

Statement from the ASHM COVID-19 Taskforce regarding the Prioritisation of COVID-19 Vaccines for People Living with Blood-borne virus-related Chronic Liver Disease

Prepared by ASHM COVID-19 Taskforce Members, March 2021*

ATAGI has recommended that:

- *the COVID-19 Pfizer vaccine be preferred over AstraZeneca for adults aged under 50 years. This is because there is a potentially higher risk of thrombosis with thrombocytopenia in people aged under 50, who receive the AstraZeneca vaccine*
- *the AstraZeneca vaccine be used in adults aged under 50, if the benefits outweigh the risks for that person – and they have made an informed decision based on the risks and benefits*
- *people who have had the first dose of AstraZeneca without any serious adverse effects, can be given the second dose. This includes people aged under 50.*

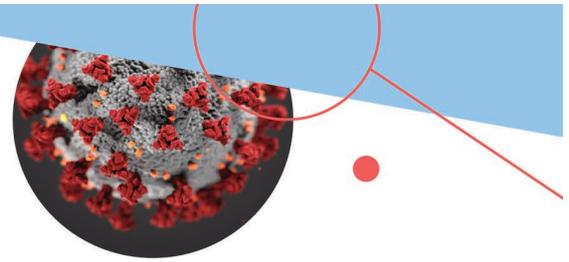
Healthcare providers may wish to continue having detailed discussions with patients about the risks and benefits of the AstraZeneca vaccine in line with ATAGI advice, regardless of the age of the patient, ensuring fully informed consent before vaccination.

Updated safety advisory – rare and unusual blood clotting syndrome (thrombosis with thrombocytopenia): <https://www.tga.gov.au/media-release/astrazeneca-chadox1-s-covid-19-vaccine>

SUMMARY STATEMENT

People living with blood-borne virus-related chronic liver disease appear to be at increased risk for poorer outcomes following infection with SARS-CoV-2.

The ASHM COVID-19 Taskforce recommends the following with respect to the provision of COVID-19 vaccines to people living with blood-borne virus-related chronic liver disease in Australia:



Recommendation 1

That all people living with blood-borne virus-related chronic liver disease in Australia who meet the Phase 1a criteria of [Australia's COVID-19 vaccine roll-out strategy](#) should be offered a vaccine during Phase 1a of the roll-out and that all remaining people living with blood-borne virus-related chronic liver disease should be offered a COVID-19 vaccine during Phase 1b of the roll-out.

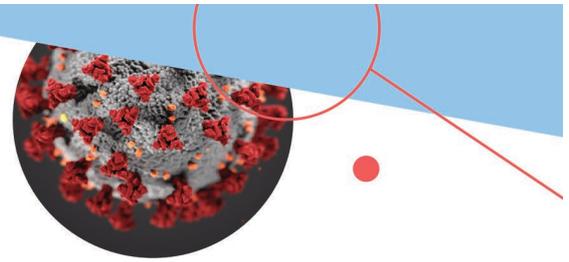
It is important to note that the majority of people with chronic hepatitis B virus (HBV) infection have not been assessed for the presence of chronic liver disease and are not receiving HBV antiviral treatment. Also, a significant proportion of people with current, or prior hepatitis C virus (HCV) infection may not have been assessed for the presence of chronic liver disease. For these reasons clinicians should err towards assuming that chronic liver disease may be present in patients with chronic HBV and patients with current, or prior HCV.

The Commonwealth, States and Territories should consult closely with hepatitis peak organisations, clinicians and researchers who specialise in viral hepatitis and liver disease to optimise the engagement of people living with blood-borne-related chronic liver disease during the roll-out of COVID-19 vaccines.

Recommendation 2

That all people living with blood-borne virus-related chronic liver disease should be offered a vaccine irrespective of whether they have a Medicare number, including people who are incarcerated, people in migrant detention centres, people living in Australia on temporary visas and people who are in Australia with an undocumented status.

All efforts should be made to address any obstacles that may arise during the roll-out of vaccines to people living with blood-borne virus-related chronic liver disease as a result of geographic, socioeconomic, language and cultural factors.

