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ORIGINAL ARTICLE

Hepatitis C virus reinfection incidence among gay and bisexual men with HIV in Australia from 2016 to 2020

Brendan L. Harney[1,2,3] | Rachel Sacks-Davis[1,2] | Daniela K. van Santen[1,2,4] | Michael W. Traeger[1,2,5] | Anna L. Wilkinson[1,2] | Jason Asselin[1] | Christopher K. Fairley[6,7] | Norman Roth[8] | Mark Bloch[9] | Gail V. Matthews[10,11] | Basil Donovan[10] | Rebecca Guy[10] | Mark Stoové[1,2,12] | Margaret E. Hellard[1,2,3,13] | Joseph S. Doyle[1,2,3]

[1]Disease Elimination Program, Burnet Institute, Melbourne, Victoria, Australia

[2]School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

[3]Department of Infectious Disease, Alfred Health & Monash University, Melbourne, Victoria, Australia

[4]Department of Infectious Diseases, Public Health Service of Amsterdam, Amsterdam, The Netherlands

[5]Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School, Harvard University, Boston, Massachusetts, USA

[6]Melbourne Sexual Health Centre, Alfred Health, Melbourne, Victoria, Australia

[7]Central Clinical School, Monash University, Melbourne, Victoria, Australia

[8]Prahran Market Clinic, Melbourne, Victoria, Australia

[9]Holdsworth House Medical Practice, Sydney, New South Wales, Australia

[10]Kirby Institute, University of New South Wales, Sydney, New South Wales, Australia

[11]St Vincent's Hospital, Sydney, New South Wales, Australia

[12]Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne, Victoria, Australia

[13]Doherty Institute and School of Population and Global Health, University of Melbourne, Melbourne, Victoria, Australia

Correspondence
Brendan L. Harney, Disease Elimination Program, Burnet Institute, 85 Commercial Rd, Melbourne, VIC 3004, Australia.
Email: brendan.harney@burnet.edu.au

Funding information
Department of Health and Ageing, Australian Government

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Abstract

Background: There is some concern that hepatitis C virus (HCV) reinfection might impact HCV micro-elimination efforts among gay and bisexual men (GBM) with HIV. However, there is a limited understanding of reinfection incidence in the context of unrestricted government-funded HCV treatment. We aimed to estimate HCV reinfection incidence among GBM with HIV in Australia from 2016 to 2020.

Methods: Data were from 39 clinics participating in ACCESS, a sentinel surveillance network for blood borne viruses and sexually transmissible infections across Australia. GBM with HIV who had evidence of treatment or spontaneous clearance with at least one positive HCV RNA test, a subsequent negative HCV RNA test, and at least one additional HCV RNA test between 1st January 2016 and 31st December 2020 were eligible for inclusion. A new HCV RNA positive test and/or detectable viral load was defined as a reinfection. Generalised linear modelling was used to examine trends in reinfection.

Abbreviations: ACCESS, Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually Transmissible Infections and Blood Borne Viruses; DAA, direct acting antiviral; GBM, gay and bisexual men; HCV, hepatitis C virus; IQR, interquartile range; IRR, incidence rate ratio; PY, person-years; RNA, ribonucleic acid.

Results: Among 12213 GBM with HIV who had at least one HCV test, 540 were included in the reinfection incidence analysis, of whom 38 (7%) had evidence of reinfection during the observation period. Over 1124 person-years of follow-up, the overall rate of reinfection was 3.4/100PY (95% CI 2.5–4.6). HCV reinfection incidence declined on average 30% per calendar year (Incidence Rate Ratio 0.70, 95% CI 0.54–0.91).

Conclusion: HCV reinfection incidence has declined among GBM with HIV in Australia since government-funded unrestricted DAAs were made available. Ongoing HCV RNA testing following cure and prompt treatment for anyone newly diagnosed is warranted to sustain this.

