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Towards eliminating hepatocellular carcinoma from Aotearoa New Zealand: a nationally coordinated programme to detect and treat chronic hepatitis?

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ABSTRACT

Hepatocellular carcinoma (HCC) is the seventh most common cancer globally, with 1 million people diagnosed and 830,000 cancer-related deaths annually, demonstrating the paucity of effective treatments, particularly for late-stage disease. Globally, and in Aotearoa New Zealand (AoNZ), chronic infection with hepatitis B (Hep-B) or hepatitis C (Hep-C) remain the most significant aetiological factors and the most amenable to intervention. Whilst Hep-B vaccination was nationally implemented in AoNZ in 1988 in children up to the age of 15 years, an estimated 3.2 million New Zealanders remain unvaccinated, each with up to a 15% likelihood of developing HCC by the age of 70 years if they contract Hep-B during their lifetime. Overall, 19,000 Māori, 15,000 Pacific and 10,000 non-Māori and non-Pacific New Zealanders are affected with undiagnosed Hep-B. Correspondingly, 45,000 New Zealanders are infected with chronic Hep-C with an appreciable long-term risk of developing HCC. Inexplicably, there has never been a nationally coordinated screening, treatment and surveillance programme established for either condition. An appropriately resourced, community-based programme to detect and treat Hep-B and Hep-C and screen for HCC in high-risk individuals, as well as optimising Hep-B vaccination rates, must be a national health priority.

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Introduction

Hepatocellular carcinoma (HCC) is the seventh most common cancer globally, with 1 million cases diagnosed and 830,000 patients dying of the disease in 2020 (Ferlay et al. 2021). The high disease-related mortality rate is attributable to a lack of curative treatment options, which currently include liver resection or liver transplantation in the minority of patients presenting with localised disease (Cucchetti et al. 2023) and an absence of any effective systemic treatment agents to downstage those with more significant disease

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burden (Cucchetti et al. 2023). In addition, over three-quarters of patients have advanced or metastatic disease, or are so highly comorbid at the initial diagnosis, that only best supportive care can be provided (Lubel et al. 2021). The most frequently observed global risk factor for the development of HCC is the presence of necroinflammatory liver disease, due to chronic infection with either the hepatitis B (Hep-B) or hepatitis C (Hep-C) viruses. Even in the absence of HCC, chronic liver disease carries a significant morbidity and mortality and, in patients with HCC, its presence often restricts treatment options due to the risk of hepatic decompensation and liver failure. Consequently, only 40% of patients with HCC will survive one year post-diagnosis, and less than 20% of patients are alive five years post-diagnosis, with most suffering from recurrent disease (Gurney et al. 2020). Public health interventions have therefore focused on prevention of both Hep-B and Hep-C. However, there must also be a strategy for early detection and treatment of both Hep-B and Hep-C infection, coupled with initiatives to detect infection-related HCC at an early and potentially curable stage (Pandey et al. 2022).

This manuscript summarises the current epidemiology of HCC in Aotearoa New Zealand (AoNZ) as well as the contribution made to this by unrecognised, and currently untreated, Hep-B and Hep-C infections currently present in AoNZ, which disproportionately affect Māori and Pacific communities. A future direction for the detection and treatment of Hep-B and Hep-C and HCC control for AoNZ will be proposed.

Epidemiology of hepatocellular carcinoma in AoNZ

The number of patients with HCC diagnosed annually in AoNZ have increased by one-fifth in the last 25 years (Hassan and Gane 2019). In our communities, the most commonly associated liver diseases are Hep-B (42% of patients), Hep-C (28% of patients), alcoholic liver disease (ALD) and non-alcoholic steatohepatitis (NASH) each affecting 10% of patients. The sustained increase in the incidence of HCC has been attributed to the progressive aging of our population, as well as an increasing prevalence of Hep-C and obesity (which contributes to NASH). Consistent with this hypothesis, the national prevalence of Hep-C-associated HCC increased from 19% to 34% and NASH-associated HCC from 4% to 15% between 1998 and 2017.