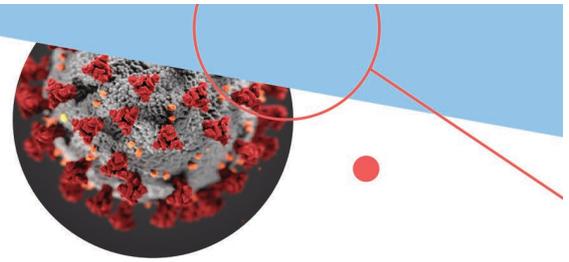


In Australia, more than 95% of new HBV diagnoses are in people who were born in a country other than Australia[1]. In 2018, 68% of the estimated 226,566 people with chronic HBV were born overseas[1]. It was also estimated that at the end of 2019, 10-15% of 121,560 people living with chronic HCV in Australia, identified as culturally and linguistically diverse[2].

Given the high proportion of people from culturally and linguistically diverse backgrounds living with HBV or HCV, it is essential that interpreters or appropriate information in the person's own language (remembering that some people may have low literacy in their own language) are available so that patients can provide informed consent for vaccination. This would also assist patients to receive subsequent doses of vaccination.

Aboriginal and Torres Strait Islander communities are disproportionately impacted by HBV, with an estimated 16,241 people living with chronic HBV in 2018[2]. Liver cancer is the second-highest cause of cancer-related mortality for Aboriginal and Torres Strait Islander peoples, and two times higher in Indigenous than in non-Indigenous peoples[3].

Special consideration should be given to a range of models of care, including outreach and peer support models, for the delivery of the COVID-19 vaccines[4]. People who are not engaged with medical services, people who are experiencing homelessness, people from culturally and linguistically diverse backgrounds (including refugees and others on temporary visas), Aboriginal and Torres Strait Islander peoples who live in regional and remote areas, and people who use drugs, for example, are not only at risk for pre-existing but untreated liver disease[3] they are also at greater risk of not receiving a COVID-19 vaccine due to potential loss to follow up and the impacts of stigma and discrimination[5]. Consideration also needs to be given to how these communities will be supported to receive the second dose between 3 weeks and three months after the first.



Recommendation 3

Australia's COVID-19 vaccine roll-out strategy should be designed to provide high levels of personal and medical confidentiality for people living with blood-borne virus-related chronic liver disease when they are engaging with healthcare providers e.g. when they are seeking a COVID-19 vaccine, when they are referred for a COVID-19 vaccine from one healthcare provider to another and at the time that they receive a COVID-19 vaccine.

COVID-19 vaccination services must not provide opportunities for linkage to Federal, State, or Territory criminal justice services that would lead to arrests and/or charges for outstanding warrants, commercial sex work, substance-use, visa expiry, undocumented status, or other charges.

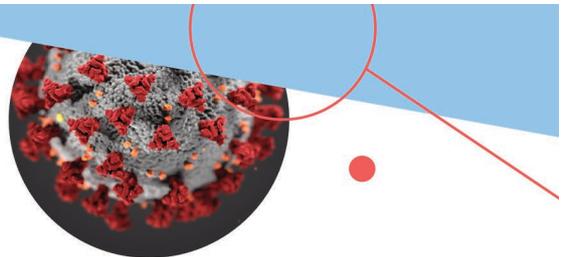
Rationale for the ASHM COVID-19 Taskforce Recommendations

Recommendation 1

The ASHM COVID-19 Taskforce's interpretation of the currently available published and pre-print literature is that there is uncertainty about whether people living with blood-borne virus-related chronic liver disease are at increased susceptibility to infection with SARS-CoV-2.

However, there is more widespread agreement that people living with blood-borne virus-related chronic liver disease have an increased risk of poorer outcomes (including death) following infection with SARS-CoV-2 (see review of literature below).

A review of the literature suggests several factors may explain the possible increased risk of infection and likely risk of poorer health outcomes with SARS-CoV-2 in people living with blood-borne virus-related chronic liver disease including the effect of deficiencies in the immune system known as cirrhosis-associated immune dysfunction (CAID) which may explain severe complications of SARS-CoV-2 in people with decompensated cirrhosis [6], the presence of comorbidities such as diabetes or



obesity, [7] age and other factors including ethnicity and socioeconomic status [6] A detailed discussion of these factors is beyond the scope of this position statement.

