in Australia

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This paper is in dedication to the late Levinia Crooks' a leading voice in the Australasian and international BBV and STI field. The idea behind this paper is Levinia's and she played a key role in an earlier draft for which the authors are truly grateful.

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Introduction:

The recent introduction of highly effective hepatitis C treatment has the potential of eliminating hepatitis C in Australia. These new treatments, which are available to everyone living with chronic hepatitis C, irrespective of the stage of their illness, have begun to change the hepatitis C landscape. However, this significant investment in universal treatment by the Australian Government, has come with challenges; most notably, finding effective ways to engage with one of the largest hepatitis C cohorts - people who inject drugs, while also strengthening existing and creating new pathways to treatment within a range of community-based settings.

This paper focuses on the current arrangements of pharmacotherapy¹ in Australia and its implications for responding to and ultimately eliminating hepatitis C treatment, asking; what are the real or additional costs of making pharmacotherapy unaffordable and inaccessible for people who undertake hepatitis C treatments. Pharmacotherapy, using opioid substitutes, typically methadone or buprenorphine, is covered by the Australian universal health insurance scheme, the Pharmaceutical Benefits Scheme (PBS). The medicine is predominantly dispensed through community pharmacists on a daily basis and participating pharmacists are required to charge a daily fee to cover their dispensing and

¹ Also referred to as Opioid Substitution Therapy (OST) and methadone maintenance therapy (MMT)

compliance costs. The weekly dispensing charges range between \$30 and \$70. Not being able to afford these costs is frequently reported as a major reason for leaving the program.

The costs associated with providing new hepatitis C treatments are substantial² and will most likely be undermined by the fragile nature of how pharmacotherapy is administered. A critical component to the current efforts to eliminate hepatitis C is to ensure treatment is available to everyone who has chronic hepatitis C. The implications of making these new treatments available to everyone, including current injecting drug users and others who are marginalised, cannot be fully appreciated without understanding the role and short comings of how pharmacotherapy is administered.

It is likely that treatment pathways will be jeopardised because people are unable to pay dispensing fees for their pharmacotherapy treatment, which will in turn reduce their engagement with their local pharmacist. As a consequence, hepatitis C treatment costs will increase if steps are not taken to ensure pharmacotherapy is accessible and sustainable. The public health relevance of ensuring pharmacotherapy is available and affordable for clients, while also sustainable for community pharmacists is even more apparent and urgent with the introduction of hepatitis C treatments. This paper directly links hepatitis C and pharmacotherapy and raises the question: What is the cost if someone gets infected or reinfected with hepatitis C because they could not maintain their pharmacotherapy?

This paper argues for a new funding arrangement with community pharmacists, so that dispensing pharmacotherapy is viable and sustainable for pharmacists and affordable for their clients. Ensuring a more robust dispensing mechanism will also ensure greater involvement with clients around hepatitis C.

Investing in new hepatitis C treatment:

In 2015, an estimated 227,306 individuals were living with chronic hepatitis C in Australia,³ with around one-third living with moderate to severe liver disease.⁴ The burden of liver disease caused by the hepatitis C virus – including liver cirrhosis, liver cancer, liver failure and the potential need for liver transplant – continues to rise. Chronic hepatitis C was estimated to be the underlying cause of liver disease in 22 per cent of liver transplants in 2012.⁵ The impact of these new highly effective treatments for hepatitis C is extraordinarily positive.⁶ The good news is that an estimated 69% of the total population living with chronic hepatitis C infection, 69% of those with cirrhosis initiated treatment up to June 2017.⁷

While initial levels of treatment uptake have been encouraging, maintaining these numbers is proving difficult. Where the national rate of treatment initiations in March 2016 was approximately 5,000 per

² The Australian Government has negotiated a multi-company agreement to spend up to \$1 Billion on the first 5 years of DDA therapy being available. This is a commercial in confidence arrangement and consequently it is impossible to assess individual cost per treatment course. Suffice the greater the number of patients treated the lower the unit cost.