HCC is the fifth most common cancer affecting Māori and accounts for nearly 50 deaths per year. The cancer has steadily increased in incidence over the last 20 years in both Māori

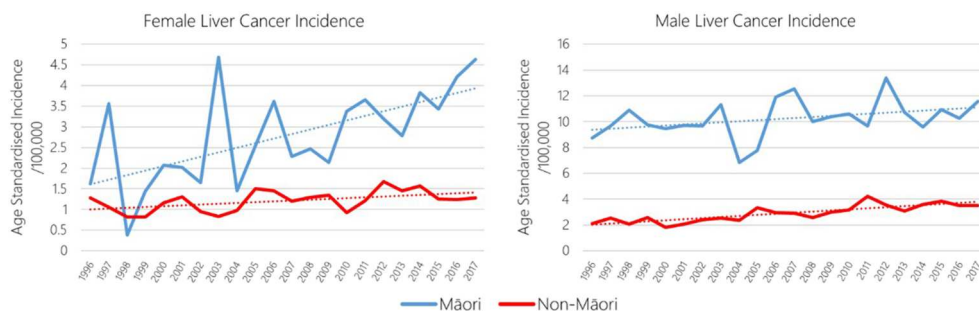


Figure 1. Incidence of primary liver cancer in NZ for Māori and non-Māori between 1996–2017, by sex (Gurney et al. 2020; Clough et al. 2022).

males and females in comparison to non-Māori New Zealanders (Figure 1). HCC is also the fifth most common cause of cancer death in Māori because of advanced stage at presentation and paucity of curative treatments (Gurney et al. 2020; Kahu 2021).

The relationship between hepatitis B and C infection and hepatocellular carcinoma

Chronic infection with Hep-B and/or Hep-C accounts for 80% of the annual global incidence of HCC (Yang et al. 2019). Consequently, HCC is the commonest tumour with a post-infectious aetiology, and this provides an important opportunity for early detection and treatment in affected populations.

Overall, 5% (300 million people) of the world's 8.2 billion population are affected by the Hep-B virus (Yang et al. 2019) and of these, one-quarter will die, primarily due to HCC (Asrani et al. 2019; McGlynn et al. 2015). Approximately half of HCC patients annually diagnosed worldwide are also affected by chronic Hep-B infection (Melaram 2021), since patients with chronic Hep-B infection are 30–60 times more likely to develop HCC over the course of their lifetime than those without Hep-B infection (Beasley et al. 1981; Franceschi et al. 2006; Rawla et al. 2018). Importantly, Hep-B infection is incurable, but neonatal and adult vaccination of non-immune individuals can successfully mitigate against infection in later life, and vaccinated populations have been shown to have consistently lower incidences of HCC than non-vaccinated populations (Franceschi et al. 2006; Villanueva 2019). In addition, in patients with elevated circulating Hep-B viral titres, oral antiviral agents can reduce circulating viral loads to zero and ameliorate infection-related hepatic necroinflammatory effects, slowing or preventing later development of HCC (Datfar et al. 2021).

Depending on the jurisdiction, chronic Hep-C infection is associated with 10%–25% of all HCC diagnosed internationally. Hep-C infection is the most common association with HCC in many economically developed countries and is associated with a 20- to 30-fold risk of developing HCC (Ghouri et al. 2017). In contrast, chronic Hep-B infection is more common in less developed regions (Villanueva 2019). Unlike Hep-B, no vaccine exists for Hep-C but curative treatment is feasible in infected individuals using direct-acting antiviral drugs. This has made eliminating Hep-C infection (World Health Organization 2016) and its complications a viable goal (Ministry of Health 2021).

The role of chronic hepatitis B and C infection as factors for HCC in AoNZ

In AoNZ, 56% of Māori patients with newly diagnosed HCC have evidence of chronic Hep-B infection in comparison to 27% of non-Māori with newly diagnosed HCC. In contrast, chronic Hep-C infection is only observed in 14% of Māori HCC patients while it is present in nearly one-quarter of non-Māori presenting with HCC. When combined, 70% of Māori with HCC have a history of Hep-B or Hep-C, compared to 50% of non-Māori (Chamberlain et al. 2013), confirming the presence of a substantial ethnic disparity for Māori in exposure to potentially treatable causes of chronic hepatitis.

