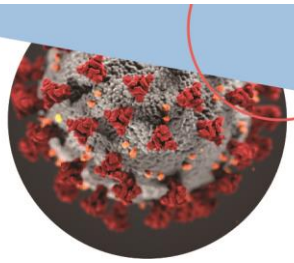


FAQS FOR CLINICIANS ABOUT COVID-19 VACCINES AND PEOPLE LIVING WITH HEPATITIS B/HEPATITIS C-RELATED CHRONIC LIVER DISEASE

Prepared by ASHM COVID-19 Taskforce Members* Updated April 7th 2021

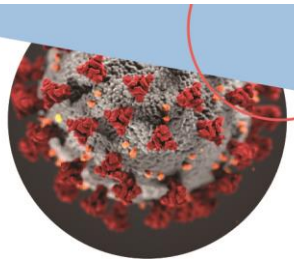
1. **Which COVID-19 vaccines has the Therapeutic Goods Administration provisionally registered?**
   - The Pfizer-BioNTech BNT162b2 mRNA vaccine (COMIRNATY) for people ≥16 years of age [1]
   - The AstraZeneca ChAdOx1 nCoV-19 (AZD 1222) vaccine for people ≥18 years of age [2]

2. **Does the Australian Technical Advisory Group on Immunisation (ATAGI) explicitly recommend these vaccines for people living with hepatitis B/hepatitis C-related (HVB/HCV-related) chronic liver disease?**
   - ATAGI has recommended that people with chronic liver disease be vaccinated[3] and this includes HBV/HCV-related chronic liver disease
   - Viral hepatitis is a disease of the liver and people who have been living with hepatitis B or hepatitis C for more than six months are determined to have chronic infection.

3. **Are all people living with HBV/HCV-related chronic liver disease eligible to receive the Pfizer-BioNTech and the Astra-Zeneca COVID-19 vaccines in Australia?**
   - Yes [4]
   - Age is the only eligibility criterion that restricts access to these vaccines:
     - Pfizer-BioNTech vaccine: ≥16 years
     - AstraZeneca vaccine: ≥18 years
   - Other than age, all people living with chronic liver disease (including HBV/HCV-related) are eligible for these vaccines irrespective of whether they have a Medicare number, whether they are here on temporary visas, whether they are incarcerated, homeless, or in migrant detention centres [4]

4. **Should people with HBV/HCV-related chronic liver disease be offered the Pfizer-BioNTech and the Astra-Zeneca COVID-19 vaccines?**
   - Yes, if they have no contraindications to these vaccines [3]

5. **Should I be using the COVID-19 vaccine roll-out as an opportunity to recommend that my patients get tested for viral hepatitis, HV and STIs?**
   - Yes.



- The COVID-19 vaccine roll-out is an excellent opportunity to recommend testing for HBV, HCV, HIV and STIs to all sexually active people and to people who may have been exposed to HIV, viral hepatitis and STIs in the past
- It is also a good opportunity to conduct a comprehensive liver health check if one has not been done in the last 6 months

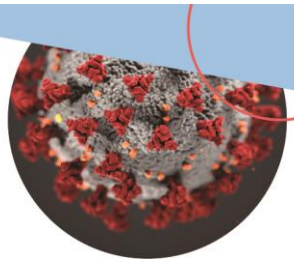
6. **The Australian COVID-19 vaccine strategy will roll out vaccines in Phases 1, 2 and 3. During which phases will people with HBV/HCV-related chronic liver disease be offered COVID-19 vaccines? [5]**
   - People with HBV/HCV-related chronic liver disease who meet the eligibility criteria for Phase 1a can receive a vaccine without declaring their HBV/HCV status
   - All other people with (HBV/HCV-related) chronic liver disease will be eligible to receive a vaccine during Phase 1b

7. **During Phase 1a of the COVID-19 roll-out strategy, how should I protect the confidentiality of my patients with HBV/HCV-related chronic liver disease?**
   - People living with HBV/HCV-related chronic liver disease will qualify to receive COVID-19 vaccines during Phase 1a if they are quarantine or border workers, frontline healthcare workers, aged care and disability care staff, or aged care and disability care residents [5]
   - These criteria alone should be sufficient for people living with HBV/HCV-related chronic liver disease to be offered a COVID-19 vaccine and their hepatitis status should not have to be cited as a reason to be vaccinated