³ Kirby Institute (2016), *Monitoring hepatitis C treatment uptake in Australia* (Issue 5), The Kirby Institute, UNSW Sydney, Sydney, Australia, September 2016, available via: http://kirby.unsw.edu.au/sites/default/files/hiv/attachment/Kirby_HepC_Newsletter_Issue5_2.pdf.

⁴ Commonwealth of Australia (2014), *Fourth National Hepatitis C Strategy 2014-2017*.

⁵ Commonwealth of Australia (2014), *Ibid*.

⁶ The Kirby Institute. *Monitoring hepatitis C treatment uptake in Australia* (Issue 6). The Kirby Institute, UNSW Sydney, Sydney, Australia, February 2017

⁷ Kirby Institute (2017) *Monitoring hepatitis C treatment uptake in Australia* (Issue 8). The Kirby institute, UNSW Sydney, Sydney, Australia, December 2017.

month, this had reduced approximately 2,000 per month by December 2016 and has remained relatively steady at this level.⁸

With the Australian Government investing over \$1 billion to subsidise these highly effective hepatitis C treatments to all people over 18 years, the broad hepatitis health sector is investing heavily in building treatment pathways, models of care and training workforces to ensure treatment is accessible and available to all. Elimination is the goal and is a realistic possibility only if a comprehensive approach to tackling this challenge is acknowledged and adopted. This includes minimizing the amount of virus circulating in the community and driving down new infections from changing behaviours including occasional syringe sharing which continues at 17 per cent.⁹

To achieve this, not only must existing treatment pathways remain open and barriers to treatment minimized, but new community-based pathways need to be supported. While specialists such as gastroenterologists provide the majority of prescriptions for treatment, the number of patients initiating treatment through general practitioners is rising (from 8% in March 2016 to 39% in June 2017).¹⁰ This positive development should be encouraged, as low threshold practitioners like GPs are better positioned to service marginalised populations.

While the widely publicised and significant cost of treatment, covered by the Australian Government, is \$1 billion, it is expected that treatment cost per patient will be approximately \$20,000.¹¹ The cost per patient will ultimately depend on how many patients are treated and will be linked to a tiered risk-sharing arrangement where costs are shared between the Australian Government and pharmaceutical companies, with profits to pharmaceutical companies scaled back above a set number of people treated.¹²

Hepatitis C prevalence among people who inject drug (PWID) remains high in Australia, at approximately 50 per cent,¹³ with the vast majority of new HCV cases among this group.¹⁴ Approximately 90 per cent of newly acquired hepatitis C infections result from unsafe injecting drug use practices.¹⁵

Australia has a mixed history of not actively encouraging people who inject drugs to access hepatitis C treatment and a relatively small number of advocates encouraging the treatment of current injectors.^{16,17,18,19} Challenges associated with past interferon based hepatitis C therapy meant treatment was not an easy or viable option for many who are marginalised and vulnerable, which is reflected in the fact that until now fewer than 2 per cent of people who inject drugs in Australia have received

⁸ Kirby Institute (2017) Ibid.

⁹ Kirwan, A., Carrottee, E., Dietze, P. Centre for Research Excellence into Injecting Drug Use (2015), Syringe coverage and Australian NSPs, Policy Brief No 9: May 2015 accessed June 30, 2018.

https://creidu.edu.au/system/policy_document/12/pdf/Policy_Brief_Kirwan_Syringe_coverage.pdf

¹⁰ Kirby Institute (2017) Ibid.

¹¹ Without public information on the deal between commonwealth government and the pharmaceutical industry, it is difficult to know exactly the costs of treatment. However, it is estimated that even if low numbers are treated the cost per patient is likely to be \$20,000 or less.