Recommendation 1 is consistent with recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI), the Australian Government's COVID-19 vaccination policy and the Australian Government's COVID-19 vaccine roll-out strategy [9-14]

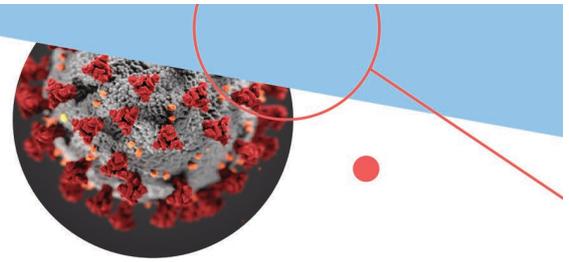
Recommendations 2 and 3

The rationale for Recommendations 2 and 3 is based upon the principles of social justice and the need to optimise the uptake of COVID-19 vaccines by people with blood-borne virus-related chronic liver disease. No person living with blood-borne virus-related chronic liver disease in Australia should be denied COVID-19 vaccination based upon their life circumstances including because they do not have a Medicare number, do not live in metropolitan areas, or are incarcerated. Confidence that strict patient confidentiality will be maintained and that no arrests, prosecutions or placement in migrant detention centres will occur when people present for a COVID-19 vaccine will help to maximise the uptake of COVID-19 vaccines by blood-borne virus-related chronic liver disease in Australia.

Recommendations 2 and 3 are consistent with the 'human right to science' as per the United Nations Committee on Economic, Social Rights, Comment 25[15] and the Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights[16].

Literature Review Informing Recommendation 1

The ASHM COVID-19 Taskforce undertook a review of available published and pre-print literature from December 2019 until February 2021 addressing COVID-19 outcomes in a person living with blood-borne virus-related chronic liver disease. This review is not a systematic review or meta-analysis of the literature, nor is it exhaustive. The Taskforce wishes to emphasise that scientific and clinical research findings regarding COVID-19 and its impact on people living with blood-borne virus-related



chronic liver disease will continue to grow and change as more research is done which includes people living with viral hepatitis and/or chronic liver disease.

Findings

Risk of Infection with SARS-CoV-2

There is disagreement about whether people with blood-borne virus-related chronic liver disease are predisposed to, or are at greater risk of, contracting SARS-CoV-2. However, there is mounting evidence that this patient population is at significantly increased risk of poorer outcomes in the event of SARS-CoV-2 infection.

Risk of poorer health outcomes following infection

Background

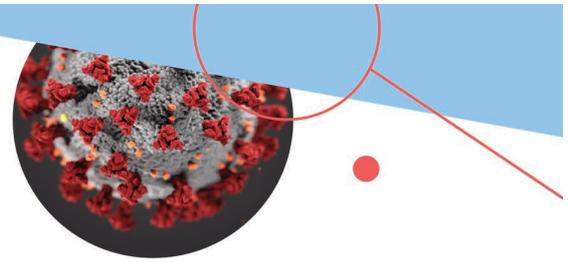
A number of early studies[17-22] variously concluded that people with HBV/SARS-CoV-2 co-infection showed no difference in liver function parameters and were not more likely to progress to serious COVID-19 illness.

However, later studies show that there is a high risk of both morbidity and mortality among people with either HBV or HCV infection and liver disease and SARS-CoV-2[23-28].

Saviano A, Wrensch F, Ghany MG et al writing for the American Association for the Study of Liver Diseases[29] observed that COVID-19 illness itself causes liver injury, particularly in more severe cases, and increases overall mortality for which there may be several reasons. They note that in patients with pre-existing cirrhosis, COVID-19 has been associated with hepatic decompensation and liver-related mortality. They also suggest that the treatment of COVID-19 may impact on healthcare services which in turn may adversely affect delivery of care and health outcomes for people with chronic liver disease.

Mortality

Increased risk of mortality



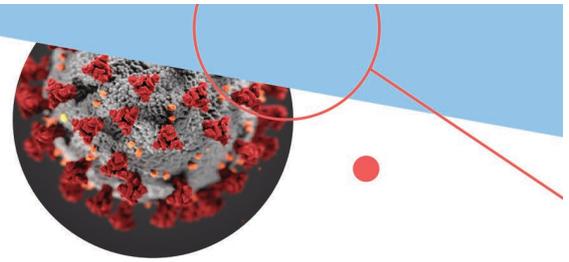
Chronic liver disease (from any cause) appears to be an independent risk factor for poorer outcomes with severe COVID-19 illness. And in some cases, COVID-19 induced liver injury occurs more frequently in people with chronic liver disease even without cirrhosis[2,22,30,32,33].