Over two-thirds of patients who present with HCC secondary to viral hepatitis in AoNZ are diagnosed at an advanced stage, when curative treatment is not possible, and Māori are unfortunately overrepresented in these cohorts. Of the 646 patients who presented with

incurable HCC due to Hep-B or Hep-C in AoNZ between 2013 and 2018, 164 (45%) of the Hep-B cases were of Māori ethnicity compared to 32% Pacific, 15% Asian and 5% New Zealand European. In contrast, 177 (64%) of Hep-C-related cases were New Zealand European, compared to 23% Māori. These patients survived, on average, only seven months after diagnosis (Schauer et al. 2020). Chamberlain et al. also observed that, of those Māori patients with known Hep-B- or Hep-C-derived disease, only 40% were under any form of regular surveillance and monitoring at the time of cancer diagnosis (Chamberlain et al. 2013). The importance of Hep-B and Hep-C infection is emphasised in the report of Weir et al. who estimated that, if chronic Hep-B and Hep-C infections were detected and appropriately treated, 52% of deaths in Māori from HCC (approximately 25 deaths annually) would be prevented (Weir et al. 2002).

Prevention of hepatitis-derived HCC in AoNZ

Transmission of hepatitis B and C

Hep-B and Hep-C are endemic within AoNZ (Ministry of Health 2021; Moyes et al. 2002; Weir et al. 2002; Mules et al. 2018; Horsfall et al. 2020) and both are spread through physical contact and exchange of body fluids, including shared eating utensils (NZ BPAC 2018). There is a close correlation between risk of Hep-B infection and poverty, with one-quarter of 17,000 Hep-B patients living in areas of high deprivation, and Māori and Pacific patients experiencing the highest median deprivation levels of any demographic in AoNZ (Horsfall et al. 2020). In contrast, Hep-C is transmitted parenterally through needles and sharp instruments (Ministry of Health 2021; Ministry of Health 2002), with unsafe intravenous practice, or patients receiving unscreened blood, blood products or organs presenting the highest risk of infection (Nesdale et al. 2000 July).

Prevention of hepatitis B

Vaccination against Hep-B is highly effective and has been available since the 1980s, with the first vaccine approved by the Federal Drug Administration (FDA) in 1981. A recombinant vaccine became widely available in 1986 (Ministry of Health 2020), when AoNZ introduced neonatal vaccination. In 1988, vaccination was made available to New Zealanders of any age (Moyes et al. 2002), however, in spite of this, many New Zealanders born prior to the 1980s remain unvaccinated and are asymptomatic carriers of the disease. Horsfall et al. (2020) and Blakely et al. (1999) estimated that, in 2018, 3.2 million New Zealanders remained unvaccinated, of whom nearly 350,000 are Māori, and a total of 94,000 New Zealanders are undiagnosed and asymptomatic carriers of Hep-B. In addition, Gane (2005) has demonstrated that, despite efforts at developing a national neonatal vaccination programme, coverage is incomplete, with 4% of patients presenting with Hep-B infection aged 15 years or younger.

For patients who are acutely exposed to Hep-B infection, Hep-B immunoglobulin can also be administered intravenously after potentially infectious events. This is particularly relevant for infants born to Hep-B carrier mothers where immunoglobulin can be administered following delivery (Moyes et al. 2002) and both mothers and families can be linked into care (Weir et al. 2002).

Prevention of hepatitis C

In contrast to Hep-B, no vaccine is available for Hep-C, and prevention relies on public health measures such as needle exchange programmes and screening of blood and blood products prior to their administration (Ministry of Health. Inter-Agency Committee on Drugs 2015; NZ Blood Service 2021).