KEYWORDS
Australia, gay and bisexual, hepatitis C, HIV, reinfection

1 | BACKGROUND

Hepatitis C virus (HCV) reinfection has been reported among gay and bisexual men and other men who have sex with men (GBM) with HIV globally.[1] Prior to the availability of direct acting antivirals (DAA) to treat HCV infection, reinfection incidence estimates ranged from 2.9 per 100 person years (100PY) in San Diego[2] to 15.2/100PY in Amsterdam.[3] In a pooled analysis of four Australian HCV treatment studies conducted between 2004 and 2015, reinfection incidence was reported to be 10.3/100PY among people with HIV; 7 of 10 reinfections were among GBM.[4]

Due to the high reinfection incidence estimates prior to the availability of DAA treatment, there is some concern that reinfection in the DAA era might hamper elimination efforts. However, there remains heterogeneity in reinfection incidence rates among GBM with HIV who are treated with DAAs. Australian cohort and treatment studies reported reinfection rates of 1.05/100PY and 2.5/100PY, respectively.[5,6] Among people attending a HIV clinic in San Diego, reinfection incidence was reported to be 2.4/100PY overall but higher at 4.4/100PY among GBM.[7] In a German study from four HIV treatment centres the rate of reinfection incidence was 6.4/100PY.[8]

While these results suggesting lower reinfection incidence in some settings are encouraging, these studies were from the early years of DAA availability. The longer-term impact of DAA scale-up and resultant reduction in HCV RNA prevalence[6,9] on reinfection incidence remains largely unknown.

To the best of our knowledge, there are only two studies, both from Western Europe, that have examined HCV reinfection over time among GBM with HIV. In The Netherlands, HCV reinfection incidence was 4.1/100PY in 2016, declining to 1.1 per/100PY in 2019.[10] Reinfection incidence also declined in Switzerland, from 2.9/100PY in 2014, to zero in 2019.[11]

HCV direct acting antiviral (DAA) treatment was listed on the Pharmaceutical Benefits Scheme, part of Australia's universal healthcare system, on 1st March 2016 with no restrictions to treatment based on liver disease or substance use.[12] In addition, prescription was also allowed by general practitioners from this date and treatment for reinfection was also government funded. In this context, we aimed to examine HCV reinfection incidence trends from 2016 to 2020 among GBM with HIV attending primary care, sexual health and tertiary outpatient infectious disease clinics across Australia.

Key points

Hepatitis C reinfection has been reported globally among gay and bisexual men with HIV and there has been some concern that this might hamper elimination efforts. However, there are limited national level data on reinfection following widespread availability of direct acting antiviral treatment. From 2016 to 2020, hepatitis C reinfection incidence declined among gay and bisexual men with HIV in Australia. This suggests a potential treatment as prevention effect for hepatitis C reinfection among GBM with HIV.

2 | METHODS

2.1 | Data collection

Data were drawn from the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually Transmissible Infections (STI) and Blood Borne Viruses (BBV; ACCESS) which has been described in detail previously.[13,14] ACCESS collates BBV and STI testing and demographic data from clinics and laboratories, linking individuals' episodes of care over-time and between services participating in ACCESS using unique nonidentifiable codes. Ethical approval for ACCESS was received from the Alfred Hospital in Melbourne, Victoria, University of Tasmania in Hobart, Tasmania and Menzies School of Health Research in Darwin, Northern Territory. Ethical reviews were also undertaken by community organisations

representing key populations including GBM and people living with HIV. The requirement for individual-level consent was waived by all ethics committees.

In ACCESS data, GBM status among people with their gender recorded as male is derived from one or more of; being recorded as GBM in patient management systems, reporting one or more male sex partners in behavioural surveys at sexual health clinics, or having ever had a rectal STI swab for chlamydia or gonorrhoea recorded in ACCESS.[15] HIV status and date of HIV diagnosis among those classified as living with HIV was derived from linked HIV test results.

2.2 | Eligibility

For this study, included GBM with HIV had at least one qualitative HCV RNA positive test or detectable viral load test (hereafter HCV RNA test), followed by at least one negative HCV RNA test (indicative of potential HCV treatment and cure) between 1st January 2012 and 30th December 2021. At least one or more HCV RNA test between the observation period of 1st January 2016 and 30th December 2020 was required to be included in the reinfection incidence analyses. There were no restrictions on time between tests.

