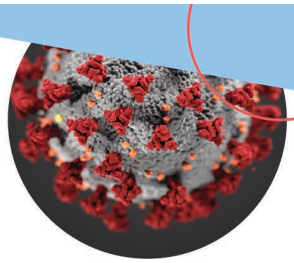


# Statement from the ASHM COVID-19 Taskforce regarding the Prioritisation of COVID-19 Vaccines for People Living with HIV

*Prepared by ASHM COVID-19 Taskforce Members*, Updated 14 April 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.*

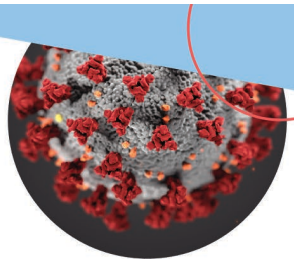
Healthcare providers may wish to continue having detailed discussions with patients about the risks and benefits of the AstraZeneca vaccine in line with ATAGI advice, regardless of the age of the patient, ensuring fully informed consent before vaccination.

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

## SUMMARY STATMENT

A number of studies to date have shown that people living with HIV (PLWHIV) appear to be at increased risk of infection with SARS-CoV-2 and 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 PLWHIV in Australia:



## Recommendation 1

That all PLWHIV 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 PLWHIV should be offered a COVID-19 vaccine during Phase 1b of the roll-out.

The Commonwealth, States and Territories should consult closely with HIV peak organisations, clinicians and researchers who specialise in HIV to optimise the engagement of PLWHIV during the roll-out of COVID-19 vaccines.

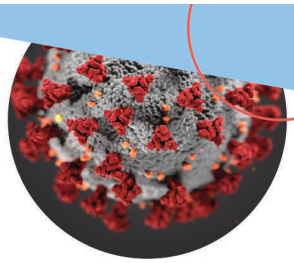
## Recommendation 2

That all PLWHIV should be offered a vaccine irrespective of whether or not 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 PLWHIV as a result of geographic, social, ethnic and cultural factors. For example, vaccine provision to Indigenous Australians who live in remote regions, to populations who are culturally and linguistically diverse, to people who are homeless, or have housing insecurity and to people who have a substance use disorder.

## Recommendation 3

That Australia's COVID-19 vaccine roll-out strategy should be designed to provide high levels of personal and medical confidentiality for PLWHIV 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 Recommendation1

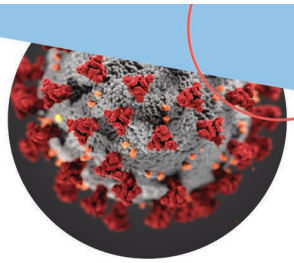
The ASHM COVID-19 Taskforce's interpretation of the currently available published and pre-print literature is that PLWHIV do have an increased risk of infection with SARS-CoV-2, and an increased risk of poorer outcomes following infection with SARS-CoV-2 (see review of literature below).

Upon review of the literature it is highly likely that there are several factors that may explain the increased risk of infection and poorer outcomes with SARS-CoV-2 in PLWHIV including [1] the effect of HIV upon the immune system, including in virologically suppressed populations, [2] the potential interplay between the impact of SARS-CoV-2 infection and HIV upon the immune system, [3] the presence of comorbidities, [4] age and [5] other factors including ethnicity and socioeconomic status which may prevent PLWHIV from being able to safely protect themselves from exposure to SARS-CoV-2 infection. A detailed discussion of these factors is beyond the scope of this position statement.

Recommendation 1 is in keeping 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 [1-5].

## Rationale for the ASHM COVID-19 Taskforce Recommendation 2 and 3:

The rationale for Recommendations 2 and 3 are based upon the principles of social justice and the need to have the highest possible uptake of COVID-19 vaccines by



PLWHIV. No person living with HIV in Australia should be denied a COVID-19 vaccination based upon their life circumstances be it, for example, that they do not have a Medicare number, do not live in metropolitan areas, or are incarcerated. The knowledge 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 all PLWHIV in Australia.

Recommendations 2 and 3 are in keeping with the 'human right to science' as per the United Nations Committee on Economic, Social Rights, Comment 25 [6].

