2020-2021 Pre-Budget Submission

Australia has a unique opportunity to save lives, save money and continue to be a leader in a significant global elimination effort.

Our vision is an end to hepatitis B and hepatitis C in Australia.

Our purpose is to enable and empower everyone in Australia to live free from the impact of viral hepatitis

Contacts:

Helen Tyrrell - Chief Executive Officer
02 6232 4257
helen@hepatitisaustralia.com

Kevin Marriott – Programs Director
0400 940 321
Kevin@hepatitisaustralia.com

Introduction

The next three years presents Australia with a unique opportunity to save lives, save money and continue to be a leader in a significant global elimination effort.

Australia has an unprecedented, but shrinking, window of opportunity to eliminate viral hepatitis by the target date of 2030. By acting now to scale up efforts in the diagnosis and treatment of hepatitis B and hepatitis C, Australia can lock in success and continue to retain our status as a global leader in addressing viral hepatitis. The National Strategies and associated 2022 national targets mean that there is a clear plan of action, and ways to monitor and evaluate our progress during the term of the current Morrison government.

Viral hepatitis leads to a range of complications including liver cancer, which result in premature death. In 2016 and 2017 there were over 2,000 deaths nationally caused by hepatitis B and hepatitis C[1]. Hepatitis B and hepatitis C are the leading causes of liver cancer in Australia; this cancer has one of the lowest five-year survival rates and is amongst the ten leading causes of Australian cancer mortality for both men and women[2]. Liver cancer is one of the fastest increasing causes of cancer death in Australia[3]. As Australia's population doubled between 1968 and 2016, the annual number of liver cancer deaths increased 16-fold over the same period[4]. The rapid rise in Australian healthcare costs associated with cancer care has been noted by cancer experts and underscores the need for effective liver cancer prevention strategies. The vast majority of deaths from complications of chronic hepatitis B and hepatitis C, including liver cancer, can be averted if people receive treatment early.

All viral hepatitis experts agree that the next few years are crucial. The longer it takes to reach viral hepatitis elimination goals, the more it will cost and the greater the risk of preventable mortality and potential for hepatitis C reinfections following a cure. Australia is currently considered a leader in the global push to eliminate viral hepatitis by 2030. However, the 2022 national targets are very unlikely to be achieved without immediate, substantial and revitalised effort, putting the 2030 global targets in jeopardy.

This pre-budget submission outlines significant opportunities for Australia to secure and accelerate the achievement of a future in which hepatitis B and hepatitis C are no longer a threat to public health. It puts forward a process for funding the required investment with minimal impact on the federal health budget.

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[1] Kirby Institute (a). 2019. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2018.
Doherty Institute. 2019. National Surveillance for Hepatitis B Indicators: Measuring the progress towards the targets of the National Hepatitis B Strategy – Annual Report 2018. (Accessed October 2019).

[2] Australian Institute of Health and Welfare. 2019. Cancer in Australia: In brief 2019. Cancer series no. 122. Cat no. CAN 126. Canberra: AIHW. (Accessed October 2019).

[3] MacLachlan J. Cowie B. https://www.mja.com.au/journal/2012/197/9/liver-cancer-fastest-increasing-cause-cancer-death-australians (Accessed Oct 2019).

[4] Australian Institute of Health and Welfare. 2018 Cancer Data in Australia; Australian Cancer Incidence and Mortality (ACIM) books: liver cancer. Canberra. (Accessed October 2019).
Australian Bureau of Statistics. 3101.0 - Australian Demographic Statistics, Mar 2019. (Accessed December 2019).

The National Strategies responding to viral hepatitis[5] provide the framework for the renewed effort and investment needed to build on the good work that has been undertaken to date.

Now is the time to act to support the more than 400,000 people directly affected by viral hepatitis[6] and to set the wheels in motion to achieve agreed national targets for 2022 within the term of this Australian Government.