Screening for hepatitis B

In AoNZ, measurement of hepatitis B surface antigen (HBsAg) is included in routine antenatal and blood donor screening (Robinson et al. 2005). However, more formalised national Hep-B screening initiatives for New Zealanders have never been implemented. As a consequence, up to 50,000 affected individuals with Hep-B and 20,000 patients with Hep-C are living in AoNZ with undiagnosed and untreated chronic hepatitis, and half of the approximately 60 patients a year who present annually with a new diagnosis of Hep-B-associated HCC are unaware of their Hep-B status and its importance in the pathogenesis of their cancers (Mules et al. 2018).

Historically, initiatives to develop screening programmes have been only regionally based. In 1994, the New Zealand Hepatitis Foundation (HFNZ) developed a primary care-based programme in the Bay of Plenty (Robinson et al. 2005). In 1998, a programme was implemented in Northland and Auckland with a particular focus on Māori, Pacific and Asian communities. This public health-based programme utilised public health staff, primary healthcare providers as well as Iwi and Pacific healthcare providers to undertake testing and provide immunisation, follow-up and surveillance (Robinson et al. 2005). Initially, HBsAg was tested for. Individuals who tested positive for HBsAg were then tested for e antigen (HBeAg), alanine aminotransferase (ALT) as a marker of hepatic inflammation and alpha-fetoprotein (AFP) as a marker of HCC (Robinson et al. 2005). The programme had a coverage aim of 70% in all communities but did not reach this, and only 27% of Māori completed screening. The reasons for the low coverage were multifactorial but included the fact the testing was individually focused rather than whānau/community focused, and a blood test was required that was used only to screen for a single condition. Following completion, it became apparent that ensuring that ongoing monitoring and surveillance of those patients diagnosed with chronic Hep-B (4081 patients in total) would be problematic since no defined pathways existed for primary healthcare providers to access specialist services for referral and routine cross-sectional imaging of their newly diagnosed patients (Robinson et al. 2005).

Screening for hepatitis C

In 2022, a nationally funded testing programme for Hep-C was made available via primary health care providers, some pharmacies and also at community events (Robotin and George 2014; Hepatitis C), involving opportunistic testing of individuals with a finger prick to test for Hep-C antibodies. If these are detected, a further test is undertaken for circulating Hep-C viral load and, if this is positive, specialist assessment is initiated through the HFNZ. This programme has now been underway since 2023 (Noller and Bourke 2020).

Surveillance of hepatitis B and C patients for HCC in AoNZ

Hepatocellular carcinomas are initially asymptomatic, and the development of symptoms is largely related to tumour size, with pain due to hepatic capsule invasion, vascular occlusion or hepatic decompensation being common presentations. Early-stage HCCs are amenable to potentially curative treatments (Cucchetti et al. 2023), however, most patients with Hep-B- or Hep-C-derived HCC in AoNZ are diagnosed at an advanced stage of the disease with limited treatment options (Schauer et al. 2020; Lubel et al. 2021). Consequently, close monitoring of patients at risk for developing HCC is an important mechanism for the diagnosis of early, small tumours that can be treated with curative intent (The Hepatitis Foundation of New Zealand). When HCC is diagnosed through routine surveillance, as is the case in 44% of new diagnoses annually in AoNZ, survival more than doubles from 43 months to 94 months, with the likelihood of receiving curative intent therapy increasing fivefold (Schauer et al. 2019).

A national HCC surveillance service was established in New Zealand in 1998, which was responsible for all cases of HCC, including those caused by the hepatitis virus (The Hepatitis Foundation of New Zealand). Patients diagnosed with chronic Hep-B infection by healthcare providers are currently referred to the Hepatitis Foundation New Zealand's (HFNZ) surveillance programme. Once enrolled, patients have regular assessments of liver function test and circulating Hep-B DNA to assess the need and effectiveness of anti-viral therapy (Horsfall et al. 2020). Imaging of the liver and assessment of AFP is undertaken every six months with the aim of detecting hepatic mass lesions (Robotin and George 2014).