¹² The risk sharing agreement is confidential between the Australian Government and pharmaceutical companies. It is believed that if treatment costs exceed the agreed limit for any single year over the five year period, prescriptions will continue to be dispensed, which will ultimately reduce profits for pharmaceutical companies

¹³ Centre for Research Excellence into Injecting Drug Use (2015), "Updated policy brief: People who inject drugs can be successfully treated for hepatitis C (HCV), and treatment has the potential to reduce the community prevalence of HCV", accessed 23 November 2016, http://creidu.edu.au/policy_briefs_and_submissions/6-updated-policy-brief-people-who-inject-drugs-can-be-successfully-treated-for-hepatitis-c-hcv-and-treatment-has-the-potential-to-reduce-the-community-prevalence-of-hcv.

¹⁴ Commonwealth of Australia (2014), *Fourth National Hepatitis C Strategy 2014-2017*.

¹⁵ Hajarizadeh B, Grebely J, Dore GJ. Epidemiology and natural history of HCV infection. *Nat Rev Gastroenterol Hepatol*. 2013; 10(9):553–562.

¹⁶ Treloar, C., et al., Knowledge and barriers associated with assessment and treatment for hepatitis C virus infection among people who inject drugs. *Drug Alcohol Rev*, 2012. **31**(7): p. 918-24;

¹⁷ Grebely J, Matthews GV, Lloyd AR, Dore GJ. Elimination of Hepatitis C Virus Infection Among People Who Inject Drugs Through Treatment as Prevention: Feasibility and Future Requirements. *Clinical Infectious Diseases*. 2013;57:1014–1020

¹⁸ Grebely J, Dore GJ. Can hepatitis C virus infection be eradicated in people who inject drugs? *Antiviral Research*. 2014;104:62–72.

¹⁹ Grebely, J., et al., Low uptake of treatment for hepatitis C virus infection in a large communitybased study of inner city residents. *Journal of Viral Hepatitis*, 2009. **16**(5): p. 352-358.

treatment. Times have changed with the availability of new highly effective DAA treatments. The elimination of hepatitis C cannot be achieved without effective engagement with injecting drug users, which remains a challenging task.

Prisoners, who are maintained on pharmacotherapy, make an excellent cohort for anti-hepatitis C therapy as they are in regular contact with a health service. Treatment for prisoners is subsidised through the PBS and administered through states. Treatment of prisoners is seen as a high priority, at state and national level in hepatitis C strategies.²⁰

Pharmacotherapy:

Opioid dependence is a complex health condition that affects not only injecting drug users, but people from all walks of life, including those who have become addicted to prescribed pain relievers.

Pharmacotherapy is an effective medical treatment to reduce people's use of heroin or other addictive opioid-based drugs such as OxyContin and Fentanyl. It is an evidence-based, cost-effective public health strategy for managing opioid dependence.²¹ The World Health Organization has declared buprenorphine and methadone as essential medicines that can significantly improve and save lives.²² It has been classified as medicines to which people should have access at all times and in sufficient amounts. The benefits are well documented, with studies showing a reduction in illicit drug use and improvement in health and wellbeing when people dependent on opioids are maintained on a daily dose.²³ Evidence also shows that hepatitis C infection is reduced when someone receives pharmacotherapy.²⁴ It also reduces the rate of criminal activity in the community,²⁵ reduces overdoses,²⁶ prevents the spread of BBVs²⁷ and assists people to stabilise their lives,²⁸ which helps them to lead more productive lives.

The demand for pharmacotherapy in Australia continues to increase (partly due to the dramatic increase in the level of opioid prescriptions). There has been a steady increase (5 per cent over the 5-year period from 2010) in number of people accessing treatment, reaching over 48,000 people in 2015.²⁹ The proportion of clients aged over 50 years more than doubled from eight per cent to 22 per cent over the ten year period from 2006.³⁰ While the number of prescribers continues to increase, with 2,556 prescribers, in Australia in 2015 (9 per cent increase from 2014), a constant demand remains for the program to expand.³¹ Community pharmacists provide the majority of dosing points (2,589 in 2015),