8. **During Phase 1b of the COVID-19 roll-out strategy, which criteria make HBV/HCV-related chronic liver disease people eligible to receive a vaccine?**
   - People will qualify to receive COVID-19 vaccines during Phase 1b if they are: [5]
     - A critical and high-risk worker
     - Indigenous and ≥ 55 years of age
     - Non-Indigenous and ≥ 70 years of age
     - A younger adult with an underlying medical condition or a disability

9. **What are the underlying medical conditions that make younger adults eligible to receive a COVID-19 vaccine during Phase 1b? [3]**

   For people under 69, underlying medical conditions include:
   - Haematological diseases or cancers
   - Organ transplant recipients who are on immune suppressive therapy
   - Bone marrow transplant recipients or those on CAR-T therapy or immune suppressive therapy for graft versus host disease
   - who have haematological diseases or cancers, diagnosed within the last 5 years
   - Non-haematological cancer having chemotherapy or radiotherapy



- Adult survivors of childhood cancers
- Chronic inflammatory conditions requiring medical treatments
- Primary or acquired immunodeficiency (this includes HIV infection)
- Chronic renal (kidney) failure with a eGFR of <44mL/min
- Heart disease (including coronary heart disease and cardiac failure)
- Chronic lung disease (excludes mild or moderate asthma)
- diabetes
- Severe obesity with a BMI ≥ 40kg/m^2
- **Chronic liver disease** (note: includes chronic liver disease related to HBV and HCV)
- Chronic neurological conditions (stroke, dementia, other)
- Chronic inflammatory conditions and treatments
- Poorly controlled blood pressure (defined as two or more pharmacologic agents for blood pressure control, regardless of recent readings)
- Significant disability requiring frequent assistance with activities of daily living
- Severe mental health conditions

Detailed information about the health conditions included in Priority Groups for COVID Vaccination Program Phase 1b

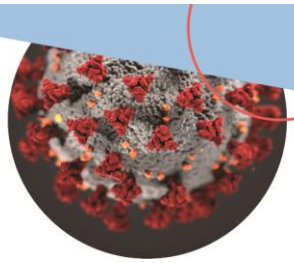
For those patients who will attend a vaccination site and may not have a referral letter or other evidence of their 1b eligibility status (e.g. My Health Record, medical history etc) and may often be Medicare Ineligible **please use this statutory declaration form:**
https://www.health.gov.au/resources/publications/covid-19-vaccination-eligibility-declaration-form

10. What if I am not sure whether my patient with HBV infection or current or prior HCV infection has Chronic LIver Disease?

- We recommend that clinicians should err towards assuming that chronic liver disease may be present in their patients with chronic HBV and patients with current, or prior HCV. This is because the majority of people with chronic HBV infection have not been assessed for the presence of chronic liver disease and are not receiving HBV antiviral treatment. Also a significant proportion of people with current, or prior HCV infection may not have been assessed for the presence of chronic liver disease.

11. During Phase 1b of the COVID-19 roll-out strategy, how should I protect the confidentiality of my patients with HBV/HCV-related chronic liver disease when I refer them to another service to receive a COVID-19 vaccine?

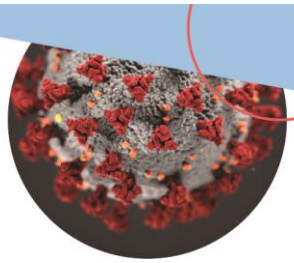
- Patients will need to access the vaccine eligibility checker to find a vaccine centre near them if their usual medical service is unable to provide the COVID-19 vaccine