We limited the observation period to the end of 2020 to limit uncertainly in estimates in the final year of data availability as people were censored at their last HCV RNA test with no extra time added and this may result in artificially inflated incidence rates.[16] Testing history prior to the reinfection observation period was included for two reasons. Firstly, some GBM may have been known to have established chronic HCV, and as such may not have had additional HCV RNA testing in close proximity prior to commencing DAA treatment (Figure S1). Secondly, people who were treated and cured prior to DAA access are part of the population potentially at risk of reinfection.

2.3 | Measuring reinfection

The outcome of an incident HCV reinfection was defined as a positive HCV RNA test following a negative HCV RNA test among people who had a previously observed HCV RNA positive test.

Person-time for GBM began at the date of a first HCV RNA negative test following a positive RNA test. Censoring occurred if there was a new positive HCV RNA test or at their last HCV RNA test event recorded or at the end of the observation period.

2.4 | Evidence of treatment

In ACCESS, electronic prescription data are extracted where available, including retrospectively, but paper-based prescriptions are not captured in ACCESS. In addition, as a de-identified surveillance system, identifying people treated in ACCESS via clinical record audits is not possible. As such, we defined evidence of HCV treatment as either definitely treated or potentially treated.

People definitely treated were classified as GBM who had a positive HCV RNA test followed by a record of at least one electronic HCV DAA prescription (Supplementary Methods) preceding their subsequent HCV RNA negative test. Data on treatment duration are not consistently captured and treatment completion data are not captured in ACCESS. In real-world settings, there is considerable variation in the timing of test-for-cure follow-up RNA testing; however, when tested, cure rates are high and unsuccessful treatment attributable to viral relapse after a negative HCV RNA test is uncommon.[6,17] Therefore, these GBM were defined as successfully treated and were included in the reinfection analyses from their first HCV RNA negative test following their treatment prescription date (Supplementary Methods Figure S2).

People potentially treated were classified using two HCV RNA testing history criteria based on a combination of Australian HCV clinical guidelines, HCV RNA testing subsidies through Australia's Medicare Benefits Schedule, and the scientific literature on HCV spontaneous clearance for people with HIV.

Firstly, GBM with two or more positive HCV RNA tests at least 6 months apart (evidence of chronic infection[12]), with a subsequent negative test were defined as potentially treated due to the low probability of spontaneous clearance in those with chronic infection (Supplementary Methods Figure S3). Furthermore, spontaneous clearance will generally occur within 6 months of infection if at all.[18]

Secondly, GBM with two or more HCV RNA tests within 12 months following their first HCV RNA negative date were defined as potentially treated (Supplementary Methods Figure S4). As per the Medicare Benefits Schedule governing testing rules and reimbursements, only one HCV RNA test is reimbursed annually if a person is not undergoing treatment[19]; it is unlikely an intermittent HCV RNA test would be paid for out of pocket.

To examine the assumptions of our potentially treated definition, we assessed how many GBM with prescription data would also be classified as potentially treated based on each of these two criteria and in combination.

2.5 | Statistical analysis

Generalised linear modelling (Poisson distribution) was used to examine trends in HCV incidence by calendar year with the infection date assigned to the mid-point between the date of a reinfection event and that persons' previous negative test event.

2.6 | Sensitivity analyses for reinfection incidence

In our first sensitivity analyses, follow-up time started from a second HCV RNA negative test. This accounts for the uncommon possibility of viral relapse following an initial HCV RNA negative test[17] and that inclusion from the first negative test may lead to a higher reinfection incidence rate.[20] Second, we conducted analyses whereby only people with an HCV RNA positive result from 2016 onwards were

included as the inclusion of people who were historically treated, or spontaneously cleared, may inflate the person-years of follow-up, and thus reduce incidence rates. Third, as people can experience more than one reinfection, we included multiple reinfection events as previous research among GBM with HIV shows variation in incidence rates when only the first compared to multiple reinfections are included in analyses.[21]

All analyses were conducting using Stata 17 (College Station, Texas, USA).