²⁰ National Hepatitis C Strategy <http://www.health.gov.au/internet/main/publishing.nsf/content/ohp-bbvs-hepc>

²¹ Dolan K; Alam Mehrjerdi Z, 2015, Medication-assisted treatment of opioid dependence a review of evidence, Australian National Council on Drugs, Canberra, ANCD research paper 32

²² WHO Expert Committee on the Selection and Use of Essential Medicines, (2006) http://www.who.int/medicines/publications/essentialmeds_committeereports/TRS946_EMedLib.pdf

²³ Feyer, A. Mattick, R., Schulman, C., Jessop, R., Soloman, J. & Pyper, D. (2008). A National Funding Model for Pharmacotherapy Dependence in Community Pharmacy. Sydney, NSW: Department of Health and Ageing, The Pharmacy Guild of Australia, National Drug and Research Centre, Price Waterhouse Coopers.

²⁴ Nolan, S., Dias Lima, V., Fairbairn, N., et al (2014) The impact of methadone maintenance therapy on hepatitis C incidence among illicit drug users. *Addiction*. 2014 December; 109(12): 2053–2059.

²⁵ Bukten, A., Skurtveit, S., Gossop, M., et al (2012) Engagement with opioid maintenance treatment and reductions in crime: A longitudinal national cohort study. *Addiction* 107(2), 393–399.

²⁶ Pierce, M., Bird, S. M., Hickman, M., & Millar, T. (2015). National record linkage study of mortality for a large cohort of opioid users ascertained by drug treatment or criminal justice sources in England, 2005–2009. *Drug and Alcohol Dependence*, 146, 17–23.

²⁷ White et al, Opioid substitution therapy protects against hepatitis C virus acquisition in people who inject drugs: the HITS-c study, *Med J Aust*. 2014; 201(6): 326–329.

²⁸ Maremmani, I., Pani, P., Pacini, M., et al. (2007) Substance use and quality of life over 12 months among buprenorphine maintenance-treated and methadone maintenance-treated heroin-addicted patients. *Journal of Substance Abuse Treatment* 33(1), 91–98.

²⁹ Data taken from a snapshot day (Date??) New South Wales has the highest rate of clients (26 per 10,000 population), followed by Victoria (24 per 10,000) and the Australian Capital Territory (24 per 10,000). Methadone continues to be the most common pharmacotherapy drug, with around two-thirds (67%) of clients treated with this drug followed by buprenorphine.

³⁰ <http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/nopsad-2015/>

³¹ This increase occurred mainly in Victoria and is likely due to the creation of Pharmacotherapy Networks in early 2014—with one of their main roles being to increase the numbers of providers in Victoria.

with many more community pharmacists reluctant to offer the service.³² The cost of treatment (excluding dispensing) is \$185 million per year,³³ which is approximately \$4,000 per client.³⁴ Financial assistance, provided by the Australian Government through the Pharmaceutical Benefits Scheme (PBS), is designed for equity of access to PBS-approved drugs through the subsidisation of the price of prescription drugs, but does not include dispensing costs for medicines listed on Section 100. While the two main drugs; methadone and buprenorphine are PBS-approved (Section 100), this leaves the associated dispensing costs ranging from \$30 to \$70 per week for a client to pay.^{35, 36}

The current model falls short for most community-based pharmacists and for clients, primarily because it is not financially sustainable for pharmacists who operate a business. The model relies on the services of a few good Samaritans. Many clients (65-75 per cent) have limited finances and are often on fixed incomes or government benefits with limited capacity to pay the daily fee.³⁷ Retaining people on opioid substitution is a well documented challenge.³⁸ As detailed in a recent Penington Institute discussion paper; *Chronic unfairness: equal treatment for addiction medicines?*³⁹ There are major obstacles to enabling more Australians to access medication-assisted treatment and to maintain that treatment.⁴⁰ Dispensing fees are arguably the single greatest obstacle to retaining people in pharmacotherapy.⁴¹ The cost has negative impacts on the quality of life for clients, 'with many having to choose between missing doses because they don't have the money, going without food, other required medications, and even rent in some situations.'⁴²

Beyond the financial challenges lie a range of practices adding to the fragile nature of the service. Stigma and discrimination towards clients is often spoken about, ranging from staff being uncomfortable with these clients to fearing aggression, theft and the belief that these clients will drive away other customers.