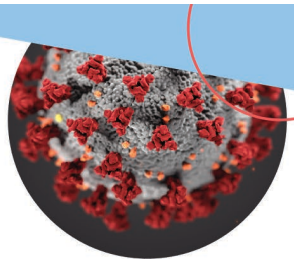
## Literature Review Informing Recommendation 1

The ASHM COVID-19 Taskforce undertook a review of available published and pre-print literature from December 2019 until January 2021 to address COVID-19 outcomes in people living with HIV (PLWHIV). This review is not a systematic review or meta-analysis of the literature, nor is it exhaustive and the Taskforce wishes to emphasis that scientific and clinical research findings regarding COVID-19 and its impact on PLWHIV will continue to grow and change.

## Findings: Infection with SARS-CoV-2

*Increased risk of infection*

A systematic review and meta-analysis of over 144,000 people hospitalised with COVID-19 infection in North America, Europe, and Asia between January and June 2020 found that the pooled prevalence of HIV infection in these patients was twice as high as the pooled prevalence of HIV infection in the countries' general populations, (1.22% (95% confidence interval (CI): 0.61%- 2.43%) versus 0.65% (95% CI: 0.48%-0.89%), respectively [7]. Another review in settings in North and South America, Europe, the United Kingdom (UK) and Asia examined the relative risk of PLWHIV being diagnosed with HIV across 23 studies. The review found that in 11/23 studies, the relative risk of PLWHIV being diagnosed with COVID-19 was significantly greater than



the expected rate based upon background rates of HIV infection in those settings [8]. Similarly, when the rates of COVID-19 diagnoses were compared across all 23 studies, the observed versus expected rate was higher in PLWHIV (Wilcoxon signed-rank test, $p < 0.01$) [8]. Other studies not included in these two abovementioned reviews, also have reported similar findings [9,10,11].

*No increased risk of infection*

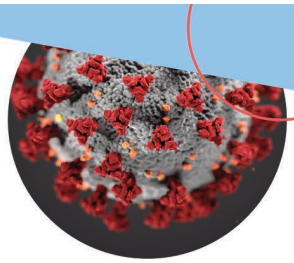
Two retrospective reviews did not find an increased risk of COVID-19 in PLWHIV [12,13] although relatively small numbers of PLWHIV with COVID-19 were included in these studies.

## Findings: Hospitalisation with COVID-19

*Increased risk of hospitalisation*

An analysis was undertaken of people diagnosed with COVID-19 in the United States across a well-established multicentre research network, TriNETX, which has access to records of over 50 million patients who are cared for predominantly in large urban centres [14]. The authors compared 404 PLWHIV diagnosed with COVID-19 to a propensity-matched cohort of 49,763 non-PLWHIV with COVID-19 to offset factors that may confound the study findings. They reported that in unmatched analyses, PLWHIV had a higher risk of hospitalisation (risk ratio (RR) 1.83, 95% CI: 1.5-2.24). The authors then performed propensity matching 1:1 for body mass index, diabetes, hypertension, chronic lung disease, chronic kidney disease, race, history of nicotine dependence and sex. The risk of hospitalisation remained higher for PLWHIV (RR 1.70, 95% CI: 1.21-2.38) [14].

Another study in New York State used matched HIV surveillance data, hospitalisation databases and laboratory-confirmed COVID-19 diagnoses [10]. In this study, Tesoriero et al also found that PLWHIV versus non-PLWHIV had a significantly increased risk of hospitalisation following adjustment for age, sex and region (standardized rate ratio



(sRR) 1.38 95% CI: 1.29-1.47) [10]. Of note in this study, hospitalisation rates were higher in those not virologically suppressed and with lower CD4+ T cell counts [10].

Johnston calculated the relative risk of hospitalisation of PLWHIV versus non-PLWHIV within the general population in nine studies. The study reported that in 7/9 studies, PLWHIV had an elevated risk of hospitalisation and this reached significance in five of the seven studies (lower bound of the 95% CI >1) [8]. However, when compared for all nine studies, there was no difference in hospitalisation rates for PLWHIV [8].

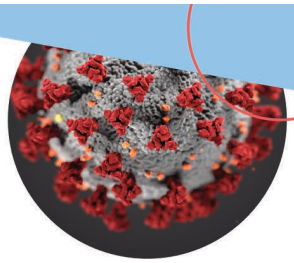
*No increased risk of hospitalisation*

Other studies compared hospitalisation rates for PLWHIV versus non-PLWHIV in in New York City's public hospitals [15] and in the US state of Georgia [16] and found no increased risk of hospitalisation for PLWHIV. Again, a relatively small number of PLWHIV with COVID-19 were included in these studies.