While there is still an enormous job ahead, we have the knowledge, tools and capacity to eliminate hepatitis B and hepatitis C as public health threats in Australia and a failure to do so cannot be countenanced.

The Issue - Hepatitis B

Hepatitis B is the most common blood borne virus in Australia and a leading cause of liver cancer and liver failure resulting in premature deaths. We anticipate a functional cure will transform the clinical management of hepatitis B within the next decade or so, however, in the meantime people with chronic hepatitis B require long-term regular monitoring and commencement on antiviral treatment during active phases of the infection. Each person who is not receiving regular clinical care for chronic hepatitis B is at heightened risk of progressing to liver cancer, liver failure and premature death.

Australia is working towards elimination of hepatitis B and has set national targets to achieve by 2022 as part of the Third National Hepatitis B Strategy 2018-2022[7]. Progress towards achievement of national targets has been slow, with only marginal gains made each year. Apart from the target for childhood immunisation coverage, on the current trajectory Australia will not meet the government endorsed 2022 Hepatitis B National Targets without significant extra effort.

Table 1 Progress towards the 2022 National Strategy Targets – Hepatitis B

Domain	2016 baseline	2017	Target by 2022
Diagnosis (a)	67.4%	67.6%	80%
Receiving care (a)	20.8%	21.3%	50%
Antiviral treatment (a)	8.2%	8.7%%	20%
Childhood Immunisation (b) Coverage (at 12 months)	94.3%	94.7%	95%
Attributable Mortality (a)	473 deaths	4.4% reduction from baseline (452 deaths)	30% reduction from baseline (<331 deaths)

Source: (a) Doherty Institute. 2019. National Surveillance for Hepatitis B Indicators: Measuring the progress towards the targets of the National Hepatitis B Strategy Annual Report 2018. (Accessed Dec 2019).
(b) ASHM. 2019. Viral Hepatitis Mapping Project: National Report 2017. (Accessed Oct 2019).

In 2017 of the estimated 221,420 people living with chronic hepatitis B there were nearly 72,000 undiagnosed; more than 174,250 not receiving care and a minimum of 24,932 who should have been receiving antiviral treatment but were not. Nearly 1,000 people died due to complications in 2016 and 2017 alone[8]. It is evident that Australia is not currently doing

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[5] Australian Government. Fifth National Aboriginal and Torres Strait Islander BBV and STI Strategy. Fifth National Hepatitis C Strategy. Third National Hepatitis B Strategy. (Accessed October 2019).
[6] *Op cit*. Kirby Institute (a).
Op cit. Doherty Institute.
[7] Australian Government. Third National Hepatitis B Strategy (Accessed October 2019).
[8] *Op cit.* Doherty Institute.

enough to address the scale and complexity of chronic hepatitis B in the community despite have the means to do so.

Meaningful progress to achieving the target of 80 per cent of people with hepatitis B diagnosed in 2022 and 50 per cent receiving care is challenging and requires a substantial and sustained increase in effort and investment to remove barriers to engagement and facilitate uptake of testing.

Culturally and linguistically diverse populations and Aboriginal and Torres Strait Islander communities make up the vast majority of the chronic hepatitis B population in Australia. Appropriate engagement with these communities requires continual effort rather than the stop-start approach we have witnessed recently, dictated by gaps in federal funding. Australia requires a strong multidisciplinary workforce of trained and motivated health professionals and community-based workers delivering high quality services to improve health literacy and provide support for engagement in long-term gold-standard monitoring and treatment while we wait for a functional hepatitis B cure to be developed.

The Issue - Hepatitis C

Hepatitis C is a virus for which there is no protective vaccine. The predominant risk of transmission in Australia is through sharing of injecting equipment. Of those who acquired hepatitis C in this way, two-thirds have historical rather than current risk factors. A smaller proportion of people contracted hepatitis C through other means including healthcare procedures. Without treatment, all people with chronic hepatitis C risk developing serious liver disease, cirrhosis and liver cancer.