- Clinicians who are not accredited to offer COVID-19 vaccines will have to refer their patients to an accredited general practice, or a purpose-built COVID-19 vaccine clinic
- Determine with the patient if they are comfortable for their hepatitis status to be recorded as the reason for eligibility for the COVID-19 vaccine under the chronic liver disease criteria
- Where the patient is not comfortable for their referral letter to state that they have (HBV/HCV-related) chronic liver disease, you can state the patient has any other eligible underlying medical condition/s
- If the patient's only underlying medical condition is HBV/HCV-related chronic liver disease and they do not wish for this status to be disclosed, you can state the following in your referral letter:
    - That your patient qualifies as a younger adult with an underlying medical condition as per guidance from ATAGI and the Australian Government Department of Health
    - That the patient has had appropriate treatment assessment
    - That you have discussed with the patient any benefits and the effectiveness of the COVID-19 vaccine in relation to the patient's underlying medical condition
- Once the patient does attend the new clinic, if they are asked about the specifics of their underlying medical condition that makes them eligible for the COVID-19 vaccine, they should state that they are not comfortable discussing this and if the clinician has any concerns about their eligibility for the vaccine, to contact the doctor who referred them
- Clinicians may also wish to inform patients that their My Health record may be accessed for the purpose of identifying eligibility for the vaccine. Although the access, use and disclosure of this information are still bound by rules of confidentiality the information may include the person's HBV/HCV infection as well as diagnostics related to liver disease depending on their individual control settings. Patients may want to discuss My Health Record access with their clinician or seek advice from a relevant support service if they wish to change these settings or what information can be accessed ahead of attending for vaccination under Phase 1b
- Patients should also know that their COVID-19 vaccination will be recorded on the Australian Immunisation Register. This will also allow them to be recalled for the second dose
- Clinicians may wish to discuss strategies patients could use to deal with other people who may question their need for early vaccination on the grounds they are young and look well

12. Do we know how acceptable the COVID-19 vaccines are to people living with HBV/HCV-related chronic liver disease in Australia?

- No, specific data about vaccine hesitancy in people with HBV/HCV-related chronic liver disease in Australia are not yet available



13. How effective are the Pfizer-BioNTech and the AstraZeneca vaccines in preventing COVID-19 disease overall?

- Both the Pfizer-BioNTech and the AstraZeneca vaccines are highly effective in preventing severe COVID-19 disease in individuals [7-8]

14. Will people living with HBV/HCV-related chronic liver disease be able to choose which vaccine they receive?

- No

15. Were people living with HBV/HCV-related chronic liver disease enrolled in the Pfizer-BioNTech and Astra-Zeneca studies?

- Yes: Pfizer included people with pre-existing stable HBV or HCV infections. They also included people with liver disease[9]. There were 217 people with liver disease but just 3 with moderate to severe liver disease.[10]
- No: AstraZeneca excluded people with severe or uncontrolled liver disease, and suspected or known current drug or alcohol dependency, [11]

16. What were the criteria that people living with HBV or HCV had to meet to be enrolled in the Pfizer vaccine studies?

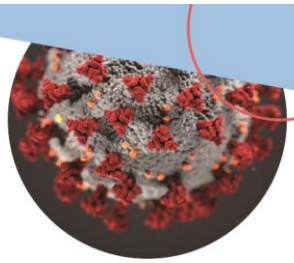
- Pfizer's inclusion criteria for HBV positive people were [12,13]:
  - Confirmed inactive chronic HBV infection, defined as HBsAg present for ≥6 months and the following:
    - HBeAg negative, anti-HBe positive
    - Serum HBV DNA
- Pfizer's inclusion criteria for HCV positive people were:[12,13]
  - History of chronic HCV with evidence of sustained virological response (defined as undetectable HCV RNA) for ≥12 weeks following HCV treatment or without evidence of HCV RNA viremia (undetectable HCV viral load).

17. How efficacious are the Pfizer-BioNTech and Astra-Zeneca COVID-19 vaccines in preventing COVID-19 disease in people with HBV/HCV-related chronic liver disease?

- No data are available about how well these vaccines protect HBV or HCV-positive people against COVID-19 disease. Data will come from 'real-world' investigation.[10]

18. Are the Pfizer-BioNTech and Astra-Zeneca COVID-19 vaccines safe for people living with HBV/HCV-related chronic liver disease?

- The number of people living with liver disease enrolled in the Pfizer-vaccine studies was small (Pfizer, n=217 and AstraZeneca did not include anyone with liver disease) [9-10]



- The Pfizer-BioNTech vaccine contains messenger RNA from the SARS-CoV-2 virus. The AstraZeneca vaccine contains a replication-defective chimpanzee adenovirus, which serves as a vector for the SARS-CoV-2 spike glycoprotein [8]
- Both vaccines are likely to be safe in people with HBV or HCV or other forms of liver disease

19. Is there specific information I should counsel my patients with HBV/HCV-related chronic liver disease about regarding the Pfizer-BioNTech and the Astra-Zeneca COVID-19 vaccines?