³² Chaar B et al (2011) Provision of opioid substitution therapy services in Australian pharmacies, *Australian Medical journal* 4, 4, 210-216.

³³ Australian Institute of Health and Welfare (2016) *Australia's health 2016*, Australia's health series no. 15. Cat. no. AUS 199. Canberra: AIHW <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129556826>

³⁴ <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129556826>. Costing systems for pharmacotherapy can be complex since each state and territory administers their own pharmacotherapy program.

³⁵ Chalmers et al. 2009

³⁶ Methadone, buprenorphine and buprenorphine/naloxone are listed under Section 100 which does not cover dispensing fees. Buprenorphine/naloxone also known as Suboxone, is also classified under Section 85 and can be prescribed for 28 days with one dispensing fee (\$6.30 for concession card holder) paid per month. Once the Safety Net is reached the medicine is free for concession card holders.

³⁷ Lord, S., Kelsall, J., and Kirwan, A., et al (2014) Opioid pharmacotherapy fees: A long-standing barrier to treatment entry and retention, Centre for Research Excellence into Injecting Drug Use, Policy Brief No.8: September.

³⁸ Rowe J. *A raw deal? Impact on the health of consumers relative to the cost of pharmacotherapy*. Melbourne: RMIT and the Salvation Army; 2007.

³⁹ Penington Institute(2015) *Chronic unfairness: equal treatment for addiction medicines?* Melbourne Australia <http://www.penington.org.au/wp-content/uploads/2015/04/Chronic-Unfairness-Penington-Institute.pdf>

⁴⁰ Penington Institute (2015) *Chronic unfairness: equal treatment for addiction medicines?* Melbourne, Australia

⁴¹ Rowe 2008 op. cit.

⁴² Rossmannith A, (2011) Fees for pharmacotherapy: an unfair burden? *Of Substance*, vol 9 no 3

Retaining post-release prisoners on pharmacotherapy treatment is problematic:

The level of funding does not take into consideration broader costs associated with drug use. The high number of people detained due to drug use and the direct relationship between pharmacotherapy and lower drug use - an expanded and well resourced pharmacotherapy program would reduce drug related incarceration. The average prisoner now costs the Victorian taxpayer around \$270 a day or \$295,168 over their average sentence of three years' imprisonment.⁴³

Pharmacotherapy in prison offers many benefits, including reducing drug related harms in the prison population, reducing the likelihood of substance use upon return to the community and a reduction of drug-related criminal activity post release. Once released from prison there are many challenges associated with maintaining pharmacotherapy. This time is critical for most people released from prison who must negotiate housing, employment and reconnecting with family, friends and the broader community. A great deal of investment in treatments provided in prison can easily fall away once released. Given the dramatically reduced treatment duration to 12 weeks for patients without cirrhosis, prison has become a viable place to provide the full course of treatment or at a minimum work with people to get them ready for treatment upon release from prison. The result of these recent hepatitis C treatment changes is that more people are leaving prison having successfully completed treatment. Ensuring people have access to pharmacotherapy upon release and for more than one month is now also vital in reducing injecting and minimising hepatitis C re-infection. The good work conducted in prison through providing pharmacotherapy and now hepatitis C treatment is compromised when an inmate leaves prison if they cannot maintain their pharmacotherapy beyond the first month. While month long access to pharmacotherapy may protect against overdose, it does not provide any long-term solution for the ongoing cost of pharmacotherapy.