3 | RESULTS

Between 1st January 2012 and 31st December 2021, a total of 12213 GBM with HIV had ≥1 HCV antibody and/or RNA test recorded in ACCESS data; 2615 (21.4%) had ≥1 HCV RNA test, of whom 905 (34.6%) had a positive test result. Following their first positive HCV RNA test, 798 (88.2%) had ≥1 additional HCV RNA test, with at least one HCV RNA negative result recorded for 687 (86.1%). Of these 687 people, 571 (83.1%) had ≥1 HCV RNA test following their first negative test (Figure 1).

Among these 571 people, 474 had some evidence of treatment; 297 (51.9%) people had a treatment recorded (definitely treated) and 177 (30.2%) had testing histories indicative of potential treatment.

Of the 177 potentially treated, 140 (79.1%) met the definition of chronic HCV infection (i.e., two positive HCV RNA tests greater than 6 months apart preceding a negative test) and 82 (46.3%) met the definition of potential treatment based on testing frequency post their first negative RNA. 45 (25.4%) met both definitions. In testing the sensitivity of these definitions of potentially treated, among people with treatment recorded, 238 (81%) people met one of these definitions based on their testing history (Supplementary Results).

3.1 | Reinfection incidence

During the reinfection incidence observation period 1st January 2016 to 30th December 2020 among 540 GBM with HIV, 38 (7.0%) had evidence of HCV reinfection. Median age at the date of inclusion in the reinfection incidence analysis was similar between those with evidence of reinfection (45; IQR 39–52) compared to those with no evidence of reinfection (47; IQR 41–54). There was minimal difference in the median number of years since HIV diagnosis among those with (7, IQR 3–7) and without (6, IQR 4–7) evidence of reinfection, and for years since first evidence of HCV infection, with a median of 3 years for both groups (IQR 1–6). The median number of HCV RNA tests since first eligible for those with evidence of reinfection was two (IQR 1–3) with a median of 5.3 months (IQR 2.8–8.8) between tests. Among those with no evidence of reinfection, the median number of tests was three (IQR 1–4) and the median time between tests was 8.8 months (IQR 6.0–14.2).

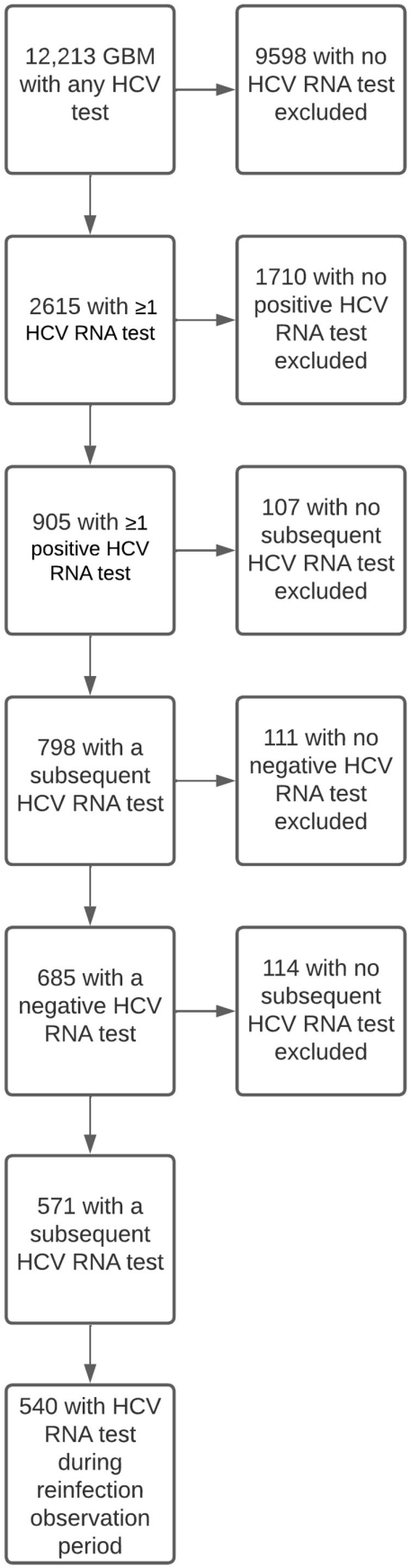

FIGURE 1 Overall eligibility for inclusion.