The APCOLIS Study[2] collated data in 13 countries from 408 people with confirmed COVID-19 diagnoses: 228 patients had chronic liver disease (185 without cirrhosis and 43 with cirrhosis including 18 decompensated cirrhosis). Comorbidities (such as fatty liver disease, diabetes, obesity) were present in nearly 80% of participants.

This study found that pre-existing liver disease presents an added risk in severe COVID-19 disease. Liver-related complications increased with the stage of liver disease, where a Child-Turcotte Pugh score of 9 or more at presentation predicted high mortality (AUROC 0.94, HR = 19.2 (95 CI 2.3–163.3), $p < 0.001$, sensitivity 85.7% and specificity 94.4%). In decompensated cirrhotics, the liver injury was progressive in 57% of patients, with >43% mortality. Patients with decompensated cirrhosis had nearly twice the mortality seen in patients with compensated cirrhosis [33% vs. 16.3%, OR = 2.5 (95 CI 0.7–9.4) $p = 0.05$][2].

Mirzaie H, Vahidi M, Shokoohi M, et al [23] reviewed 28 studies of SARS-CoV-2 patients with HBV or HCV co-infection. They found 235 patients with HBV and 22 patients with HCV. One third (34.1%) of SARS-CoV-2/HBV co-infection and 76.2% of SARS-CoV-2/HCV co-infection also reported one other comorbidity other than HBV/HCV infection. The proportional mortality rate was 6% among those with HVB/SARS-CoV-2 co-infection and 13% in those with HCV/SARS-CoV-2 co-infection. The authors concluded there was a high risk of morbidity and mortality among people with HBV or HCV and SARS-CoV-2 co-infection.

An international study[31] analysed data from 745 patients with chronic liver disease and SARS-CoV-2 infection (386 with and 359 without cirrhosis) from two international registries and compared the data with non-chronic liver disease patients with SARS-CoV-2 infection from a UK hospital network. The study demonstrated that baseline

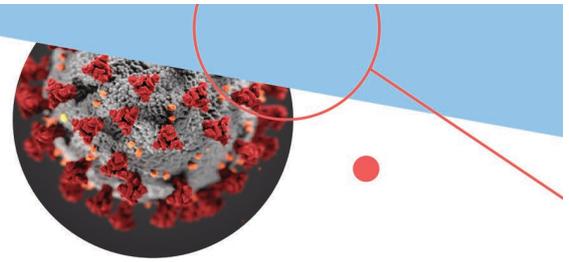


liver disease stage and alcohol-related liver disease were independent risk factors for death from SARS-CoV-2 infection. Mortality was 32% in people with cirrhosis compared to 8% without.

A multicentre retrospective study, conducted in the Lombardy region of Italy examined outcomes in patients with cirrhosis and SARS-CoV-2 infection[32]. Lavarone M, D'Ambrosio R, Soria A, et al, recruited 50 people with cirrhosis and confirmed SARS-CoV-2 infection from 9 hospitals across Northern Italy. Survival in this small cohort was compared with a control group of people hospitalised previously with liver decompensation due to bacterial infection. Mortality was compared with mortality rates due to COVID-19 illness in patients without cirrhosis in the same period. Mortality rates from COVID-19 illness in the general population were used as the benchmark[32].

One-third (34%) of patients died a median 10 days following COVID-19 diagnosis. COVID-19 with respiratory failure was considered the cause of death in 12 (71%) cases and five (29%) from end-stage liver disease. All the patients required respiratory support. Three (18%) of the 17 were awaiting liver transplants. The 30-day cumulative probability of mortality was 34%. The corresponding features for COVID-19 and liver-related mortality were 25% and 12%[32].

