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Foreword

This is the second special issue of our COVID-19 series. It details an analysis of HIV as a COVID-19 comorbidity using routine public sector patient data from South Africa's Western Cape Province. Importantly, the data show that people living with HIV have a modestly elevated risk of poor COVID-19 outcomes, irrespective of viral suppression, and especially if they have other comorbidities.

As this is likely the largest assessment of SARS-CoV-2 and HIV co-infected patients to date, we trust that you will find this information especially useful and informative, given its public health importance. The authors, contributors and reviewers are thanked for their inputs.

Prof Basil Brooke, Editor

RISK OF COVID-19 DEATH AMONG PEOPLE WITH HIV: A POPULATION COHORT ANALYSIS FROM THE WESTERN CAPE PROVINCE, SOUTH AFRICA

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SUMMARY

Using routine public sector patient data on 3 456 253 adults aged ≥20 years from the Western Cape Province during the period 1 March through 4 June 2020, people with HIV had a modestly increased risk of COVID-19 death compared with HIV-negative patients (adjusted hazard ratio [aHR] for death in COVID-19 cases: 1.78; 95% confidence interval [CI]: 1.38; 2.29), irrespective of viral suppression. A small proportion (less than 10%) of all COVID-19 deaths in the province were attributable to HIV. Older age, male sex, diabetes mellitus, current and previous tuberculosis, chronic kidney disease and other comorbidities were also associated with increased COVID-19 mortality. While these findings may over-estimate the effect of HIV on COVID-19 death due to the presence of residual confounding, people living with HIV should be considered a high-risk group for COVID-19 management with modestly elevated risk of poor outcomes, irrespective of viral suppression, and especially if they have other comorbidities.

INTRODUCTION

Interacting effects of the HIV and coronavirus disease-19 (COVID-19) pandemics in sub-Saharan Africa are unknown. Studies to date suggest that there is no increased risk of adverse outcomes in co-infected patients, but these are small cohort studies from Europe and North America.[1-7] These studies were often limited to hospitalized patients, and may not be relevant to sub-Saharan Africa where people living with HIV (PLWH) are younger and have a different comorbidity profile. People living with HIV may experience more severe COVID-19 disease due to HIV-related immune suppression, which may be exacerbated by transient immune deficiency caused by coronaviruses.[8,9] In support of this hypothesis is the increased risk of COVID-19 death in patients with immunosuppressive co-morbidity, including PLWH, reported in a large UK cohort study.[10] Two factors may reduce the risk of severe COVID-19 in PLWH: dysfunctional cellular immunity could protect against the cytokine storm,[11,12] and some antiretroviral drugs (tenofovir and lopinavir-ritonavir) have *in vitro* activity against coronaviruses.[12]

The aim of this analysis was therefore to establish if PLWH are at increased risk of COVID-19 death. We used linked data from patients attending public sector health facilities in the Western Cape Province, South Africa, to identify factors associated with COVID-19 death, including HIV.

METHODS

The Western Cape has nearly 7 million inhabitants, of whom ~520 000 are PLWH, and more than 90% of whom are dependent on public sector health services. The Western Cape Provincial Health Data Centre (WCPHDC) has previously been described in detail.[13] Briefly, the WCPHDC consolidates administrative, laboratory and pharmacy data from routine electronic clinical information systems used in all public sector health facilities, with linkage through a unique identifier. Multiple data sources are triangulated to enumerate health conditions such as diabetes mellitus, hypertension, tuberculosis and HIV. Patients are deemed to be PLWH if they have a positive HIV diagnostic test and/or CD4 and HIV viral load test and/or have received antiretroviral therapy (ART). COVID-19 diagnosis was based on a positive SARS-CoV-2 PCR test. PLWH were considered "well on ART" if they had either a most recent viral load of <1000 copies/ml within the last 3 years AND ART dispensed in the last year, or a most recent viral load <1000 copies/ml within the last 18 months if no record of ART dispensed within the last year. Diabetic control was categorized according to glycosylated haemoglobin (HbA1c) measurement within the last 2 years as <7% (controlled); 7-8.9% (poorly controlled), ≥9% (uncontrolled). All laboratory tests for SARS-CoV-2 infection in both public and private sectors are routinely imported into the WCPHDC and are linked with existing patient data. Hospital admissions and all deaths in SARS-CoV-2 positive cases are recorded and reviewed daily in the WCPHDC.

