BHIVA, DAIG, EACS, GESIDA, Polish Scientific AIDS Society and Portuguese Association for the clinical study of AIDS (APECS)

Statement on risk of COVID-19 for people living with HIV (PLWH) and SARS-CoV-2 vaccine advice for adults living with HIV

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COVID-19 & HIV

Most initial case series or cohort analysis of people living with HIV (PLWH) with COVID-19 [1-17] showed no clear evidence for a higher COVID-19 infection rate or different disease course in people with and without HIV. These case series of PLWH however, were largely underpowered and often reported a younger age than in HIV-negative hospitalised COVID-19 patients.

As more data is becoming available, most studies are now reporting a higher risk of poor outcomes in HIV- and COVID-19 coinfected individuals. Indeed, two large cohort studies from the United Kingdom (UK), have reported an increased mortality among PLWH. An analysis of hospitalised patients showed an adjusted hazard ratio [aHR] of 1.69 (95% confidence interval [CI] 1.15-2.48; p=0.008) albeit with no data on antiretroviral therapy (ART), viral load (VL) or CD4 count collected [18]. Secondly, an analysis of UK primary care data demonstrated, after adjustment for age, sex, deprivation, ethnicity, smoking and obesity, an aHR of 2.59 (95% CI 1.74–3.84; p<0·0001) though was similarly unable to fully adjust for confounders, including HIV variables; importantly, most PLWH who died had other co-morbidities [19]. Recently, data has also been submitted from New York state demonstrating that COVID-19 hospitalisation was higher among people living with diagnosed HIV (RR [95% CI]: 2.61[2.45-2.79], sRR [95% CI]: 1.38[1.29-1.47], 896 PLWH), as was in-hospital death [20]. Of note, more advanced HIV disease stage and unsuppressed VL were significantly associated with increased hospitalisation risk [20]. An analysis from the Western Cape, after adjusting for other risk factors, also found that HIV increased a COVID-19 patient's death risk by a factor of 2.14 (95% CI 1.70-2.70) [21]. The larger prevalence of HIV in Africa permits study of higher participant numbers but there may be important differences in baseline characteristics and risk factors for COVID-19 mortality compared to other parts of the world including age, comorbidities (including tuberculosis), obesity and socioeconomic status (the latter two were not captured). A much smaller analysis from South London, UK indicated there might be substantial morbidity and mortality from COVID-19 among black PLWH, even among those on suppressive ART [22]. Similar data was also reported from France [23]. This observation raises the question whether African regions with a high prevalence of HIV infection may be particularly vulnerable to the impact of the COVID-19 pandemic.

Interestingly, as more information on PLWH with COVID-19 disease emerges, a more pronounced immunodeficiency (defined as a current CD4 count <350/µL) has been associated with an increased risk for severe COVID-19 (adjusted odds ratio 2.85, 95% CI 1.26-6.44, p=0.01) [24]. The only HIV-related factor associated with mortality in this study was a low nadir CD4 count [24]. Similarly, in the Western Cape study among hospitalised PLWH, a CD4 count <200/µL was also associated with an increased mortality risk [21].

Current evidence indicates that the risk of severe COVID-19 illness increases with age, male gender and with certain chronic medical problems such as arterial hypertension, cardiovascular disease, chronic lung disease, obesity and diabetes. Indeed, almost half of PLWH in Europe are older than 50 years and co-morbidities are more common in PLWH. Most interestingly, in the UK study the excess mortality risk in people with HIV relative to those without HIV was limited to people with additional co-morbidities.

In summary, the recent findings suggest that PLWH and either uncontrolled HIV-infection or advanced immunodeficiency, or in the context of additional co-morbidities might have a higher risk for COVID-19 death. PLWH, therefore, need priority consideration for SARS-CoV-2 vaccination. Nevertheless, the need for continued data collection in PLWH and COVID-19 coinfection has to be highlighted to increase the level of certainty around risk factors for worse COVID-19 outcomes and to better define PLWH at particular need for vaccination interventions.

As a risk factor for respiratory infections, smoking cessation should be encouraged for all. Influenza and pneumococcal vaccinations should be kept up to date as recommended by BHIVA/EACS Guidelines.