Australia is working towards elimination of hepatitis C and has set national targets to achieve by 2022 as part of the National Hepatitis C Strategy 2018-2022[9]. However, if current trends persist, Australia will not meet these government endorsed 2022 targets.

Table 2 Progress towards the 2022 National Strategy Targets – Hepatitis C

Domain	2016 baseline	2017	Target by 2022
Diagnosis (a)	80.0%	80% (end of 2017)	90%
DAA treatment (b)	227,306 living with hepatitis C	24% (55,100 people treated to end of 2017)	65% (~148,000 people treated)
Hepatitis C attributable mortality (a)	658 deaths	11% reduction from baseline (583 deaths in 2017)	65% reduction from baseline (<230 deaths)

Source: (a) 2019 Kirby Institute HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2018. (Accessed Oct 2019).
(b) This data is estimated from multiple sources including market share, sales data and PBS treatment data.

At the end of 2017 of the estimated 182,144 people living with chronic hepatitis C there were 36,306 people undiagnosed, and more than 1,200 had died as a result of complications of hepatitis C in 2016 and 2017 alone[10]. It is evident that Australia is not currently doing enough to address the scale and complexity of chronic hepatitis C in the community despite have the means to do so.

Less than half of all people formally classified as "diagnosed" have undergone ribonucleic acid (RNA) testing[11] to confirm a current infection. The validity of the figure of 80 per cent "diagnosed" is therefore questionable. Many who were "diagnosed" decades ago (when

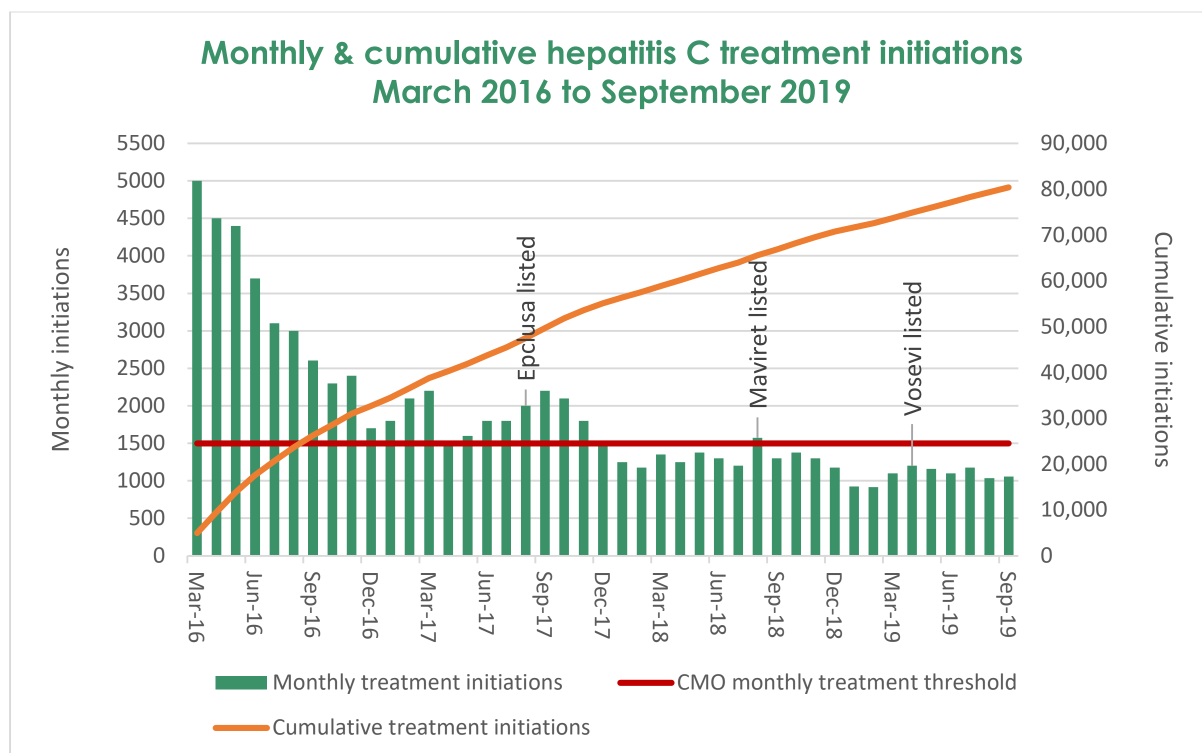
[9] Australian Government Fifth National Hepatitis C Strategy (Accessed Oct 2019).
[10] *Op cit*. Kirby Institute (a).
[11] *Ibid.*