We analysed de-identified data extracted from adult public sector patients (age ≥20 years) with documented sex and age, and known to be alive on 1 March 2020 (before the first diagnosed COVID-19 case in South Africa and several weeks before the first COVID-19 death) and included all follow-up through 4 June 2020. We used Cox-proportional hazards models adjusted for age, sex and other comorbidities recorded in the WCPHDC to examine the association between HIV and COVID-19 death among (i) all adult public sector patients with ≥1 health visit in the 3 years before 1 March 2020 (considered "active patients"), (ii) all adult public sector laboratory-diagnosed COVID-19 cases and (iii) hospitalized adult COVID-19 cases who had been diagnosed in the public sector. Patients were censored on the date of death if they died without a COVID-19 diagnosis or on 4 June 2020, whichever was earlier. Since socio-economic status and some comorbidities associated with COVID-19 death are not recorded in the WCPHDC, including body mass index (BMI), we calculated E-values to determine the minimum strength of association that an unmeasured confounder (such as socio-economic status or raised BMI) would need to have with both HIV positive status and COVID-19 death, to fully account for any association between HIV and COVID-19 death.[14] We also calculated the standardized mortality ratio (SMR) of the actual number of COVID-19 deaths in people with HIV vs. the number that would be expected if PLWH had the same risk of COVID-19 death as HIV-negative people of the same age and sex. We used data on the age, sex and HIV status of all COVID-19 deaths (public and private sector) and the Thembisa Western Cape HIV model to estimate the size of the Western Cape population and HIV prevalence, by age and sex, in 2020.[15] We used 1000 bootstrap replications to calculate 95% confidence intervals (CI) for the SMR.

RESULTS

Among 3 456 253 “active” public sector adult patients, there were 12 522 diagnosed with COVID-19 and not deceased by database closure, and 435 COVID-19 deaths (Table 1). The proportion of males was lower among COVID-19 cases compared to non-cases (30% vs. 42%), likely due to initial cases occurring amongst essential workers in sectors predominantly employing women. Higher proportions of the COVID-19 cases, as compared to non-cases, had diabetes mellitus (13% vs. 8%), hypertension (20% vs. 16%) and HIV (18% vs. 16%). COVID-19 deceased patients were older than surviving patients (median age [interquartile range] 63 years [54-71] vs. 37 [30-48]) and several comorbidities were more common among deceased patients (Table 1). Of the surviving and deceased COVID-19 PLWH, 69% and 66% respectively were considered “well on ART.”

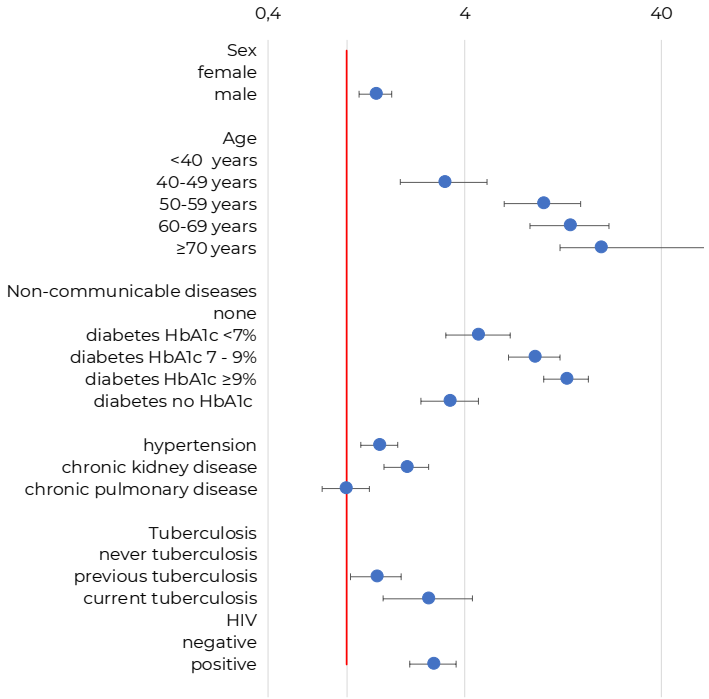
Table 1. Characteristics of (i) Western Cape Province, South Africa, active public sector patients ≥20 years of age according to COVID-19 outcome (ii) COVID-19 cases diagnosed in the public sector and (iii) hospitalized COVID-19 cases diagnosed in the public sector, and associations with mortality using Cox-proportional hazards regression

