Hepatitis B Protocol Review – Evidence used and rationale

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Rationale:

The Kimberley has the highest rate of chronic hepatitis B (CHB) in Australia (by Primary Health Network) with a prevalence of 3.88%. This is over FOUR times the national average of 0.95%. This rate climbs to 8.4% for Aboriginal and Torres Strait Islander people living in very remote areas of WA. This is almost NINE times the national average.

There is poor care uptake (treatment and monitoring) of CHB in the Kimberley, with only 4.5% of people with CHB receiving treatment and/or monitoring for their condition. This is compared to the national average of 20.2% and falls far short of national targets.

Hepatitis B is a complex disease. Evidence tells us that inadequate hepatitis B knowledge among primary health care providers and people with the virus are critical contributions to poor monitoring and management. There is also evidence that a lack of a systems-based approach to clinically managing the infection contributes to poor management.

The Kimberley Hepatitis B protocol provides Kimberley specific screening, vaccination, monitoring and management guidelines for hepatitis B in the Kimberley. It is informed by Australian guidelines, Kimberley specific research, research on other Aboriginal and Torres Strait Islander groups with hepatitis B, Kimberley public health data and by local Kimberley medical and public health practitioner's experience. It should address the need for a systems-based approach to clinically managing CHB, and simplify the complexities involved in the care of people with CHB for primary health care providers in the Kimberley. It also specifically addresses the importance of education and support to patients with CHB in order to maximise the capacity for those affected by CHB to engage with primary care providers and optimise their own health.

Changes from previous protocol and discussion points:

Screening for hepatitis B

The screening section has been split into 'screening for infection/immunity' and 'screening for risk factors' to try and simplify this confusing practice.

In the Kimberley region, the routine vaccination schedule has excellent coverage, with the majority of people born during or after 1989 thought to be fully vaccinated. A completed vaccination course generally provides long-lasting protection even though HBsAb levels may decline over time and become undetectable. There is some contention around this however, as there is some evidence of vaccine failure and peculiar serological patterns in the Kimberley. This might suggest we should be screening for infection/immunity even in those that have a record of completed vaccination. It was determined however by the working group of this protocol that there is not enough evidence at this stage to be able to change our current practice and to sway from AIH recommendations.

It was decided that determining an individual's risk status is the most important aspect of determining their need for screening for infection/immunity.

Screening for infection/immunity is NOT needed for 'low risk' people (i.e no High Risk factors as per table 2) who have completed a vaccination course OR have serological evidence of immunity to hepatitis B (HBsAB >10 mIU/ml) on any previous blood test. But these individuals do need yearly screening for High Risk factors. Please review all previous blood test results, check AIR and/or KPHU records and update the patient file accordingly.

Screening is also NOT needed for those who have serological evidence of immunity (HBsAb>10 IU/ml) on ANY previous blood test despite their risk status.

'Screening for High Risk factors' is an important element of screening for hepatitis B and this should be done annually for EVERYONE. People who are determined to have high risk factors (as per table 2) who are not known to be immune (no evidence of HBsAb>10 mIU/ml on any previous blood test) should be screened for infection/immunity with HBsAb, HBsAg and HBcAb despite their vaccination status. If they are found not to be infected but also not immune to hepatitis B, table 2 should be used to determine if they are eligible for a free hepatitis B vaccination course or booster. If a person with a high risk factor is not infected and not immune, but they are also not eligible for free vaccination, they should continue to be screened yearly for high risk factors and hepatitis B infection/immunity if required. If they cease to have a high risk factor, i.e they are no longer an IVDU, then they do not need ongoing screening.

It is important to remember however that screening is different to testing and that anybody who requests testing, reports high risk behaviours, has other positive STIs or is a named contact requires immediate testing for Hepatitis B (if they consent) despite their immunisation or serological evidence of immunity status.

Table 2

Table 2 is new to this protocol. Hepatitis B screening and vaccination recommendations by AIH, AHSM and GESA, do not necessarily meet the Western Australian (WA) state

government funding eligibility for FREE hepatitis B vaccinations. Of particular note and for example, ALL Aboriginal and Torres Strait Islander people are recommended to receive vaccination for hepatitis B if non immune by these peak bodies in Australia, but the WA state government has never funded hepatitis B vaccination for all Aboriginal and Torres Strait Islander people in WA. It is a common misconception that all Aboriginal and Torres Strait Islander people are eligible for free vaccination and many primary health providers provide unfunded hepatitis B vaccines because they aren't fully aware of the eligibility criteria. We have an elected government body that decides such eligibility and it is taxpayer's money that pays for these vaccinations. It is our responsibility to ensure we are not misusing taxpayer's money.