## Findings: COVID-19 Mortality

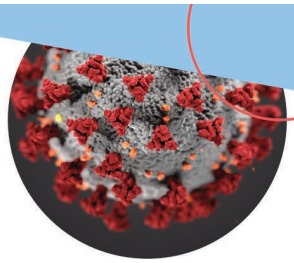
*Increased risk of mortality*

In a large retrospective cohort study of adults from the United Kingdom, Bhaskaran and colleagues linked an electronic primary care dataset to national death registrations [17]. 17, 202, 905 people were evaluated of whom 27,480 were PLWHIV. The authors compared the risk of mortality for adults diagnosed with COVID-19 depending on whether they were PLWHIV or non-PLWHIV. COVID-19 deaths occurred in 25 PLWHIV and in 14,857 non-PLWHIV. The authors found that PLWHIV with COVID-19 had a higher risk of mortality after adjusting for age and sex (hazard ratio (HR) 2.09 (95% CI:1.96-4.30; p< 0.0001). Following further adjustment for comorbidities, smoking, ethnicity and deprivation, the risk of mortality remained significantly higher for PLWHIV (HR 2.59 (95% CI: 1.74-3.85; p <0.001) [17]. Of note, the study did not include data on CD4+ cell counts, HIV viral loads, or prior AIDS illnesses.



A population cohort study undertaken in South Africa was designed to evaluate risk factors for COVID-19 death in the general population. The study analysed linked data from approximately 3.5 million patients living in the Western Cape Province who attended public health sector facilities, and of whom 16% were HIV seropositive [18]. Data were available on CD4+ cell counts, HIV viral loads and antiretroviral use for PLWHIV. Of 3,460 932 people, 22,308 people were diagnosed with COVID-19. 625 COVID-19 deaths occurred in public sector patients, of whom 115 were PLWHIV. Notably HIV virological suppression was prevalent in PLWHIV. The study found that in all public sector patients, HIV was associated with an increased hazard for mortality after adjusting for age, sex and comorbidities (adjusted (a) HR 2.14 (95% CI: 1.70-2.70). This finding was irrespective of whether PLWHIV were viraemic or immunosuppressed. In hospitalised patients, HIV remained significantly associated with an increased risk for death (aHR 1.45 (95% CI: 1,14-1.84)) [18]. Finally, the authors estimated the standardized mortality rate (SMR) of PLWHIV (e.g. the number of deaths in PLWHIV you would expect to see if they had the same risk as non-PLWHIV of the same age and sex). The SMR of PLWHIV vs non-PLWHIV was significantly higher at 2.39 (95% CI 1.96-2.86) [18].

Other studies from international jurisdictions have reported increased COVID-19 mortality in PLWHIV compared to non-PLWHIV populations. Geretti et al prospectively examined outcomes of patients hospitalised with COVID-19 across 207 centres in the UK [19]. 47,592 patients were evaluated and 122 (0.26%) were HIV positive. The authors reported that the overall 28- day mortality was not different between PLWHIV and non-PLWHIV. However, in people under 60 years of age, PLWHIV had increased mortality compared to non-PLWHIV (21.3% versus 9.6%, $p < 0.01$). In further analyses, after adjusting for sex, ethnicity, age, 10 comorbidities and baseline hypoxia, PLWHIV had a higher mortality rate (aHR 1.63 (95% CI: 95% CI 1.07-2.4; p=0.02)), which was even higher in people less than 60 years of age. The study did not include data on CD4+ cell counts, HIV viral loads, or prior AIDS illnesses [19].



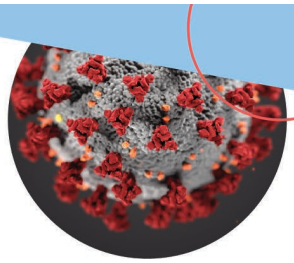
Tesoriero et al's population study from New York State, described above, also found a higher mortality rate in younger hospitalised HIV positive people [10]. Overall, hospitalised PLWHIV with COVID-19 died a rate 2.55 fold higher than that of non-PLWHIV (95% CI: 2.22-2.93), thought to be a result of much higher hospitalisation rates for PLWHIV. In those PLWHIV under 40 years of age the unadjusted mortality rate was high at 5.74 (95% CI: 2.14-15.42) [10]. Similarly, Vizcarra and colleagues who undertook a single centre prospective cohort study of hospitalised PLWHIV in Madrid found that mortality in PLWHIV aged 50-59 years was double that of the general Spanish population (8% vs 4%) [20].