Over 1124 person-years of follow-up, the rate of reinfection was 3.4/100PY (95% CI 2.5–4.6). Observed reinfection incidence was highest in 2017, with an incidence rate of 5.6/100PY, before declining in 2018 to 4.1/100PY and in 2019 to 2.6/100PY; there were no observed reinfection events in 2020 in this analysis (Table 1). HCV reinfection incidence declined on average 30% per calendar year (IRR 0.70, 95% CI 0.54–0.91).

3.2 | Sensitivity analyses

In our sensitivity analyses where people were included from their second negative HCV RNA test, only people who had a positive HCV RNA test from 2016 onwards were included, and multiple reinfection events were included, there was modest variation in overall reinfection rates, and similar declines in reinfection incidence over time (Supplementary Results Tables S1–S3).

3.3 | Reinfection incidence stratified by GBM with and without treatment data

Among 288 GBM with treatment prescription data who had a HCV RNA test during the observation period, 18 (6.3%) were defined as having an HCV reinfection over 586 person-years for an overall rate of 3.1/100PY (95% CI 1.9–4.9).

Of the 252 GBM without treatment prescription data, inclusive of both those potentially treated and those without evidence of treatment, 20 (7.9%) were defined as having an HCV reinfection over 538 person-years for an overall rate of 3.7/100PY (95% CI 1.7–4.1). The peak of reinfection in these stratified analyses was in 2017 with a decline thereafter; however, there was some variation in incidence by calendar year (Supplementary Results Tables S4 and S5).

4 | DISCUSSION

In this analysis of HCV reinfection incidence among GBM living with HIV attending primary care, sexual health and hospital-based infectious disease clinics across Australia, we found reinfection incidence was 3.4/100PY between 2016 and 2020, which was considerably lower than that reported among people with HIV in Australia prior to DAA access at 10.3/100PY.[4] Furthermore, our findings indicate that reinfection incidence has declined over time since the early years of universal DAA availability, consistent with declining transmission anticipated as HCV prevalence declines with more people with HCV successfully treated.

TABLE 1 Hepatitis C reinfection rate by calendar year among GBM with HIV in Australia ($n = 540$).

Year	Person-years	Reinfections	Rate/100PY	95% CI
2016	160.8	6	3.7	1.7–8.3
2017	270.1	15	5.6	3.3–9.2
2018	265.5	11	4.1	2.3–7.5
2019	229.7	6	2.6	1.2–5.8
2020	197.8	0	0.0	

The reinfection incidence rate we found was higher than reported in Australian cohort[5] and treatment studies[6] during the DAA era. Many GBM with HIV enrolled in these studies likely attend a clinic that would have contributed data to our analyses. However, it is likely that we also included people who were never enrolled in these studies as our data were from routinely collected surveillance data and there were no additional study requirements nor consent processes. It is also possible that our data captured reinfections among people who never had an SVR test recorded via these studies due to our longer follow-up time, or reinfections after the end follow-up. The incidence we observed was similar to the 4.4/100PY incidence rate reported among GBM with HIV attending a single HIV clinic study in San Diego between 2014 and 2019[7] and lower the than the 6.4/100PY incidence rate reported across four HIV clinics in Germany between 2014 and 2018.[8]

We found reinfection incidence declined over time which aligns with results reported from Dutch and Swiss cohort studies of people with HIV, whereby a decline has also been reported in recent years among GBM.[10,11] This suggests that in addition to a treatment as prevention effect for primary incidence as also reported in these settings,[22] there is likely also a potential treatment as prevention effect for reinfection among GBM with HIV.