treatment options were limited) did not have the RNA test and have been lost to follow up. Without a registry of "diagnosed" patients there is no easy means to find them again.

The 2022 target of treatment initiations for 65 per cent of the 2016 prevalent population (approximately 148,000 people) acknowledges the importance of 'front-loading' the bulk of initiations in the early years following the listing of the hepatitis C cures on the Pharmaceutical Benefits Scheme (PBS). This target recognised that locating, engaging and curing those who are not treated will inevitably become progressively more difficult over time as it requires us to find tens of thousands of people lost to follow up and unaware of the new cures.

The initial uptake of hepatitis C treatment following the PBS listing in March 2016 was strong, driven by those engaged in care and well-informed about the new treatments. However, instead of the monthly treatment initiations plateauing out around 1,500 per month as expected, they have continued on a downward trend. Since the beginning of 2018 treatment initiations have consistently been below the Chief Medical Officer's stated threshold of 1,500 per month and are currently running at little more than 1,000 per month.

Table 3 Hepatitis C Treatment Initiations 2016 – 2019



Source: These data estimated from multiple sources including market share, sales data and PBS treatment data.

To achieve the 2022 treatment target, over 19,000 people will need to be initiated on treatment each year, which is far higher than the 13,000 total initiations expected in 2019 based on current trends. It is clear that momentum has been lost over the last two years and avoidable premature deaths due to liver cancer and other complications will be the inevitable outcome if the current downward trend is not quickly reversed.

Immediate Priorities

While there is still an enormous job ahead in relation to eliminating hepatitis B and hepatitis C in Australia, we are in the fortunate position of having the knowledge, tools and capacity to reach this goal if investment is provided in line with the scale and complexity of the issue.

Hepatitis Australia and other experts are advocating a 'push – pull' approach to lift community awareness of the treatments available and to promote the benefits of early treatment to avert liver cancer and other complications of long-standing chronic hepatitis B and hepatitis C. A greater involvement of primary care providers to test and treat people with chronic hepatitis B or hepatitis C makes up the other side of the 'push - pull' approach. These two factors need to be implemented in tandem; while they work well synergistically, neither is particularly effective on its own.

1) Community Awareness & Education: Hepatitis B

Investment sought: $10m over three years for hepatitis B community awareness, education and engagement initiatives

Hepatitis B is poorly understood across the whole community, including in communities that have an elevated prevalence. The greatest burden of chronic disease in Australia is among people who acquired hepatitis B early in life. Chronic hepatitis B disproportionately affects people born in intermediate or high prevalence areas often in the Western Pacific region and Aboriginal and Torres Strait Islander peoples.

Lack of significant symptoms can lead people to believe that regular monitoring and treatment is not a priority even though liver damage may be silently progressing. Stigma also acts as a significant barrier to care. The National Hepatitis B Strategy identifies the need for greater awareness and understanding of hepatitis B among affected populations and the broader community.

Liver cancer is a critical concern. People who are either not diagnosed or who do not have regular monitoring are at much higher risk of developing liver cancer. In most cases liver cancer can be avoided through access to gold standard hepatitis B care. Despite this the burden of liver cancer in Australia is growing rapidly. To turn this around all individuals, families and communities who are at risk of hepatitis B need to have an improved understanding of how hepatitis B testing and treatment reduces their risk of liver cancer.