However, the diagnosis of chronic Hep-B in AoNZ currently only relies on *ad hoc* screening of patients by motivated general practitioners and other primary care providers. This means there is no coordinated national approach to systemically capturing and screening at-risk populations—particularly Māori and Pacific. In addition, despite diagnosis, many patients are not referred to or do not access the HFNZ surveillance programme. By November 2019, only 19% of patients diagnosed with Hep-B had been recruited onto the HFNZ programme (Schauer et al. 2019; Horsfall et al. 2020), and three-quarters of patients presenting with advanced HCC were not under the care of a surveillance programme (Horsfall et al. 2020). The reasons for the lack of uptake in this programme are not clear, however, self-referral is required and patients must be eligible for government-funded healthcare in AoNZ.

However, one-quarter of patients presenting with Hep-B- or Hep-C-related advanced HCC were receiving guideline optimal surveillance at the time of diagnosis. This emphasises the, at times, aggressive nature of the disease, and also the limitations of current diagnostics (Mules et al. 2018). One-third of HCC cases will have a measured AFP in the normal range, and false positive elevations may be produced by Hep-B infection alone or by pregnancy. Small HCC may be difficult to visualise ultrasonographically in livers with fibrotic or regenerative parenchyma. Other imaging methodologies are available, such as magnetic resonance imaging (MRI) and contrast-enhanced ultrasound, to sequentially monitor for the development of HCC—particularly in patients with cirrhotic or steatotic livers (Mules et al. 2018)—but they are more expensive and more invasive, and therefore less likely to be accessible for many patients.

Recommendation 1: a national commitment to a population-based Hep-B, Hep-C and HCC screening programme for AoNZ

Chronic infection with Hep-B and Hep-C is a significant health issue in AoNZ, particularly in Māori and Pacific communities. Aotearoa New Zealand has a health sector that currently has the capability, if not the capacity, to support the diagnosis, follow-up, treatment and evaluation of patients with Hep-B and/or Hep-C infections and any subsequent complication such as HCC. In this respect, screening for HCC in patients with chronic viral hepatitis has been shown to be cost effective and to have a similar cost-effectiveness ratio to already implemented national screening strategies (colorectal and breast cancer) (Arguedas et al. 2003; Lin et al. 2004). Aotearoa New Zealand is one of the 194 member nations to adopt the 2016 World Health Organization (WHO) strategy to eliminate viral hepatitis as a major public health issue by 2030 (World Health Organisation 2022). However, the historical weakness of AoNZ in the detection of untreated Hep-B and Hep-C, as well as HCC, has been a lack of a nationally coordinated programme—either universal or risk-group based screening and the reliance on opportunistic screening in the community prior to referral for specialist assessment.

Both Hep-B and Hep-C meet the World Health Organization criteria for disease screening (Owens et al. 2020):

- The condition is an important health problem for the person and the community
- Highly accurate diagnostic tests are available
- There is a long asymptomatic period of infection
- Treatments are available and they are effective when started earlier in the course of the disease
- Based on cost-effectiveness studies, the cost of diagnosis and treatment is economically balanced in relation to healthcare costs as a whole.

In 2020, the United States Preventative Services Task Force stated that all adults should be offered screening for both Hep-B and Hep-C infection (Owens et al. 2020). Building on this work, investigators in Australia have recently proposed that universal screening for Hep-B should also be applied in that country (Allard et al. 2021), since risk-based testing and opportunistic testing is failing to detect one-third of patients living with Hep-B in Australia—a situation that is remarkably similar to AoNZ. Currently, up to 2 million Europeans, 333,000 Māori and 215,000 Pacific people in AoNZ remain unvaccinated for Hep-B, and 10,000 Europeans, 19,000 Māori and 15,000 Pacific Islanders have undiagnosed and unmanaged chronic Hep-B infection (Horsfall et al. 2020), while over 20,000 patients with chronic Hep-C are in the same position (Schauer et al. 2020). Not surprisingly, the mortality and incidence of HCC, the most significant complication of chronic hepatitis infection, has continued to increase over nearly 30 years in spite of the various initiatives undertaken.