Victorian State Department of Justice acknowledges the challenges experienced by post-release prisoners when they reintegrate back into the community by funding one month of pharmacotherapy treatment. This assistance is vital in not only helping to build some stability upon release from prison but essential in reducing a range of risks associated with injecting, including infection or re-infection with hepatitis C and opioid related overdose due to reduced tolerance to opioids.⁴⁴ Reducing the number of deaths due to overdose is one often sighted argument for providing pharmacotherapy on release. It is unrealistic to expect that one month financial assistance to pay for dispensing fees will be long enough for people to establish stability.

Linking pharmacotherapy to hepatitis C treatment:

Sustained pharmacotherapy will decrease infection and reinfection of HCV. A recent global review assessing the impact of needle and syringe programs and pharmacotherapy in reducing the risk of becoming infected with hepatitis C has found evidence that pharmacotherapy in combination with high coverage of NSP can reduce hepatitis C transmission.⁴⁵ Pharmacotherapy plays an important role in reducing injecting, resulting in minimising hepatitis C infections as clients of pharmacotherapy are more likely to be offered hepatitis C treatment, to be treated for HCV and fully adhere to treatment. In

⁴³ Victorian Ombudsman, Investigation into the rehabilitation and reintegration of prisoners in Victoria September 2015

⁴⁴ Stuart A Kinner, David B Preen, Azar Kariminia, et al., Counting the cost: estimating the number of deaths among recently released prisoners in Australia, *Med J Aust* 2011; 195 (2): 64-68.

⁴⁵ Platt L, Minozzi S., Reed, J et al., Needle syringe programmes and opioid substitution therapy for preventing hepatitis C transmission in people who inject drugs. Cochrane Database of Systematic Reviews 2017, Issues 9. Rt. No.: CD012021

contrast, people injecting and not receiving pharmacotherapy are less likely to be engaged with the broader health system and will remain harder and more expensive to reach.

There appears to be a dose-response protective effect of increasing methadone exposure on hepatitis C incidence. A Sydney based study (HITS-c study) shows that participation in pharmacotherapy appears to be highly protective against hepatitis C incidence among people who inject drugs.⁴⁶ Findings from the study show that pharmacotherapy was protective against HCV seroconversion and was associated with a reduced risk of incident infection among those who mainly injected heroin or other opioids. In addition to the Sydney study, three prospective cohort studies of illicit drug users in Vancouver, Canada, between 1996 and 2012, found that MMT (methadone maintenance therapy) exposure was protective against HCV seroconversion.⁴⁷

Midgard and colleagues calculated cumulative HCV treatment uptake, estimated annual treatment rates, and identified factors associated with HCV treatment among individuals who have received OST in Norway. They found that HCV treatment uptake was not associated with age or gender, but associated with duration of active OST, whereby high continuity of OST over time and absence of heavy benzodiazepine use predicted HCV treatment uptake.⁴⁸

Proposed next steps:

That further discussions be progressed with key stakeholders, to the extent possible as a function of the ASHM Removing Barriers Project, to further explore this issue, with the view that new arrangements need to be developed with community pharmacists and other primary health workers so that dispensing pharmacotherapy is viable and maximised for clients.

1. One or more sustainable models need to be piloted that do not rely on only the good Samaritans throughout the broad workforce of community pharmacists. To not act to make pharmacotherapy more sustainable within community pharmacy settings has the potential to undermine the gains achieved from the introduction of subsidised hepatitis C curative treatments.
2. One or more pilots that bring together a multidisciplinary team consisting of primary health, primary mental health and pharmacotherapy programs for persons being released from prison are implemented. These services need to be integrated with existing alcohol and drug treatment, housing and employment services to ensure greater impact on a client's overall wellbeing.

⁴⁶ White, *op cit*.

⁴⁷ Nolan, *op. cit*

⁴⁸ Midgard H, Bramness JG, Skurtveit S, Haukeland JW, Dalgard O (2016) Hepatitis C Treatment Uptake among Patients Who Have Received Opioid Substitution Treatment: A Population-Based Study. PLoS ONE 11(11): e0166451. doi:10.1371/journal.pone.0166451