The Hepatitis B Community Education Program that was conducted through 2015-2018 demonstrated the capacity of Hepatitis Australia and our member organisations to engage broadly and deeply with diverse communities effected by hepatitis B. Over 40 separate projects were delivered in partnership with 220 community partners in all parts of Australia. The project connected with more than 30,000 people face-to-face through over 900 community education sessions, community events and workforce education sessions. As a legacy of this project, more than 50 digital resources in over 22 languages, including Asian, African and Australian Indigenous languages were developed to assist ongoing education among affected communities.

The government funding that supported this program ended in June 2019 and currently there is no national hepatitis B community awareness and education program being conducted in Australia.

2) Community Awareness & Education: Hepatitis C

Investment sought: $10m over three years for hepatitis C community awareness, education and engagement initiatives

A substantial majority of people living with chronic hepatitis C have historical rather than current risk factors for hepatitis C, are dispersed in the community, and are not connected to care for their hepatitis C. This group cannot be reached through services for people with current risk factors for hepatitis C, different engagement strategies are required.

This heterogeneous population of Australians with historical risk factors includes many people aged over 50 years who were diagnosed decades ago when there was no effective cure for hepatitis C. Over the years a substantial proportion have been lost to follow up care for their hepatitis C. Lack of significant symptoms can lead people to believe treatment is not a priority even though liver damage may be silently progressing. Stigma also remains a barrier to treatment and linkage to clinicians who are not judgemental is essential.

In addition to ongoing programs for treatment uptake among people who currently inject drugs, scaled-up investment is also needed to find tens of thousands of people who are a 'hidden population' dispersed across Australia and not engaged in clinical care for their long-standing hepatitis C infection.

Hepatitis Australia and its member organisations have demonstrated their expertise and ability to mobilise people not currently connected to care through the implementation of the TEST CURE LIVE hepatitis C treatment campaign[12] that is being managed nationally and rolled out in conjunction with our member organisations across all states and territories. This campaign seeks to engage with and motivate people living with hepatitis C to seek testing and/or the hepatitis C cure through their General Practitioner (GP). The locations for this Australian Government funded campaign in each state and territory are informed by the Viral Hepatitis Mapping Report[13] which identifies areas of higher geographic prevalence of hepatitis C and areas of lower hepatitis C treatment uptake. The number of locations selected has been limited to fit the available budget.

Internal evaluations to date indicate that the broad range of communication strategies have been well received by the over 50s age group (the key target demographic), and have resulted in an increased understanding of the benefits of hepatitis C treatment.

The Australian Government funding associated with this initiative expires in mid-2020. Continuity of community awareness and education initiatives combined with greater involvement of primary care providers to test and treat people with hepatitis C is essential to achieve the national 2020 targets.

3) Primary Care: Identifying, testing and treating people with hepatitis B and hepatitis C in primary care

Investment sought: $25m over three years to support a suite of incentive initiatives to identify, test and treat people living with chronic hepatitis B and hepatitis C

Increasing testing is the first step to achievement of the 2022 national hepatitis B and hepatitis C targets for diagnosis, treatment and care. Approximately 32 per cent of people with hepatitis B and 20 per cent of people with hepatitis C were undiagnosed at the end of 2017, representing over 108,000 people in total. In addition, less than half of people who had a hepatitis C positive antibody test went on to have a confirmatory ribonucleic acid (RNA)

[12] Hepatitis Australia. 2019. Test Cure Live. (Accessed October 2019).

[13] ASHM. 2019. Viral Hepatitis Mapping Project: National Report 2017. (Accessed Oct 2019).

test[14], suggesting this group of nearly 70,000 partially diagnosed people have been lost to clinical follow up.

The slow progress towards the diagnosis targets under previous national strategies[15] and the large number of people currently undiagnosed or only partially diagnosed makes initial and confirmatory testing a key area for action.