Recommendation 2: establish an implementation group for a population-based screening programme

The National Screening Committee provides advice to government on large screening programmes, and budget for programme establishment and implementation is approved

by cabinet. Cancer screening programmes are managed by the National Screening Unit. Programme pilots (such as bowel cancer and lung cancer screening) are undertaken and evaluated by Te Whatu Ora/Health New Zealand. Both primary and secondary health-care services are administered and funded through Te Whatu Ora/Health New Zealand, and this provides an opportunity to establish the integrated care pathways from community screening events through specialist assessment and radiological investigations, required for a population-based screening programme to be effective. Such an implementation group should include representatives of the HFNZ, the National Screening Committee, The National Screening Unit, Te Whatu Ora/Health NZ, primary health-care, Māori, Pacific and immigrant communities and would be required to consider the following questions (Hei Āhuru Mōwai - Māori Cancer Leadership Aotearoa 2021).

Where would screening take place?

A programme to detect and treat Hep-B and Hep-C, as well as screen for HCC, should be undertaken through primary care, community care providers (including pharmacies) as well as mobile screening units with adequate resourcing and clearly established pathways for patient referral and escalation of investigation and treatment. However, many New Zealanders and Māori in particular (possibly as high as 50% in some communities) currently do not have access to primary healthcare providers (Newshub). During the COVID-19 epidemic, appropriately resourced Māori and Pacific health providers demonstrated that a widespread vaccination programme could be undertaken, with high levels of effectiveness in many high-needs communities outside of normally accepted channels of healthcare delivery (Beehive.govt.nz). Leveraging the insights gained in AoNZ from the national response to COVID-19 by credentialing a non-clinical workforce to undertake screening tests and administer vaccinations demonstrates the potential for successful training initiatives in this context. One viable solution to bolster primary and community care teams in screening for Hep-B and Hep-C involves investing in the training of non-clinical staff to conduct targeted screenings within the communities they both know and serve. This strategy would facilitate the integration of established pathways, including those of the HFNZ, within primary care teams for further investigation, treatment options and surveillance.

What would screening entail?

Previous regional screening initiatives have initially tested for Hep-B (HBsAg) and Hep-C (Hep-C Ab); those with positive results should undergo further testing including Hep-B/Hep-C circulating viral load, liver function tests (bilirubin, ALT, alkaline phosphatase, gamma glutamyl transferase), INR (international normalised ratio) and platelet count. HBsAg-positive patients will additionally be tested for Hep-B e antigen. HBsAg- and Hep-C Ab-positive patients should also be tested for AFP (Figure 2).

Who should be screened?

Currently the HFNZ recommends screening for anyone over 35 years of age unless they have been fully vaccinated for Hep-B, particularly individuals of Māori, Pacific Island or South

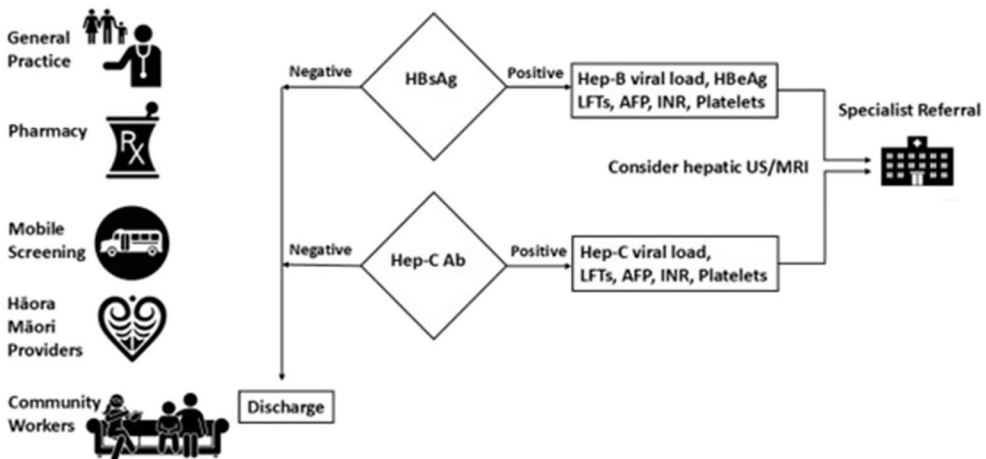


Figure 2. Proposed structure of nationally coordinated screening programmes for hepatitis B, C and HCC in AoNZ (HBsAg: hepatitis B surface antigen, Hep-C Ab: hepatitis C antibodies, Hep-B: hepatitis B, HBeAg: hepatitis B e antigen, LFTs: liver function tests, INR: international normalised ratio, AFP: alpha-fetoprotein, US: ultrasound, MRI: magnetic resonance scan).