- Clinicians should broadly explain that there are very limited data currently available on the safety and efficacy of the Pfizer-BioNTech and the Astra-Zeneca COVID-19 vaccines in people living with HBV/HCV-related -chronic liver disease, but that data will be available in the near future
- All Australians, including people living with HBV/HCV-related-chronic liver disease, need to be advised that they have to take ongoing protective measures against SARS-CoV-2 infection because COVID-19 vaccines were designed to prevent COVID-19 disease, not to prevent SARS-CoV-2 infection or transmission. Further data are expected about these vaccines' ability to prevent SARS-CoV-2 infection and transmission.

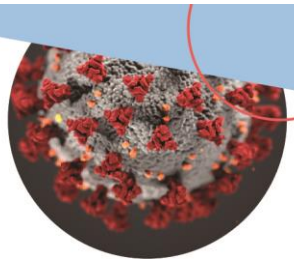
20. Should I vaccinate my patients living with HBV/HCV-related chronic liver disease if they have already had COVID-19?

- Yes
- Please note that although ATAGI recommends that a person who has had PCR-confirmed SARS-CoV-2 infection may defer their COVID-19 vaccine for six months from the time of infection (3), clinicians should not delay offering COVID-19 vaccines to their patients with HBV/HCV-related chronic liver disease with prior SARS-CoV-2 infection
- Vaccinating someone with prior COVID-19 has been shown to result in higher levels of antibodies, which likely means enhanced immunity to future infections
- There have not been any safety concerns for people who have had prior SARS-CoV-2 infection and go on to receive the Pfizer-BioNTech or the AstraZeneca vaccine[3].

Note: Several studies [14-20] have shown that infection with SARS-COV19 can cause liver injury particularly in more severe cases. People with HBV or HCV and COVID-19 co-infection are at a higher risk of morbidity and mortality [14,21] than people with COVID-19 without HBV/HCV

21. Should people living with HBV or HCV who are pregnant receive the Pfizer-BioNTech or the Astra-Zeneca COVID-19 vaccines?

- The advice that ATAGI provides regarding offering these two vaccines to pregnant people without HBV or HCV should be applied to pregnant people living with HBV or HCV. The advice is as follows [3]:



    - Neither vaccine is routinely recommended in pregnancy, nor are they contraindicated in pregnancy
    - There are no clinical trial data on the safety of either vaccine in pregnancy or in pregnancy outcomes
    - People who are pregnant may choose to accept either of these COVID-19 vaccines if their risk of SARS-CoV-2 infection is high, or if their underlying medical conditions put them at high risk of severe COVID-19 disease
- There are no data available about the safety of either vaccine in people living with HBV or HCV- who are pregnant and neither has ATAGI provided specific advice for people living with HBV or HCV who are pregnant

22. Should people living with HBV or HCV who are planning pregnancy, or who are breastfeeding receive the Pfizer-BioNTech or the Astra-Zeneca COVID-19 vaccines?

- The advice that ATAGI provides regarding offering these two vaccines to people not living with HBV or HCV who are planning pregnancy, or who are breastfeeding should be applied to people living with HBV or HCV who are planning pregnancy, or who are breastfeeding. The advice is as follows [3]:
    - People who are breastfeeding or who are planning pregnancy can receive a COVID-19 vaccine. There are no theoretical concerns regarding the safety of either vaccine in these groups

23. Should I test my patients living with HBV/HCV-related chronic liver disease for their immune response to these vaccines?

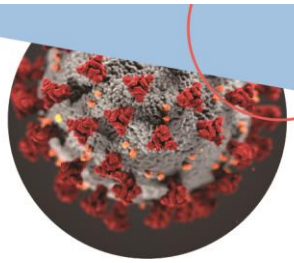
- No
- ATAGI does not recommend testing for anti-spike antibodies or neutralising antibodies against SARS-CoV-2 following COVID-19 vaccines [3]. This is because there is currently no recognised immune correlate of protection against infection with SARS-CoV-2 or COVID-19 disease [3]

24. What is the best time interval for giving my patients living with HBV/HCV-related chronic liver disease a COVID-19 vaccine and other vaccines?