The authors concluded that the 30-day mortality rate was higher in patients with moderate/severe respiratory failure and in those who had worse liver function, as indicated by the increased MELD and CLIF-OF scores at COVID-19 diagnosis. The comparison with the 30-day mortality rate amongst non-cirrhotic patients was significantly lower but with a higher median age of deceased patients. The study also highlighted that infection with SARS-CoV-2 led to a rapid clinical deterioration in otherwise stable cirrhotic patients. And this was even worse for patients with pre-existing decompensated disease. The high 30-day mortality rate in patients with cirrhosis and SARS-CoV-2 was further confirmed when compared to the group hospitalised due to bacterial infection even when the MELD score was lower.



Multivariate analysis confirmed that COVID-19 illness, together with high CLIF-OF, was independently associated with 30-day mortality. Although this was a small study, it demonstrated that patients with cirrhosis (with or without decompensated liver disease) and who have COVID-19 illness have poor outcomes[32].

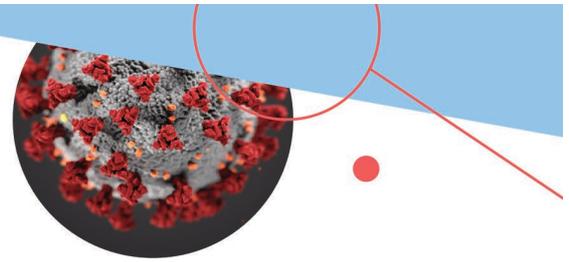
In their review of available data on liver injury in the context of COVID-19 disease in patients with or without pre-existing liver disease, Morgan K et al [33] concluded that pre-existing liver disease was an independent risk factor of death in SARS-COV-2 related infection and that the severity of liver damage most likely correlates with COVID-19 disease severity.

No increased risk of mortality

A study of 620 patients, 70 with HBV and COVID-19, from seven hospitals in China showed that compared to patients with COVID-19, patients with HBV had a higher rate of severe disease (32.86% vs 15.27%, $P = 100$)[34].

The study reported that, despite more severe disease, a higher rate of liver injury and increased susceptibility to COVID-19, all patients with HBV recovered and were discharged whilst in the non-HBV COVID-19 patients, 14 patients died – a rate of 2.55% (although this was lower than average in China). When the duration of hospitalisation and the length of time to return a negative nucleic acid test were compared, there was little difference between the two groups. The study authors suggest that the similarity in results between patients with co-infection and patients with COVID-19 alone may be because most people with HBV had their liver disease under control with anti-viral therapy before hospital admission and they were provided with targeted treatments after admission. They also conceded that the number of patients in the study was low ($n=70$).

In a new study published on 3 February 2021[35], Butt AA, et al concluded people with HCV were more likely to be hospitalised with COVID-19 particularly those with higher FIB-4 scores. However, there was no indication that overall mortality was greater in people with HCV than without.



Using data from the Electronically Retrieved Cohort of HCV Infected Veterans (ERCHIVES), the authors were able to identify 975 matched pairs (HCV+ and HCV-) for age, race, gender and multiple co-morbidities other than smoking. People with co-infection with HIV and/or HIV were excluded from the study.

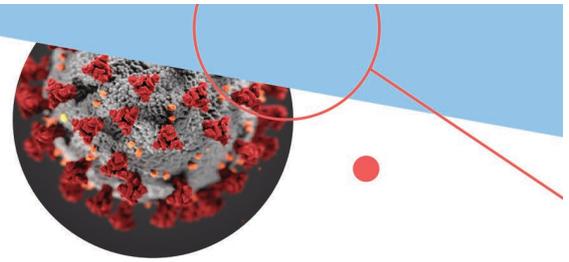
In comparing the groups, the authors found that the only factor associated with higher rates of COVID-19 disease-related hospital or ICU admission in people with HCV was advanced fibrosis measured by FIB-4 score. When comparing subgroups of people with and without HCV but with the same FIB-4 score, rates of both hospitalisation and ICU admission were far higher in those with HCV. However, being admitted to ICU or mortality was not different between people with or without HCV with the same degree of liver fibrosis.

The authors conclude that the increase in the risk of adverse outcomes in people with HCV is not dependent solely on the degree of liver fibrosis. They concede that more studies are needed to investigate the association between the severity of SARS-CoV-2 infection and HCV and whether the difference is due to viral or host factors.