Additionally, there are another set of recommendations by AIH as to who should be tested for immunity after vaccination, which does not include all high risk groups, or even those that have access to free vaccination in WA. All in all, this makes knowing who to screen, who to vaccinate and who to test for immunity after vaccination very confusing.

Table 2 seeks to provide some clarity around who is considered to be high risk for contracting and/or developing severe hepatitis B, who is eligible for free hepatitis B vaccination in WA and who should be tested for immunity after vaccination. Hopefully this helps to clarify some of the confusion and to ensure we are utilising government funds more appropriately. If there is still confusion around any of this, please discuss with KPHU or the Kimberley Regional Physician Team.

'Carrier' of hepatitis B

During the immune tolerance and immune control phases, patients have in the past been called 'healthy carriers' or 'inactive carriers'. This is an outdated and very confusing term as it implies that the person doesn't actually have hepatitis B, but that they simply 'carry' it and that they don't require any follow up. This is NOT the case. ALL people with CHB are at risk of progressive liver damage and the development of cirrhosis and HCC. ALL require regular monitoring, screening and management. There is no such thing as a 'healthy carrier' or 'inactive carrier' of the hepatitis B virus. These terms are still unfortunately seen on patient files and on pathology reports. Please refrain from using them.

Inclusion of Hepatitis B GP prescribers

Whilst there are not a lot of Hepatitis B GP prescribers in the Kimberley currently, it is hopeful this number will increase so that we can support the currently physician led treatment of CHB patients. If a patient is uncomplicated and requires medication management for their hepatitis B, a GP prescriber is a very suitable referral person. GP Hepatitis B prescribers have access to a WACHS physician mentor for support at all times.

Management section changes:

The previous Kimberley Hepatitis B protocol focuses management on whether patients are 'deemed suitable' for treatment or not by their primary health care provider. This element of the protocol is particularly an issue given the evidence around the lack of knowledge amongst primary health care providers and people living with CHB being a contributing factor to poor treatment uptake. Evidence also tells us that the majority of patients with CHB

would be willing to use treatment if their disease progressed. This is critical and underpins the importance of improved patient education and support around their CHB.

The management section of the protocol has been overhauled. It focuses on providing education and support to the patient so that they can be empowered to take control of their hepatitis B. It also provides primary health professionals with a simplified clinical management plan which includes determining the phase of CHB, arranging regular monitoring and screening and a guide as to when medical treatment should be considered. It aims to involve the patient with every step of management and to improve patient and primary health provider's knowledge around hepatitis B with the ultimate goal of increasing our rates of care uptake (treatment and monitoring) in the Kimberley.

Screening for fibrosis/cirrhosis

All patients with CHB require regular screening for fibrosis/cirrhosis. It was felt yearly was appropriate as this is the recommended interval by ASHM and GESA. Ideally, all patients with CHB in the Kimberley could be screened for fibrosis/cirrhosis using a fibroscan which is the best non-invasive screening modality available for fibrosis/cirrhosis. Unfortunately, at the time of writing, fibroscan is not yet available in the Kimberley. It is hoped ultrasound elastography will soon be available in the Kimberley. APRI score should be utilised as our primary source of screening for fibrosis/cirrhosis. It can be easily calculated using the APRI calculator linked in the protocol and only requires an AST and platelet value. Hepascore can be used, but at the time of writing, was not medicare rebateable. If concerned about fibrosis or cirrhosis, please discuss with the Kimberley Regional Physician Team.

Screening for HCC

Screening for HCC has been changed to Aboriginal and Torres Strait Islander people with CHB who are aged over 50. The previous protocol advised to screen in these patients from 40 years of age. This protocol was written when there was no recommendation for Aboriginal and Torres Strait Islander people and so it was decided at the time that using the Asian male guideline would suffice. Since then, there has been research done around the increasing incidence of CHB and stratified risk of HCC in Aboriginal and Torres Strait Islander people aged >50 in the Northern Territory. ASHM now also provide specific recommendation for Aboriginal and Torres Strait Islander people to be screened for HCC if over 50 years of age.

Table 3

Table 3 is new to this protocol but is similar to appendix 1 in the previous protocol. It is now an all-inclusive guide to determining the phase, arranging monitoring and screening and determining when to consider treatment of CHB. It is an amalgamation of ASHM, GESA and Kimberley physician recommendations.

Considerations for next review:

CHARM study: emerging evidence of different genotypes in NT possibly contributing to vaccine failure – likely to have implications for our patients in the Kimberley.

Resources and References used in reviewing this protocol:

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