A likely major contributor to the decline in HCV reinfection incidence in our findings is government-funded universal access to HCV DAA treatment via Australia's Pharmaceutical Benefits Scheme (PBS). Of direct relevance to these analyses, treatment for reinfection, including multiple reinfections, was also government funded. From the first date of availability via the PBS, there were no restrictions based on liver disease or ongoing substance use. General practitioners could also prescribe treatment, as could authorised nurse practitioners since 2018. This was not the reality in many countries in the early years of DAA access, including other high-income countries[23,24] and a number of these barriers remain in place in some countries.

While we observed a decline in HCV reinfection incidence, ongoing HCV RNA testing is likely warranted to detect any new infections, promptly treat them, and sustain HCV elimination efforts to date. In some settings, multi-component interventions including home-based HCV RNA testing and GBM-specific harm reduction supply programmes among those potentially at risk of reinfection have been studied.[25,26] In addition, behavioural interventions have been part of test and treat studies[11] or are currently underway.[27] Whether similar programs specifically for GBM in Australia would be warranted is beyond the scope of this work. Given that HCV is already highly stigmatised, including among GBM with HIV,[28] rather than focus on changing the behaviours of a limited number of individuals who may theoretically be at risk of reinfection, it may be of greater benefit to consider a broader health promotion

campaign for HCV tailored to GBM. This may include efforts to raise awareness of HCV and reduce stigma related to HCV among all GBM. In addition, ensuring appropriate HCV testing occurs, and prompt treatment where required, will be critical. This may have even greater impact, given evidence suggests that HCV testing is somewhat sub-optimal more broadly among GBM with HIV and GBM using PrEP.[29]

A particular consideration with these data is that we were not able to perform a clinical audit to determine treatment status as the data were from a deidentified sentinel surveillance system. Given Australia has among the least restrictive hepatitis C treatment guidelines globally,[30] it is conceivable that some of the GBM without treatment data were indeed treated. Data from Australian treatment and cohort studies alone indicate that more than 300 people with HIV, the vast majority of whom were GBM, have been treated.[6,9] While still an underestimate, the approximate 50% with treatment data, and 30% with evidence of potential treatment, a total of approximately 80%, is more aligned with results from these studies. Furthermore, only approximately 50% of GBM with HIV having evidence of definite treatment in these data does not align with expert knowledge from senior clinicians working at clinics that contribute a substantial proportion of data to these analyses. Conversely, assuming all those without treatment data spontaneously cleared would also conflict with established evidence showing spontaneous clearance is uncommon among GBM with HIV.[31] Discussions are ongoing with relevant stakeholders to link these surveillance data to data from Australia's Pharmaceutical Benefits Scheme which would help to address this in the future.

Some limitations need to be considered in the interpretation of our findings. Firstly, we did not have access to clinical samples to undertake phylogenetic analyses to distinguish between unsuccessful treatment and reinfection as has been done in some other studies, and there is a possibility that some of the people classified as having a reinfection were unsuccessfully treated. Similarly, genotype data were not systematically available both before and after treatment to use changes in genotype or subtype to define reinfection as has been done in some other studies[5] Secondly, these data were from routine clinical care and as such, there was no specified time between tests meaning that some reinfections may be missed as they may have spontaneously cleared. Likewise, although post-treatment testing was generally quite high, not everyone had evidence of post-treatment testing in these data. While it is conceivable that these people may not have been engaging in behaviours that would warrant ongoing testing, we are not able to determine this in these analyses. Thirdly, it may be possible that our results were influenced by a lack of HCV RNA testing during COVID lockdowns experienced in Australia. For example, in Melbourne which experienced prolonged lockdowns in 2020, HCV testing declined in health services that provide care to people who inject drugs.[32] Likewise, asymptomatic STI testing also declined.[33] However, given these are all GBM with HIV, many still likely had HCV RNA testing as part of their HIV viral load monitoring. Finally, although this is the largest and most representative analysis of HCV reinfection among GBM with HIV undertaken in Australia to date, our findings may not be generalisable to GBM with HIV attending clinics that are not part of this sentinel surveillance network.

