

Background: Inpatient ineligibility for Commonwealth subsidised hepatitis C treatment

A joint evidence summary

Overview

In March 2016, curative treatments for hepatitis C, direct acting antivirals (DAAs), were listed on the Pharmaceutical Benefits Scheme (PBS) enabling Commonwealth subsidisation supporting Australia's goal of eliminating hepatitis C as a public health threat by 2030. This was a landmark moment in the history of hepatitis C as DAAs were unrestricted, meaning that people could be prescribed DAAs regardless of their injecting behaviours or previous infection with hepatitis C. This announcement also included a commitment to provide access to DAAs to people in prison – people who are typically ineligible for Commonwealth subsidised medicines.

Under the PBS, DAAs can be prescribed by medical practitioners and nurse practitioners in the community and outpatient settings via the the General Schedule (s85) or the Highly Specialised Drugs Program (s100). However, PBS subsidy is not accessible in public hospital inpatient settings, meaning admitted patients in public hospitals are prevented from accessing curative DAAs for hepatitis C until discharged from their inpatient stay, unless the hospital is able to cover the large cost of prescribing DAAs to inpatients, which is rarely the case. This disproportionately impacts patients who are long-stay inpatients, such as those on psychiatry wards.

Admitted patients with hepatitis C

Patients admitted to hospital represent an important group for hepatitis C testing and treatment and research shows that people who inject drugs often require frequent hospital admissions.¹ Opportunistic testing of admitted patients is recommended to identify people with hepatitis C especially if the patient has a history of injecting drug use, are Aboriginal and/or Torres Strait Islander, have ever been in prison or have migrated from a high prevalence country.² One study of 260 patients admitted to four psychiatric units in South Australia over a year found 28 (11%) had been exposed to hepatitis C (antibody positive) of which 16 had a current hepatitis C infection (RNA positive).³

International evidence has shown that people are more likely to complete hepatitis C treatment if it is commenced during their hospital admission compared to referral to outpatient care upon discharge.⁴ Many people with hepatitis C are lost to follow-up when they are referred to outpatient settings or to their GP.⁵ This is due to a combination of individual and structural factors including competing priorities, low health literacy or socioeconomic disadvantage as well as stigma and discrimination and inadequate services to meet the needs of this

population.⁵ Furthermore, if DAAs are supplied on discharge, the patient must present back to a pharmacy to have their repeat prescriptions dispensed to complete the course. Many patients do not return (often due to the reasons listed above) and therefore do not receive the full course of treatment.

There are also additional costs to the health system for each inpatient who is diagnosed and lost to follow-up. Estimates suggest that it would cost between \$885⁶ and \$5,878⁷ to find and re-engage each individual into care (excluding the cost of treatment).

Despite the opportunities that an admission presents to test people and commence them onto treatment, Australian research shows that there are many missed opportunities within the hospital setting to link inpatients diagnosed with hepatitis C into appropriate care and treatment.^{5,8} There are several policy and regulatory barriers that may prevent that inpatients diagnosed with hepatitis C being prescribed DAAs within the hospital setting. These are described briefly below.

Policy and regulatory environment

National Health Reform Agreement and Pharmaceutical Reform Agreements

Under section 11(c) of the *2020-25 National Health Reform Agreement* (NHRA) state and territory governments have a responsibility to provide and fund pharmaceuticals to admitted patients.⁹ Specifically, the NHRA states that "States affirm their commitment to ... providing and funding pharmaceuticals for public and private admitted patients, and for public non-admitted patients in public hospitals (except where Pharmaceutical Reform Arrangements are in place)" (page 9). Under the Pharmaceutical Reform Agreements, approved public hospitals are able to "prescribe and dispense PBS-subsidised medicines, chemotherapy drugs and highly specialised drugs to day-admitted patients, outpatients, and patients upon discharge".¹⁰ Again, this excludes admitted patients from receiving PBS-subsidised medicines.