There has been an ongoing discussion whether use of certain HIV antiretrovirals (ARVs) may protect against a COVID-19 infection. In a Spanish study evaluating COVID-19 incidence and risk of hospitalisation among 77,590 PLWH on ART, the risk of hospitalisation by non-nucleos(t)ide reverse transcriptase inhibitor (NRTI) treatment was lowest for those on tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) [25]. Noteworthy, PLWH who remain on TDF/FTC are less likely to have renal disease, arterial hypertension or diabetes, all medical comorbidities associated with worse COVID-19 outcomes [26]. Further analysis suggested that confounding due to unmeasured clinical characteristics does not completely explain TDF/FTC signal in the Spanish study [27]. In the Western Cape study among COVID-19 cases in PLWH on ART, receipt of TDF (vs. other therapies) was also associated with reduced COVID-19 mortality even after adjusting for renal disease, viral suppression and ART duration [21].

Although not all studies have demonstrated an association between HIV surrogate markers and COVID-19 mortality, we continue to advise that immune suppression, indicated by a low CD4 count (<200 cells/µL), or not receiving ART, should be considered a risk factor. For PLWH with low CD4 counts (<200 cells/µL), or who experience a decline in CD4 count during a COVID-19 infection, remember to initiate opportunistic infection (OI) prophylaxis (to prevent complications through additional OIs rather than impact COVID-19 per se). More information regarding recommendations for prophylaxis and treatment of specific opportunistic infections can be found in the → BHIVA (https://www.bhiva.org/ClinicalGuidelines)/→ EACS (../guidelines/eacs-guidelines/eacs-guidelines.html) Guidelines for HIV/AIDS.

The potential for COVID-19 vertical transmission remains controversial. Although few case reports have claimed perinatal transmission several other large case series could not find any case of vertical transmission [28-32]. Pregnant women with critical COVID-19 who deliver during their disease course mostly deliver preterm via caesarean section [32]. Although most mothers have been discharged without any major complications, severe maternal morbidity because of COVID-19 and perinatal deaths have been reported. Careful monitoring of pregnancies with COVID-19 and measures to prevent neonatal infection are warranted.

Existing national guidelines should be followed in terms of reducing risk for acquiring a COVID-19 infection and managing symptoms [33-36].

COVID-19 treatment: individual ARVs

Expedited research and publication are welcomed with the caveat that many results have been disseminated pre-

publication and/or published without usual peer review, and some subsequently altered or withdrawn. Randomised clinical trials (RCTs), including the large RECOVERY trial, investigating ritonavir boosted lopinavir- (LPV/r) demonstrated no benefit over standard care in adults hospitalised with COVID-19 [37,38]. There is no evidence to support the use of other protease inhibitors (PIs); structural analysis demonstrates no darunavir (DRV) binding to COVID-19 protease, consistent with lack of impact on COVID-19 risk or severity in an Italian case series [39].

Data regarding the activity of TDF against SARS-CoV-2 is conflicting. In Silico data suggests that TDF may bind to SARS-CoV-2 Nsp1 protein [40] as does an unpublished paper based on a cell-free assay [41]. In vitro studies yield conflicting results: one in vitro study supports antiviral activity of TDF [42] and an animal model suggests shortened duration of symptoms, and possibly infectiousness [43]. However, two studies have failed to demonstrate any in vitro activity of tenofovir against CoV-2 [44,45] so more data is required.

A large randomised phase 3 placebo-controlled study in Spain and Latin America using TDF/FTC and low-dose hydroxychloroquine (HCQ) as COVID-19 prophylaxis in health workers is ongoing [46]. There is also a study looking at TDF/FTC for treatment of mild COVID-19 cases.

Currently no evidence is available to justify switching PLWH from their usual ART. HIV Pre-exposure prophylaxis (PrEP) should be taken as directed and there is no current evidence that PrEP is effective against COVID-19.

CCR5-inhibitors have been suggested to have activity against SARS-CoV-2 and maraviroc (MVC) is predicted to bind to SARS-CoV-2 protease [47]. At the time of writing there are two recruiting trials, and one planned, investigating MVC as a COVID-19 treatment. PRO 140 (leronlimab) is a humanised monoclonal antibody targeted against the CCR5 receptor under investigation as a potential HIV therapy. Results from 10 people treated with leronlimab for critical COVID-19 infection (two doses of leronlimab via individual emergency use indication) showed statistically significant reduction in plasma IL-6, restoration of the CD4/CD8 count ratio, and resolution of SARS-CoV2 plasma viremia [48]. Encouraging safety data and a high clinical recovery rates in hospitalised severe/critical COVID-19 patients receiving compassionate use leronlimab support larger clinical trials [49].