5 | CONCLUSION

HCV reinfection incidence among GBM with HIV in Australia in the DAA era is lower compared to what was reported in Australian studies in the pre-DAA era. There is some evidence that reinfection incidence has declined since the early years of universal DAA treatment availability, indicating a potential treatment as prevention effect for HCV reinfection. While this is encouraging, post-treatment testing, and at least annual HCV RNA testing thereafter, is likely warranted to detect any new HCV infections and offer prompt treatment to sustain hepatitis C elimination efforts to date among GBM in Australia.

AUTHOR CONTRIBUTIONS

Conceptualisation: B. L. H., R. S.-D., M. E. H. and J. S. D. Methodology: B. L. H., R. S.-D., D. K. v. S., M. T. and A. L. W. Data analysis and writing of the original draft: B. L. H. Data interpretation: B. L. H., R. S.-D., M. E. H. and J. S. D. Data collection: C. K. F., N. R. and M. B. Data curation: M. T. and J. A. Funding acquisition: B. D., R. G., M. S. and M. E. H. Review and editing of the manuscript: All authors.

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CONFLICT OF INTEREST STATEMENT

M. T. has received speaker's honoraria and support to attend the 2019 Hitos en Investigación Básica y Clínica en VIH/SIDA conference and investigator-initiated funding from Gilead Sciences. G. M. has received grants from Gilead Sciences and AbbVie Inc paid to her institution and payment from Janssen for chairing a meeting. M. S. served as an advisory board member for and received honoraria from Gilead Sciences and has received investigator-initiated funding from Gilead Sciences, AbbVie, and Bristol-Myers Squibb (BMS). M. E. H. has received investigator-initiated funding from Gilead Sciences, Merck, AbbVie and BMS. J. S. D. has received investigator-initiated funding from AbbVie, BMS, Gilead Sciences and Merck; consultancies from Gilead Sciences and AbbVie; support for attending meetings and/or travel from Gilead Sciences. D. K. v. S. reports payment to her institution (Public Health Service of Amsterdam) for Liver debate, sponsored by Gilead, AbbVie and Norgine. M. B. reports grants paid to his institution for clinical research from Gilead Sciences, ViiV Healthcare, MSD, AbbVie, Eli Lilly, Novartis and Pfizer; has received consulting fees for attendance at medical advisory boards from Gilead Sciences, ViiV Healthcare and AbbVie; has received payment or honoraria from presentations/lectures from Gilead Sciences and AbbVie; has received payments to attend scientific meetings or advisory boards from Gilead Sciences, ViiV Healthcare and GSK. R.G. has received research support funding from Gilead Sciences. All other authors report no potential conflicts of interest.

DATA AVAILABILITY STATEMENT

Deidentified individual participant data included in this study cannot be shared publicly because of the sensitive nature of participant data anonymously extracted from participating clinical services. Access to deidentified data is available via the Burnet Institute, Melbourne, Victoria, Australia, with approval from the Alfred Hospital Human Research Ethics Committee for researchers who meet the criteria for access to confidential data. The ACCESS study protocol has been published previously.

ETHICS STATEMENT

Ethics approval was provided by the human research ethics committees at Alfred Hospital (248/17), Central Australia (CA-19-3355), Northern Territory Department of Health and Menzies School of Health (08/47), University of Tasmania (H0016971), Aboriginal Health and Medical Research Council (1099/15), AIDS Council of New South Wales (2015/14), Victorian AIDS Council and Thorne Harbour Health (VAC REP 15/003), Western Australian Aboriginal Health Ethics Committee (885) and St Vincent's Hospital (08/051).

PATIENT CONSENT STATEMENT

As these are deidentified data collected under the auspices of public health surveillance, individual patient consent was not required. Individuals were able to opt out of the surveillance system at will.

ORCID

Brendan L. Harney https://orcid.org/0000-0001-9288-6942
Michael W. Traeger https://orcid.org/0000-0002-3452-350X

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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