Highly Specialised Drugs Program

In terms of the Highly Specialised Drugs Program, section 8 of the *National Health (Highly specialised drugs program) Special Arrangement 2021* outlines the eligibility of a patient to receive Commonwealth subsidised medication including DAAs for hepatitis C treatment.¹¹ To be eligible, a patient must be receiving medical treatment from a medical practitioner or nurse practitioner at a public hospital and be receiving treatment as:

- i. a non-admitted patient of the hospital; or
- ii. a day admitted patient of the hospital; or
- iii. a patient on discharge from the hospital

If a person meets this eligibility criteria, they can then receive PBS subsidised medication. If they do not meet these criteria, such as being an admitted patient of a public hospital, it is then the requirement of the state or territory government via the hospital to fund the medication.

Although we also note that there are **some exemptions to these rules allowing inpatients to access Commonwealth subsidy** for eculizumab (a drug used for atypical haemolytic uraemic syndrome) and COVID-19 oral therapies (such as paxlovid) when it is unrelated to the reason for admission (e.g. for trauma patients).

The issue

The above policies and legislation do not preclude a patient from receiving DAAs as an inpatient, but they do prevent PBS subsidy in the public inpatient setting, which is critical to access due to its high cost. A treatment course of DAAs without PBS subsidy currently costs over \$30,000, and was previously over \$65,000 when first listed in 2016-17. Given the high cost of DAAs, hospital and pharmacy budgets and policies may limit the ability of a hospital to pay for DAAs while the patient is admitted and may instead wait until the patient has been discharged or is an outpatient to prescribe DAAs under the PBS. This is particularly problematic for patients who are admitted to long-stay mental health units.

We are aware of instances where admitted patients with hepatitis C have been denied access to DAAs on the basis of cost to the hospital. This issue has also been documented in the 2017 PBS Pharmaceuticals in Hospitals Review¹⁰ and again in a recent review of the Pharmaceutical Reform Agreements.¹² In both reports, hepatitis C was used as an example of a high-cost drug with dispensing often delayed until the patient is discharged.

Policy alignment

In order to eliminate hepatitis C as a public health threat by 2030, the *draft Sixth Hepatitis C Strategy 2023-2030* has made a commitment to leave no one behind in hepatitis C elimination efforts.¹³ However, without urgent change we will continue to leave people behind; leaving people with hepatitis C lost of follow-up, without adequate treatment and increasing their risk of developing liver disease, liver cancer and liver failure.

Furthermore, we consider inpatient ineligibility to be inequitable and in conflict with the Federal Government's 2016 announcement to provide universal access to DAAs for all Australians with hepatitis C, this announcement also made provision for people in prison to be treated through this program, despite people in prison being ineligible for Medicare and Commonwealth-subsidised pharmaceuticals outside of s100 listings. As a result, prisoners may receive s100 drugs through state and territory arrangements between health and justice departments that involve treating people in prison as an outpatient of state public hospitals or via other state/territory operated services.

We also consider the ineligibility of inpatients to receive DAAs to be in conflict with the 'equity and access' principle of the National Medicines Policy which seeks to ensure that "*All Australians have timely, safe and reliable access to effective, high-quality medicines...*".¹⁴

Case study

In 2024 a middle-aged male was admitted to hospital for a condition unrelated to hepatitis C. This patient has been diagnosed with hepatitis C for more than 20 years. This was his fourth admission since 2017 as an inpatient. In his most recent admission, he spoke with an Addiction Medicine nurse about accessing hepatitis C treatment and he expressed interest starting on treatment. However, he was unable to be commenced onto treatment while an inpatient. The patient was discharged with a referral to attend the outpatient addiction medicine and hepatitis C clinic but did not attend.

This case study highlights multiple instances where the inability to commence hepatitis C treatment from hospital was a barrier to this individual easily accessing cure.

Potential solutions

- Amend section 8(C) of the *National Health (Highly specialised drugs program) Special Arrangement 2021* to enable admitted patients with hepatitis C to be eligible to be commenced DAAs for treatment similar to what exists for eculizumab.

or

- Establish agreements between State/Territory governments and the Commonwealth government (similar to those that exist for people in prison) to allow for an exemption for admitted patients to receive Commonwealth subsidised treatment for hepatitis C.