COVID-19 treatment: other options

HCQ has been extensively studied for therapeutic use in COVID-19 infection [50]. Unfortunately, several large RTCs demonstrated no clear clinical benefit and raised important safety concerns including cardiac arrhythmias and methaemoglobinaemia [51-54]; Therefore, World Health Organisation (WHO) Guidelines strongly recommended against using HCQ at any stage of COVID-19 [55]. Despite this recommendation and the lack of evidence for the therapeutic benefit of HCQ therapy there are 137 recruiting or planned HCQ studies listed on → clinicaltrials.gov (https://clinicaltrials.gov/) at the time of writing. Studies evaluating HCQ in post-exposure or pre-exposure prophylaxis studies have not been powered to establish definite benefit from this intervention [56]. Given that the (if any) effects of HCQ will be of a much smaller magnitude than from vaccines, it appears a lot more promising to focus on vaccines from now onwards.

The first licensed drug for COVID-19 treatment is remdesivir, originally developed for Ebola therapy, with broad in vitro antiviral activity against SARS-CoV-2 [57]. First cases from the remdesivir expanded access program suggested potential clinical benefit [58] but the first RCT from China demonstrated no statistically significant clinical benefits in adults with severe COVID-19 [59] with higher adverse event-driven discontinuations than in the control group: 12% vs 5%, respectively [59]. The Adaptive COVID-19 Treatment Trial (ACTT) demonstrated faster recovery amongst hospitalised patients randomized to remdesivir compared to placebo, with a median recovery time of 11 days and 15 days, respectively [60] and a possible survival benefit, with a mortality rates of 8.0% versus 11.6%, respectively (p=0.059) [60]. Meanwhile the SIMPLE study "similar improvement in clinical status" for 5-day and 10-days of remdesivir [61] and many remdesivir trials are ongoing. Importantly, the large SOLIDARITY trial showed no substantial mortality benefit with remdesivir across a variety of health care settings [53]. Unanswered questions include when best to start remdesivir therapy, the patient profiles associated with greatest benefit, does remdesivir add any benefit to dexamethasone therapy, and the role for remdesivir in combination with other drugs.

Following the NIAID Adaptive COVID-19 Treatment Trial 2 (ACTT-2), the Food and drug administration (FDA) has granted an emergency use authorization for Baricitinib, an oral, selective inhibitor of Janus kinase (JAK) 1 and 2 (licensed in the United States and Europe for the treatment of rheumatoid arthritis), in combination with remdesivir in patients with COVID-19 requiring oxygen. In ACTT-2 study patients randomized to baricitinib plus remdesivir recovered a median of 1 day faster than patients on remdesivir and placebo (median, 7 days vs. 8 days; rate ratio for recovery, 1.16; 95% CI 1.01-1.32; p=0.03) with fewer serious adverse events in the combination arm [62]. The median time to recovery among patients on noninvasive ventilation or high-flow oxygen was 10 days in the combination group and 18 days in the control group (rate ratio for recovery, 1.51; 95% CI 1.10-2.08) with Kaplan–Meier estimates of mortality at day 28 of 5.1% and 7.8%, respectively (HR for death, 0.65; 95% CI 0.39 1.09). Additional large studies are currently underway.

The efficacy of interleukin-6 receptor antagonists particularly in critically ill patients with COVID-19 has been investigated in several large trials. In a recently published study in the New England Journal of Medicine tocilizumab was not effective for preventing intubation or death in moderately ill hospitalised patients with COVID-19 [63]. The authors however cautioned that some benefit or harm cannot be ruled out, because the confidence intervals for efficacy comparisons were wide. More positive results were recently presented from the REMCAP investigators [64]. In this study adult patients with COVID-19, within 24 hours of commencing organ support in an intensive care unit, were randomized to receive either tocilizumab (8 mg/kg) or sarilumab (400mg) or standard care (control). Hospital mortality was 28.0% (98/350) for tocilizumab, 22.2% (10/45) for sarilumab and 35.8% (142/397) for control, thereby demonstrating a survival benefit for the IL-6 receptor antagonist therapy, respectively [64]. Cumulative moderate-certainty evidence shows that tocilizumab reduces the risk of mechanical ventilation in hospitalized COVID-19 patients. In light of the controversial results, recommendation for the use of tocilizumab vary between countries and settings. A recent meta-analysis concluded with moderate certainty that tocilizumab reduces the risk of mechanical ventilation in hospitalized COVID-19 patients [65]. In the German Guidelines for management of hospitalised COVID-19 patients, however, use of tocilizumab is not recommended [66] whereas in the UK an interim position statement was updated in January 2021, to support the off-label use of tocilizumab and sarilumab in adult patients admitted to intensive care with COVID-19 pneumonia [67]. In the Spanish Guidelines, tocilizumab is considered as an alternative treatment to corticosteroids in patients with contraindications for the use of corticosteroids or within clinical trials [68].