As people with chronic viral hepatitis may have no symptoms until liver damage has occurred, there can be substantial delays in diagnosis. Health care practitioners need to be proactive in their approach to testing people with either historical or current risk factors, and the system needs to be opportunistic in engaging with individuals prior to them feeling unwell. Early testing and diagnosis is of paramount importance to provide the gold-standard care that will reduce the risk of liver cancer, liver failure and premature death.

Recent studies overseas concluded that a strategy of universal one-time screening for chronic hepatitis C infection was cost effective compared to either birth cohort–based screening or no screening[16]. Despite this there is little apparent appetite for consideration of a one-time universal screening strategy at this point in time.

Cost-effectiveness studies should be undertaken as soon as possible to confirm the value of universal screening programs in Australia if the current international data is considered insufficient to support this approach. In the meantime, action is still required and Hepatitis Australia urges the government to support the introduction of a risk-based testing program within primary health care settings.

A risk-based testing approach for people who meet certain criteria is proposed. This would provide a significant chance to opportunistically engage with individuals, families and households who may be living with hepatitis B or hepatitis C. A relatively simple risk matrix can be constructed for both hepatitis B and hepatitis C for use by health practitioners in primary care. Barriers to engagement in testing such as stigma can be reduced by grouping risk factors together (i.e. asking patients to disclose whether they may have been exposed via any of a list of risk factors, rather than needing to specify a particular risk factor) and introducing the program as a one-time opt-out initiative.

Advancements in prescribing policies and the availability of safe and effective medicines enable the majority of people with hepatitis B and hepatitis C to be safely managed in primary care. Despite this the transition of uncomplicated hepatitis B and hepatitis C management and treatment from specialists to primary care practitioners is unfinished business.

Overall, between 2016 and 2018, 49 percent of individuals were prescribed hepatitis C treatment by specialists and 29 per cent by GPs[17]. In the 12 months to February 2018 only 3,493 GPs in Australia prescribed hepatitis C medication, representing around 10 per cent of all GPs in Australia, despite virtually all GP practices being likely to have between two and ten people living with hepatitis C in their care[18].

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[14] Kirby Institute (a). 2019. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2018.

[15] The Kirby Institute. National blood-borne viruses and sexually transmissible infections surveillance and monitoring report, 2017. Sydney: Kirby Institute, UNSW Sydney; 2017. (Accessed October 2019).

[16] Clinical Gastroenterology Hepatology 2019. Cost-effectiveness of universal screening for hepatitis C in the era of direct-acting, pangenotypic treatment regimens

[17] The Kirby Institute (b). 2019. Monitoring hepatitis C treatment uptake in Australia (issue 10). (Accessed December 2019)

[18] Drug utilisation sub-committee (DUSC) Report September 2018 (Accessed Nov 2019).

Firmly embedding hepatitis B and hepatitis C clinical management responsibility within primary care must be underpinned by information and education for general practitioners, practice nurses and others to support management of hepatitis B and hepatitis C in primary care. However, much more is required to reach elimination targets. Hepatitis Australia recommends that the Australian Government should consider a range of new incentive-based approaches, such as:

- practice incentives programs to support case-finding of people in general practices who may be living with chronic hepatitis B or chronic hepatitis C but are undiagnosed or not engaged in care for their hepatitis
- temporary three-year Medical Benefits Schedule (MBS) items for use by General Practitioners to support an increase in primary care hepatitis risk assessment, testing and treatment for chronic hepatitis B and hepatitis C
- consideration of using Primary Health Network (PHN) Population Health indicators to support health care providers to improve identification and management of people living with chronic hepatitis B and hepatitis C, particularly in locations of elevated prevalence for hepatitis B and hepatitis C and/or suboptimal treatment uptake.

The Investment Proposal

Australia remains at the forefront of a global effort to eliminate hepatitis B and hepatitis C, conditions that impact more than 400,000 Australians, over 325 million people worldwide, and can lead to premature death from liver cancer and other complications. The next three years provides a window of opportunity for Australia to leverage the work done to date. A modest investment within this period will have a significant return on investment –in terms of averting direct costs to the health budget, indirect costs to the economy and real costs to individuals and families who require viral hepatitis treatment, care and support.