COVID-19 vaccination in people with liver disease

The Australian Government has recognised that people with liver disease are at an increased risk of severe COVID-19 illness[9-13] and are, therefore, prioritised for vaccination.

In a recent commentary[36], Marjot et al pointed out that people with advanced liver disease have cirrhosis-associated immune dysfunction (CAID) and this immune dysfunction may account, in part, for severe complications of COVID-19 observed in patients with decompensated cirrhosis and contribute to lower immune response with existing vaccinations e.g. influenza. However, the authors argue that people with decompensated cirrhosis should be prioritised for vaccination because of the high COVID-19 mortality rate in these patients.



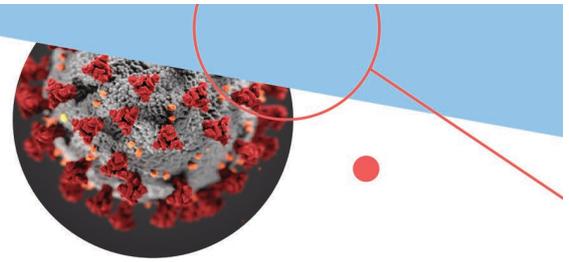
Cornberg et al in the European Association for the Study of the Liver (EASL) position paper[37] concluded there is no evidence to suggest the safety or immunogenicity of currently approved vaccines (Pfizer, Moderna [not available yet in Australia] and AstraZeneca) will be compromised for people with chronic liver disease, hepatobiliary cancer or in immunocompromised patients after liver transplantation.

The United States Centers for Disease Control and Prevention[38] have released a list of medical conditions known or suspected to increase the risk of severe COVID-19 disease where people living with these conditions should be prioritised for vaccination. The latest guidance includes people immunocompromised due to solid organ transplant in the CDC list of conditions with sufficient evidence to draw conclusions. However, people with an immunocompromised state from a number of causes including HIV or immunosuppressive medications, and people with liver disease, are included in the list of conditions where there is limited data on the risk for severe illness from SARS-CoV-2 infection.

The lists are based on the strength and amount of evidence of an association with severe illness from SARS-CoV-2 infection and are regularly updated as more evidence comes to hand. Given that much of the evidence available for the effects of SARS-CoV-2 infection on people living with blood-borne virus-related chronic liver disease is still emerging, the priority to vaccinate people with these conditions may be upgraded in the future.

The Australian Government has listed chronic liver disease as a risk factor for severe COVID-19 disease recommending that people living with chronic liver disease, people who have received organ transplants and those who are immunosuppressed be prioritised for vaccination. This is reflected in several documents including *Clinical Guidance on the use of COVID-19 vaccine in Australia in 2021 (v2.0)* released on 26 February 2021[14].

This is consistent with a range of international guidance/advice. The American Association for the Study of Liver Disease[39], The World Hepatitis Alliance[40], The



UK Department of Health and Social Care[41], and The British Society of Gastroenterology and BASL[42] have all recommended that people with chronic liver disease, especially those with cirrhosis, on immunosuppressive therapy or after liver transplantation should be prioritised for vaccination.

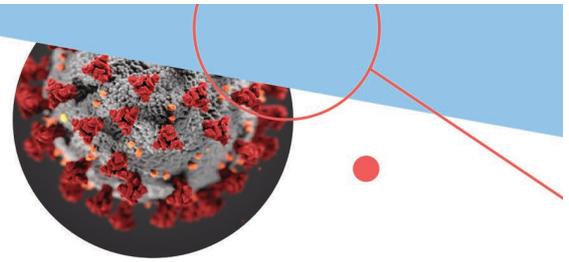
The general global consensus is that while COVID19 vaccine trials did not specifically include people with chronic liver disease, there are no data to suggest that any of the vaccines will do harm. It is known that other vaccines may have less efficacy in people with chronic liver disease and those who are transplant recipients, but the consensus is that COVID-19 vaccines will offer some level of protection.

Literature Review Informing Recommendation 2 & 3 Findings

In 2018 there were an estimated 226,566 people in Australia living with chronic HBV[2]. More than 68% were born overseas[2] and 7.2% identified as Aboriginal and Torres Strait Islander[3]. Other population groups with a high prevalence include people who inject drugs and men who have sex with men.