A further agent under investigation for COVID-19 treatment is famotidine. Following the observation of lower mortality amongst hospitalised COVID-19 patients on famotidine, a small single-arm study described improved patient reported outcomes in non-hospitalised COVID-19 patients starting famotidine [69]. Retrospective data for patients hospitalised with COVID-19 in New York showed famotidine to be associated with a reduced risk of intubation or death [70]. Five ongoing or planned trials were listed on → clinicaltrials.gov (https://clinicaltrials.gov/) at the time of writing.

A recent study reported in vitro activity for ivermectin against SARS-CoV-2 in experimentally infected cells [71] but the concentrations yielding antiviral activity in laboratory cultures were high and doses approved by the FDA for treatment of parasitic diseases in humans may not be sufficient to yield clinical benefit. However, interim results from a meta-analysis of 11 RTCs including 1,452 patients, demonstrated faster time to viral clearance, shorter duration of hospitalisation, 43% higher rates of clinical recovery and 83% improvement in survival rates following ivermectin therapy [72]. More trials are currently ongoing to clarify the role ivermectin can play in COVID-19 treatment.

Finally, first data from a meta-analysis of trials from Iran studying the HCV direct acting antivirals sofosbuvir and daclatasvir were presented at the AIDS 2020 virtual conference suggesting a potential mortality benefit [73]. However, not all included data was derived from RCTs, and the overall number of treated patients was low. More recently, results from a RTCs in outpatients with mild COVID-19 who were randomized to either sofosbuvir/daclatasvir (n=27, treatment arm) or the control arm (n=28) were published [74]; sofosbuvir/daclatasvir did not impact symptoms or hospitalization rates [74].

The full results from these trials, as well as other ongoing clinical trials especially in early COVID-19 disease, are eagerly awaited. A list of currently ongoing or planned COVID-19 studies in PLWH can be found under:
→ https://www.clinicaltrials.gov/ct2/results?term=hiv+covid&Search=Search (https://www.clinicaltrials.gov/ct2/results?term=hiv+covid&Search=Search)

Maintaining HIV care during the COVID-19 pandemic

Implementation of quarantine, social distancing, and community containment measures have reduced access to routine HIV testing, which challenges completion of UNAIDS' first 90-90-90 target globally [75]. Moreover, timely linkage to HIV care as well as ART continuation, will be hindered during the COVID-19 pandemic, as many physicians from HIV-clinics are sharing HIV care and COVID-19 care duties as recently demonstrated from the Euro Guidelines in Central and Eastern Europe (ECEE) Network Group for more than 50% of clinics in central and Eastern Europe [76]. In many countries with high COVID-19 case load, there is a need to prepare for operating under minimal medical resources with the aim to secure retention on ART. Non-governmental organisations are essential to second medical efforts to ensure continuity of ART delivery for treatment and prevention. All HIV services should ensure they have contingency plans to provide minimum standards of care and monitoring of outcomes, and patient experience are essential to guide response to future waves of COVID-19, and any similar pandemics we may face in the future. In Spain, GeSIDA has issued Guidelines for teleconsultation [77].

SARS-CoV-2 vaccine advice for adults living with HIV

In general, PLWH and more pronounced immunodeficiency (defined as CD4 count <350/µL), detectable viraemia and those with additional comorbidities, may be at increased risk for severe COVID-19; therefore, prioritized COVID-19 vaccination is recommended. In addition, prioritized vaccination is recommended for all PLWH with risk factors for a worsened COVID-19 outcome similar to the general population (age, comorbidities, social and economic deprivation, etc.).

The first results from SARS-Cov-2 mRNA vaccine trials following a two-dose regimen of Pfizer's BNT162b2 (tozinameran; 2 vaccinations 3 weeks apart) or Moderna's mRNA-1273 (2 vaccinations 28 days apart) in adults conferred 95% and 94,1% protection against COVID-19, respectively [78,79]. Safety over a short-term period of around 2 months in both trials was similar to that of other viral vaccines. Of note, severe allergic reactions have been noted in rare cases following vaccination with the Pfizer vaccine but mostly in patients with a history of multiple allergies. Both mRNA vaccines have been approved by the European Medicines Agency (EMEA). A third vaccine by AstraZeneca so far has not undergone European regulatory approval but is already licensed and in use in the UK. This particular vaccine uses an adenovirus viral vector (AdV) and has been up to 90 percent effective in clinical trials, depending on the initial dosage [80]. The STEP HIV vaccine study, which found that uncircumcised men who had received the active AdV based HIV-vaccine (and who had naturally previously been exposed to Ad5) were at slightly higher risk of becoming HIV positive, raised cautions about COVID vaccines that use an adenovirus (specifically Ad5) [81,82]. The question whether using a similar Ad5 platform for a vaccine against COVID-19 might also increase the risk of HIV in countries where HIV incidence is still high, so far has remained unanswered. There is no data to suggest that the vector might increase the risk of coronavirus infection, though. Data on SARS-CoV-2 vaccines PLWH is limited but based on their safety profiles to date, and the nature of the vaccines, there is no reason for additional concern at present. PLWH, in particular those with more advanced immunodeficiency (defined as CD4 count <200/µL) can produce weaker responses to some vaccines but it is currently unknown whether this also applies to SARS-CoV-2 vaccines. PLWH were eventually included in the Pfizer and Moderna trials but no separate safety or efficacy analysis for this subgroup has yet been presented. For those with previous SARS-CoV-2 infection, vaccination is also recommended, as it is possible that post-infection immunity will wane. The ideal timing of vaccination has not yet been determined.