Ranges of mortality in PLWHIV were evaluated in a systematic review and meta-analysis that evaluated seven studies spanning populations in Europe and New York City [7]. The combined mortality rate was 14.09 % (95%CI 5.78-30.50) with the highest combined country mortality rate being 35.4% in the United States [7].

Several other retrospective studies, using different designs and statistical analyses, have shown that HIV positive serostatus is associated with, or affords higher rates of mortality [21-27].

*No increased risk of mortality*

No difference in mortality between PLWHIV and non-PLWHIV has been reported in several studies. One systematic review and meta-analysis [28] evaluated seven studies, three of which are discussed above [18,19,14]. The study evaluated 172,451 HIV seronegative people and 4,735 HIV seropositive people with COVID-19. No increased risk of mortality was observed in PLWHIV (risk ratio 0.99 (95% CI: 0.82-1.19)) [28]. Similarly, Johnston calculated the relative risk of mortality in PLWHIV across 13 studies, which reported deaths of 192 PLWHIV with COVID-19 [8]. The review found that in 10/13 studies mortality was lower than that of the general population, but this reached significance in only one study [8]. Cooper et al undertook a systematic review of eight studies that evaluated only 70 PLWHIV with COVID-19

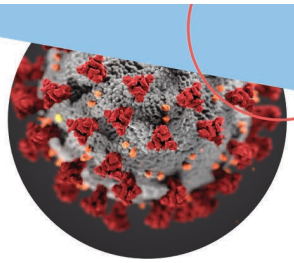


and found that PLWHIV did not have poorer outcomes overall, however mortality was not independently assessed as an outcome [29].

In a population-based cohort study in Wuhan the standardised case-fatality rates in PWLHIV (3.68) were similar to that of the general population of Wuhan (7.74) [30]. The abovementioned TriNETX research network reported on mortality in their propensity matched cohort. They found that in univariate analysis, PLWHIV had a higher 30-day mortality rate (RR 1.55, 95% CI 1.01-2.39). However, after 1:1 propensity score matching, no difference in mortality was observed between PLWHIV and non-PLWHV (RR 1.33, 95% CI 0.68-2.57) [14].

Several retrospective reviews including case-matched studies of populations in Europe, the United States and South Africa, have not found an increase in mortality in PLWHIV [31-39,11,40]. Of note, many of these studies have small sample sizes.

There are several other studies reporting on COVID-19 in PLWHIV that have not reported on outcomes of PLWHIV versus non-PLWHIV and are listed here for completeness's sake [41-47]. Many of these studies are small, descriptive case studies.



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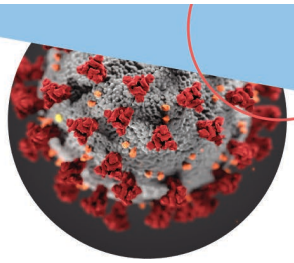

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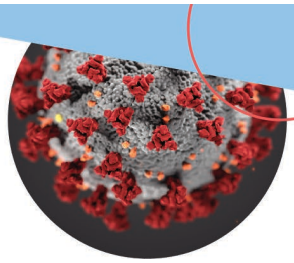

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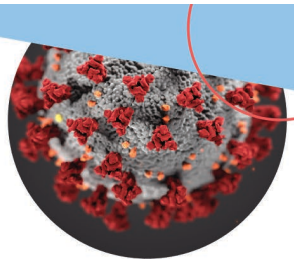

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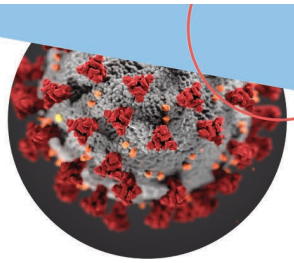

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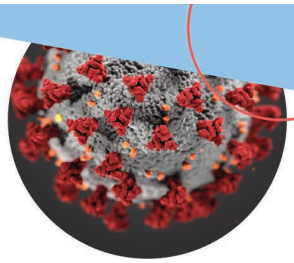

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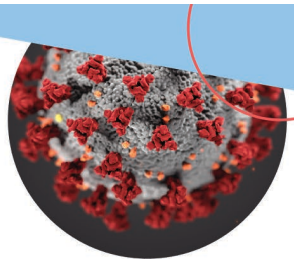

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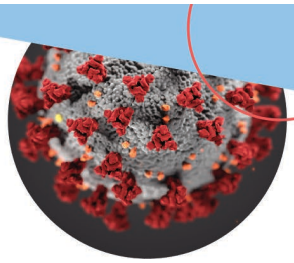

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