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¹ Matthews, G. and Erratt, A. (2024) Treatment of Hospitalised Inpatients for hepatitis C (TOPIC), available online at: <https://www.kirby.unsw.edu.au/research/projects/treatment-hospitalised-inpatients-hepatitis-c-topic>, accessed 25 July 2024.

² Chiong, F. and Post, J. Opportunistic assessment and treatment of people with hepatitis C virus infection admitted to hospital for other reasons: A prospective cohort study, *Int J Drug Policy*, 2019, 65:50-55.

³ Ramachandran J, Budd S, Slattery H, Muller K, Mohan T, Cowain T, Tilley E, Baas A, Wigg L, Alexander J, Woodman R, Kaambwa B, Wigg A. Hepatitis C virus infection in Australian psychiatric inpatients: A multicenter study of seroprevalence, risk factors and treatment experience. *J Viral Hepat*. 2019 May;26(5):609-612. doi: 10.1111/jvh.13056.

⁴ Midgard H, Malme KB, Pihl CM, Berg-Pedersen RM, Tanum L, Klundby I, Haug A, Tveter I, Bjørnstad R, Olsen IC, Finbråten AK, Dalgard O. Opportunistic Treatment of Hepatitis C Infection Among Hospitalized People Who Inject Drugs (OPPORTUNI-C): A Stepped Wedge Cluster Randomized Trial. *Clin Infect Dis*. 2024 Mar 20;78(3):582-590. doi: 10.1093/cid/ciad711.

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- ⁵ Raja SS, Edwards S, Stewart J, Huynh D. Missed opportunities for hepatitis C treatment at a tertiary care hospital in South Australia. *World J Hepatol.* 2022 Aug 27;14(8):1576-1583. doi: 10.4254/wjh.v14.i8.1576.
- ⁶ Palmer, A. Y., Chan, K., Gold, J., Layton, C., Elsum, I., Hellard, M., ... & on the EC Partnership. (2021). A modelling analysis of financial incentives for hepatitis C testing and treatment uptake delivered through a community-based testing campaign. *Journal of Viral Hepatitis*, 28(11), 1624-1634.
- ⁷ Palmer, A. Y., Wade, A. J., Draper, B., Howell, J., Doyle, J. S., Petrie, D., ... & Scott, N. (2020). A cost-effectiveness analysis of primary versus hospital-based specialist care for direct acting antiviral hepatitis C treatment. *International Journal of Drug Policy*, 76, 102633.
- ⁸ Roder C, Cosgrave C, Mackie K, McNamara B, Doyle JS, Wade AJ. Missed Opportunities: A Retrospective Study of Hepatitis C Testing in Hospital Inpatients. *Viruses.* 2024 Jun 18;16(6):979. doi: 10.3390/v16060979.
- ⁹ 2020-2025 National Health Reform Agreement (2020) available online at: <https://www.health.gov.au/initiatives-and-programs/2020-25-national-health-reform-agreement-nhra> accessed 29 March 2022.
- ¹⁰ Department of Health, PBS Pharmaceuticals in Hospitals Review: Final Report, 2017, available from: <https://www.pbs.gov.au/reviews/pbs-pharmaceuticals-in-hospitals-review-files/PBS-Pharmaceuticals-in-Hospitals-Review.pdf> accessed 29 March 2022.
- ¹¹ National Health (Highly specialised drugs program) Special Arrangement 2021 (Cwlth) available from: <https://www.legislation.gov.au/>
- ¹² Department of Health and Aged Care (2024) Pharmaceutical Reform Agreement Review Report, available online at: <https://m.pbs.gov.au/reviews/pharmaceutical-reform-agreement-review-files/Pharmaceutical-Reform-Agreement-PRA-Review-Report.pdf>, accessed 25 July 2024.
- ¹³ Department of Health and Aged Care (2023) Sixth National Hepatitis C Strategy 2023-2030: for consultation, available online at: <https://www.health.gov.au/sites/default/files/2023-05/sixth-national-hepatitis-c-strategy-2023-2030.pdf>, accessed 3 October 2024
- ¹⁴ Department of Health and Aged Care (2022) National Medicines Policy, available online at: <https://www.health.gov.au/sites/default/files/2022-12/national-medicines-policy.pdf>, accessed 25 July 2024