The question how far PLWH at higher risk should be prioritized for SARS-Cov-2 vaccination has not be answered unanimously throughout Europe. Some countries have recommended that all PLWH should be given priority for vaccination against COVID-19 together with other groups of people with comorbidities, once the most at-risk groups such as the elderly >80 years and frontline healthcare workers have received their vaccination. In Germany, all PLWH will be included in a third tier of priority patients along with individuals above 60 years of age, people with comorbidities such as chronic heart, renal and liver disease, and those working in key sectors like education. In the UK PLWH aged 16-65 years will be included in the sixth priority group for vaccination, after those aged 65 years and over, healthcare workers and people who are clinically extremely vulnerable. The Portuguese vaccination plan does not refer to PLWH in particular so the vaccination will occur according to the criteria of the national plan and the comorbidities present in PLWH.

Further information for health care professionals about the licensed SARS-Cov-2 vaccines in Europe can be accessed here: → https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19 (https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19).

COVID-19 data collection & resources

A COVID-19 drug interactions website (→ www.covid19-druginteractions.org (http://www.covid19-druginteractions.org/)) has been developed for the experimental drugs being trialed to treat COVID-19 in different parts of the world. EACS and BHIVA are happy to announce that they have agreed to financially support this very useful website. A useful Spanish interaction resource can be found under: ⓓ http://www.interaccionesvih.com/docs/Interacciones%20importantes%20con%20Kaletra%20e%20Hidroxicloroquina_20%20marzo%202020_COVID.pdf (http://www.interaccionesvih.com/docs/Interacciones%20importantes%20con%20Kaletra%20e%20Hidroxicloroquina_20%20marzo%202020_COVID.pdf).

We would like to highlight three resources for reporting COVID-19 cases:

- The NEAT ID Foundation has developed a 'data dashboard' to monitor COVID-19 case numbers, hospitalisations and mortality in people with HIV and/or hepatitis at European and country level. The data will be available for public viewing via → www.NEAT-ID.org (http://www.neat-id.org/) and if your centre has not signed up, you can do so via this → link (https://mailchi.mp/neat-id/covid-19-hiv-co-infection-data-dashboard-4783628?e=cba33da850).
- The Lean European Open Survey on SARS-CoV-2 Infected Patients (LEOSS) launched by the German Society for Infectious Diseases (DGI) and ESCMID's Emerging Infections Task Force (EITaF) an open register based on anonymous questionnaires and they are keen to collaborate with other registries. See → https://leoss.net (https://leoss.net/), contact them by email at ✉ info@leoss.net (mailto:info@leoss.net) and the register can be accessed here → https://leoss.net/statistics (https://leoss.net/statistics)
- EASL is supporting a registry which can be found under the following link → https://www.covid-hep.net/ (https://www.covid-hep.net/)

The coronavirus outbreak is rapidly evolving. APECS, BHIVA, DAIG, EACS, GESIDA and the Polish Scientific AIDS Society will continue to share any updates to specific guidance for PLWH. Wishing you all well. Stay healthy.

For further information please contact ✉ info@eacsociety.org (mailto:info@eacsociety.org).

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BHIVA, DAIG, EACS, GESIDA & Polish Scientific AIDS Society Statement on risk of COVID-19 for people living with HIV (PLWH)

→ 25 May, 2020 (../home/covid-19-and-hiv.html)

→ 5 August, 2020 (/home/bhiva-daig-eacs-gesida-and-polish-scientific-aids-society-statement-on-risk-of-covid-19-for-people-living-with-hiv-plwh.html)

EACS-BHIVA Statements

→ 20 March, 2020 (/home/eacs-bhiva-statement-20-march.html)

→ 1 April, 2020 (/home/eacs-bhiva-statement-1-april.html)

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