Asian ethnicity, individuals born outside of AoNZ in a country with high hepatitis B endemicity, including Asia, the Pacific Islands, Africa, the Middle East and southern Europe, individuals who have a mother or close family member with Hep-B, live with someone who has Hep-B or Hep-C, have ever had unprotected sexual contact with an Hep-B- or Hep-C-infected person, or have ever used intravenous drugs or shared needles (The Hepatitis Foundation of New Zealand). Given the prevalence of undiagnosed and untreated Hep-B and Hep-C in AoNZ, a case can be made for initially screening all adult New Zealanders aged 18 and over.

When and how often should liver cross-sectional imaging take place?

The optimal imaging interval and modality is not yet established. Many screening programmes rely on annual trans-abdominal ultrasound examinations. Ultrasound has the advantage of being non-invasive and units can be easily transported to communities. MRI scans are more detailed but must be performed in a hospital setting and are invasive. Two recently developed HCC risk scoring systems (REACH B and REAL B) (Yang et al. 2011; Yand et al. 2020) developed and validated in Asia may assist in defining a high-risk group of AoNZ patients with chronic hepatitis, if validated in AoNZ, who would require detailed and frequent imaging follow-up.

Where does the care of screen positive patients take place?

Patients who test positive for either Hep-B or Hep-C will require either lifelong suppressive or definitive antiviral therapy. Those with evidence of hepatic dysfunction, cirrhosis or raised AFP will require more detailed assessment with liver fibroscan, hepatic cross-sectional imaging and multidisciplinary team review. Currently, primary healthcare providers can face difficulties referring patients to public hospitals for specialist opinions and cross-sectional imaging, although the national breast screening service has shown that an

integrated approach to both diagnostics and treatment can be achieved. Multiple hāuora providers within community settings hold contracts for cancer screening and navigation services across AoNZ and also have established relationships with secondary and tertiary providers. There is an option for further resource and skills investment into hāuora providers to support the screening and referral process for further investigations for those who test positive for HBsAg and Hep-C with abnormal liver function tests and AFP (Hei Āhuru Mōwai). Additionally, community-based providers could support specialist outreach clinics for patient assessment and care.

How would such a screening programme fit within AoNZ's current screening strategy?

A recent international review of cancer screening in Indigenous communities (Han et al. 2024) emphasises the importance of consolidating screening opportunities for cancers such as colon, lung and breast into single screening episodes, rather than multiple single condition-specific screening events. Screening of multiple individuals in families or other groups is also valued. Consolidating screening for multiple conditions creates an opportunity for using culturally appropriate information strategies, including oral and visual mass media in Indigenous languages, alongside community outreach events that combine education with peer support, the potential for opportunistic screening and the involvement of community leaders. It must be acknowledged that screening of families and individuals is potentially stressful and lifechanging for those involved. Consequently, specialist navigators, psychologists and support services must also be an integral part of this process.

Conclusion

While our primary healthcare system and our hospital-based healthcare system are currently struggling to manage resources and demand, an integrated national hepatitis screening programme and, by extension, HCC surveillance programme does not require development of any new testing or diagnostic facilities, and the current treatments (immunoglobulin, antiviral agents, hepatic resection and transplantation, embolisation and ablation) are already established and available. Many of the secondary diagnostic and treatment pathways required have also been established by the HFNZ. Such a programme would provide a template on how prudently directed and coordinated resources could essentially eliminate a major cause of cancer death and medical morbidity from AoNZ within a generation.

Disclosure statement

This work has not previously been presented or accepted for presentation or publication. There are no conflicts of interest pertaining to this investigation.

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