- ATAGI recommends that the minimal interval between either COVID-19 vaccine and the annual influenza vaccine and all other vaccines should be 14 days [3]

25. Are more COVID-19 vaccine studies in younger adolescents and children underway?

- Yes. Pfizer has enrolled 2,259 children aged 12-15 years into a study and plans to commence a study of children aged 5-11 years in the near future [22]
- Moderna has commenced a study which will vaccinate 3,000 12-17-year-old children



- AstraZeneca and Johnson & Johnson plan to commence studies in adolescents [23]

26. Where can I find reliable and up to date information on blood clotting concerns and the AstraZeneca vaccine?

Please see this link for all updated information for Australian providers: https://www.health.gov.au/news/atagi-statement-healthcare-providers-specific-clotting-condition-reported-after-covid-19-vaccination

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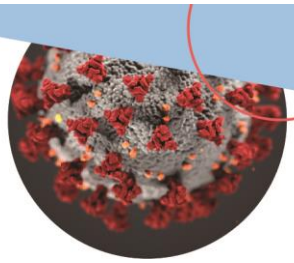

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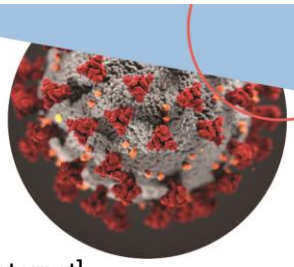

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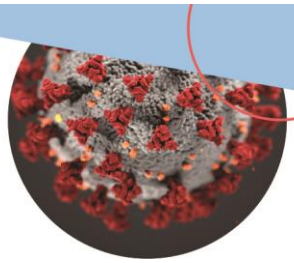
* This document was written by Ms. Karen Seager and was reviewed by the ASHM Taskforce Chair and Co-Chair, members of the Virology, HBV, HCV, Research and Understanding Data, Clinical Practice and Nursing Cluster Groups and the ASHM CEO.

ASHM COVID-19 Taskforce Chair: A/Prof Edwina Wright

ASHM COVID-19 Taskforce Co-Chair: Mr. Scott McGill

Members of the Virology, HBV, HCV, Clinical Practice, Nursing and Research & Understanding the Data Clusters

Virology	Prof. Martyn French Prof. Sharon Lewin Dr. Thomas Rasmussen
HBV	Prof. Ben Cowie Dr. Nicole Allard Dr. Michelle Giles Mr. Kevin Marriott Dr. Nick Medland Dr. Anne Balcombe Dr. Jacqui Richmond Ms. Jana Van der Jagt Ms. Nafisa Yussf Ms. Sally Watkinson Mr. Jack Wallace Ms. Gabrielle Bennett Ms. Sandy Davidson Dr. Thao Lam Dr. Jessica Howell
HCV	Prof. Greg Dore Prof. Margaret Hellard Mr. Joseph Doyle Dr. Jessica Howell Dr. Michelle Giles Mr. Kevin Marriott Dr. Nick Medland Dr. Anne Balcombe Dr. Jacqui Richmond Ms. Jana Van der Jagt Dr. Thao Lam Ms. Sally Watkinson Ms. Sandy Davidson Ms. Justine Doidge (JD) Ms. Jude Byrne
Clinical Practice	Dr. David Baker Dr. Elizabeth Crock Ms. Penny Kenchington Ms. Alison Duncan Mr. Bruce Hamish Bowden



	Dr. Nick Medland Ms. Sally Watkinson Ms. Donna Tilley Ms. Leanne Myers
Nursing	Dr. Elizabeth Crock Ms. Penny Kenchington Dr. Jacqui Richmond Ms. Jana Van der Jagt Ms. Marrianne Black Ms. Sally Watkinson Ms. Shannon Woodward Ms. Bradley Whitton Ms. Donna Tilley Ms. Melissa Cromarty Ms. Gabrielle Bennett Ms. Leanne Myers
Research and Understanding the Data	Prof. Carla Treloar Prof. Charles Gilks Ms. Gail Matthews Mr. Graham Brown Mr. Jack Wallace Dr. James McMahon Mr. John Rule A/Prof. Julian Elliott Ms. Lisa Maher

ASHM Staff Members who are members of these Cluster Groups
Mr. Scott McGill, Ms. Karen Seager, Ms. Bianca Leber, Ms. Sami Stewart, Ms. Shelley Kerr
***ASHM CEO,** Mr. Alexis Apostolellis*