Through engagement with affected individuals and communities, and by incentivising primary health care practitioners there are opportunities to reach the hepatitis B and hepatitis C 2022 interim elimination targets within the term of this Australian Government.

Hepatitis Australia is proposing a $45 million investment from 2020 – 2023 to reduce attributable deaths from liver cancer and other complications of viral hepatitis and support the achievement of the 2022 diagnosis and treatment targets.

Hepatitis B community awareness, education and engagement initiatives	$10 million over 3 years
Hepatitis C community awareness, education and engagement initiatives	$10 million over 3 years
A suite of Incentive initiatives to support increased identification, testing and treatment of people with hepatitis B and hepatitis C in primary care settings	$25 million over 3 years

Off-setting the investment

In 2016 the Australian Government invested more than $1 billion over five years in provision of hepatitis C DAA treatment on the PBS[19]. Hepatitis Australia is aware that the upcoming Pharmaceutical Benefits Advisory Committee review of the DAA hepatitis C treatments will assess the cost-effectiveness of current pricing and notes that monthly treatment initiations have been consistently below the Chief Medical Officer's threshold of 1,500 per month since January 2018. Any downward price adjustment will generate government savings against the initial $1 billion investment currently in place. Hepatitis Australia notes that any savings, against the already committed $1 billion investment, are driven solely by the drop in the number of people initiating treatment since the beginning of 2018. We also note that the National Strategy targets by 2022 will not be achieved without significant extra effort to support treatment uptake.

Hepatitis Australia therefore proposes that $45 million, as a proportion of any savings generated by the hepatitis C treatment cost-effectiveness review, is re-directed back into initiatives to support increased testing and treatment for both hepatitis C and hepatitis B. This investment in turn will assist the achievement of the national hepatitis B and hepatitis C targets by 2022, which the Australian Government has endorsed. Additionally, knowing the eyes of the world are on us, it will help Australia to maintain our status as a world leader in the response to viral hepatitis. Failure to reach elimination targets cannot be countenanced.

Significant investments in breast and cervical screening have been supported for many years by the Australian Government and over $95 million was provided over four years for the National Bowel Cancer screening program to accelerate screening for 50-74 year olds from 2015-2020[20]. There is now an opportunity to re-direct savings and invest in finding people with viral hepatitis through primary care risk-based testing to avert the growing burden of liver cancer and reduce the preventable deaths which exceeded 2,000 in 2016 and 2017 alone. Linking this liver cancer prevention initiative to the implementation of the National Strategies also allows for systematic monitoring and evaluation of impact over time.

Conclusion

In summary, the 2022 targets of the National Strategies for Hepatitis B and Hepatitis C can be achieved if action is taken now. The proposed measures can be funded through a redirection of a small proportion of the $1 billion investment which the Australian Government previously provided to make revolutionary hepatitis C treatments available on the PBS.

There is no economic downside to this investment in hepatitis B and hepatitis C testing and treatment in the short-term and substantial health and economic gains in the medium-term. All proposed measures are consistent with the priorities identified in the National Hepatitis B Strategy 2018-2022 and National Hepatitis C Strategy 2018-2022[21] and would contribute significantly to the achievement of the 2022 targets already endorsed by the Australian Government and maintenance of Australia's status as a global leader.

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[19] The Guardian https://www.theguardian.com/society/2015/dec/20/government-pledges-1bn-for-hepatitis-c-treatment-in-effort-to-eradicate-disease (accessed November 2019).

[20] Australian Government Department of Health Cancer Factsheet (accessed November 2019). https://www1.health.gov.au/internet/main/publishing.nsf/Content/A091E85A15E4F93DCA25814E0005C8EE/$File/20180709%20Cancer%20Fact%20Sheet.pdf

[21] *Op cit.* Australian Government.