According to the Burnet Institute and Kirby Institute's report *Australia's progress towards hepatitis C elimination Annual Report 2020*[2], an estimated 121,560 people were living with chronic HCV in Australia in 2019, of whom an estimated 10-15% came from culturally and linguistically diverse backgrounds.[2]

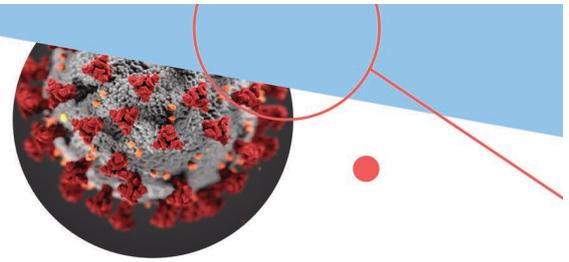
In June 2020, The Australian Red Cross reviewed a range of factors associated with COVID-19 disease and its health and social impacts on refugees and other temporary visa holders[43]. Along with financial and housing insecurity, gaps in healthcare (inability to afford health insurance or fees associated with care including medications) and deterioration of mental health, was the fear that accessing COVID-19 testing or treatment may lead to being referred to immigration authorities because they do not have a valid visa, or they cannot afford health insurance which would place them in breach of a visa condition. Among the recommendations made in the



report, the authors suggest there should be support for on-going healthcare coverage and medical care including COVID-19 testing and treatment for people on temporary visas. This should include financial support to cover gaps in health care costs, they also recommend a separation between healthcare providers and immigration officials and access to a COVID-19 vaccine for everyone in Australia regardless of their visa status.

A report[44] examining the second wave of COVID-19 infection in Victoria found that most of the COVID-19 hotspots were in low socio-economic suburbs that are typically culturally and linguistically diverse with large, recent immigrant communities. The report identified social determinants of health (over-crowding, poverty, lower education, exclusion, poorer access to health) coupled with cultural, religious and linguistic differences as impacting how well public health messages and initiatives are received, understood and acted on. In relation to Victoria's second wave, they argued that traditional communication methods (reliance on English language media, e.g. free-to-air television) often resulted in a lack of engagement with at-risk communities leading to increased risk and harm in an already vulnerable group.

A research study[45] involving 18,728,893 patients from 50 studies in the USA (42) and the UK (8) found a greater rate of infection among the broad ethnic groups they analysed (Black and Asian) resulting in disproportionate impacts on those communities. They noted that contact tracing data provides strong evidence that close proximity with someone who is infected leads to greater transmission, and there are elevated levels of infection among ethnic minority groups. They suggested several possible reasons for this: many individuals from ethnic minority backgrounds lived in multi-generational households, were more likely to have a lower socio-economic status which may also have led to over-crowded housing or accommodation with shared facilities and communal areas, and many were employed in essential services with more frequent exposures to infection and proximity to others (such as in health care, food services and transportation[46]), and therefore unable to work from home. Racism and discrimination within healthcare services may also have contributed to

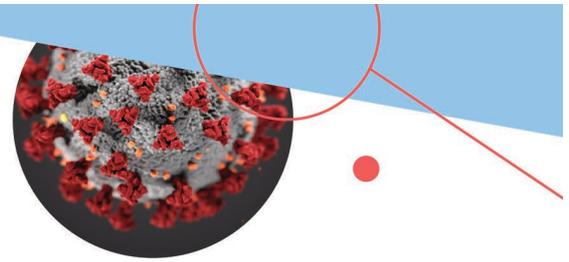


inequities in the delivery of care, barriers to accessing care, loss of trust, and psychosocial stressors. This in turn meant that many people were less likely to follow public health protocols and less likely to get tested or seek care when experiencing symptoms. The authors suggest that public health strategies must minimise exposure risk to SARS-CoV-2 infection in ethnic minority groups by providing appropriate healthcare resources, targeting the social determinants, racism and occupational risks that cause inequity.

The US Centers for Disease Control and Prevention[47] identified many similar factors disproportionately affecting minority racial and ethnic communities. They also identified lower education leading to lower literacy and numeracy levels compounded by programs not meeting the language needs of these groups. They stated: *Long-standing systemic health and social inequities have put many racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19*[47].

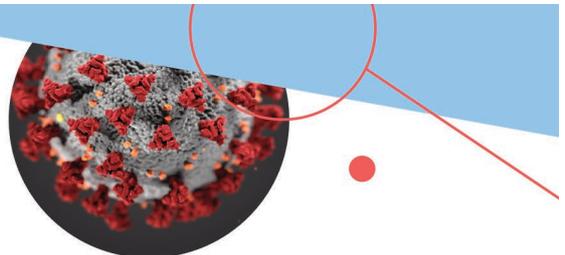
The most recent report on progress to address COVID-19 health inequalities[49] produced by the Race Disparity Unit, in the Cabinet Office of the UK Government, found that most of the increased risk of infection and death from Covid-19 among people from ethnic minorities is explained by factors such as occupational status, where people live, their household composition, and pre-existing health conditions[49]

Writing in News GP, Anastasia Tsirtsaki in her article *How is race affecting COVID-19 outcomes?*[50] quoted Dr. Kate Walker, Chair of the RACGP Refugee Health Specific Interests Network, who stated: 'in addition to previously identified factors seen in the UK research, refugee and asylum seeker patients in Australia have multiple barriers around making appointments, and language and health literacy barriers within the consultation'.

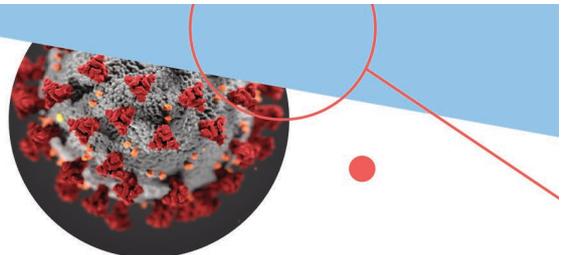


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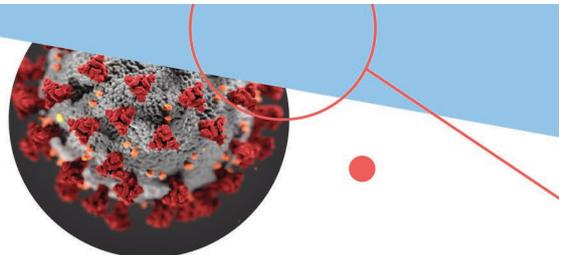
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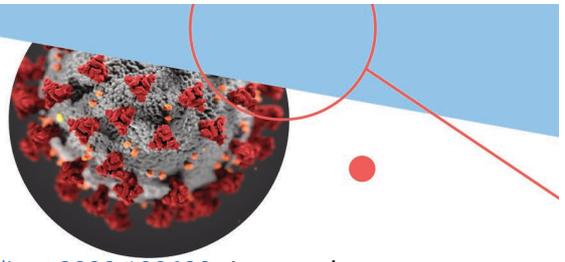
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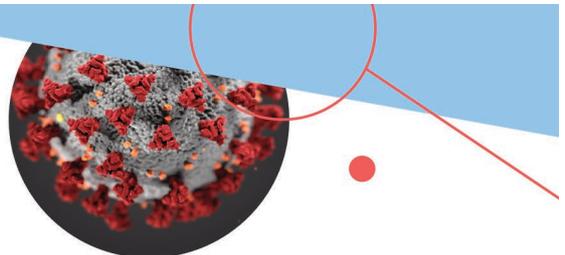


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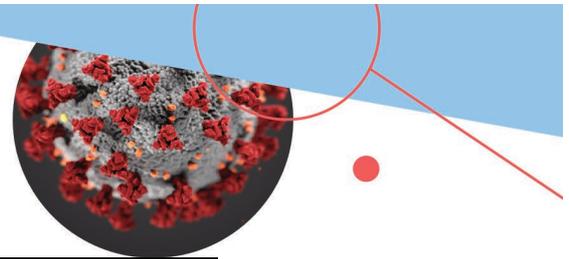
*** This document was written by Ms. Karen Seager and was reviewed by the ASHM Taskforce Chair and Co-Chair, members of the Virology, HBV, HCV, Research and Understanding Data, Clinical Practice and Nursing Cluster Groups and the ASHM CEO.**

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