	All public sector patients						**All public-sector SARS-CoV-2 cases**					**Hospitalized public-sector SARS-CoV-2 cases**				
	No diagnosed COVID-19 n=3 456 253	**"COVID-19 not deceased n=12 522"**	**"COVID-19 deceased n=435"**	**Adjusted HR**	**95% CI**	**p-value**	**"COVID-19 not deceased n=15 446"**	**"COVID-19 deceased n=532"**	**Adjusted HR**	**95% CI**	**p-value**	**"COVID-19 not deceased n=1 999"**	**"COVID-19 deceased n=463"**	**Adjusted HR**	**95% CI**	**p-value**
Sex																
female	1 986 980 (58%)	8791 (70%)	238 (55%)	Ref			9 990 (65%)	280 (53%)	Ref			1,205 (60%)	248 (54%)	Ref		
male	1 456 316 (42%)	3731 (30%)	197 (45%)	1,4	1,16; 1,70	0,001	5,456 (35%)	252 (47%)	1,50	1,26; 1,78	<0.001	794 (40%)	215 (46%)	1,18	0,97; 1,42	0,095
Age																
20-39 years	1 918 830 (56%)	7 251 (58%)	25 (6%)	Ref			8,742 (57%)	36 (7%)	Ref			675 (34%)	35 (8%)	Ref		
40-49 years	606 064 (18%)	2 562 (20%)	40 (9%)	3,12	1,88; 5,17	<0.001	3 313 (21%)	54 (10%)	3,36	2,20; 5,14	<0.001	416 (21%)	47 (10%)	2,09	1,34; 3,25	0,001
50-59 years	448 552 (13%)	1,617 (13%)	123 (28%)	9,92	6,34; 15,54	<0.001	2,061 (13%)	146 (27%)	12,28	8,43; 17,90	<0.001	426 (21%)	122 (26%)	4,86	3,30; 7,18	<0.001
60-69 years	275 952 (8%)	691 (6%)	124 (29%)	13,55	8,55; 21,48	<0.001	844 (5%)	157 (30%)	29,66	20,20; 43,55	<0.001	271 (14%)	139 (30%)	8,6	5,80; 12,73	<0.001
≥70 years	193 898 (6%)	401 (3%)	123 (28%)	19,53	12,20; 31,26	<0.001	486 (3%)	139 (26%)	39,57	26,64; 58,78	<0.001	211 (11%)	120 (26%)	8,51	5,68; 12,73	<0.001
Diabetes*																
none	3 181 027 (92%)	10 906 (87%)	169 (39%)	Ref			13,832 (90%)	239 (45%)	Ref			1310 (65%)	204 (44%)	Ref		
diabetes HbA1c <7%	45 125 (17%)	254 (16%)	36 (14%)	4,65	3,19; 6,79	<0.001	259 (16%)	43 (15%)	2,85	2,02; 4,02	<0.001	111 (16%)	41 (16%)	1,25	0,89; 1,77	0,199
diabetes HbA1c 7 - 8.9%	47 414 (18%)	286 (18%)	69 (26%)	8,99	6,65; 12,14	<0.001	284 (18%)	75 (26%)	3,94	2,98; 5,21	<0.001	120 (17%)	67 (26%)	1,66	1,24; 2,21	<0.001
diabetes HbA1c ≥9%	65 811 (25%)	601 (37%)	114 (43%)	13,02	10,06; 16,87	<0.001	602 (37%)	129 (44%)	4,10	3,24; 5,18	<0.001	311 (45%)	111 (43%)	1,41	1,10; 1,80	0,006
diabetes no HbA1c measurement	103 919 (40%)	475 (29%)	47 (18%)	3,34	2,39; 4,68	<0.001	469 (29%)	46 (16%)	2,34	1,69; 3,25	<0.001	147 (21%)	40 (15%)	1,01	0,72; 1,43	0,940

Other non-communicable diseases																
hypertension	563 535 (16%)	2 478 (20%)	256 (59%)	1,46	1,18; 1,81	<0.001	2 429 (16%)	251 (47%)	0,92	0,75; 1,12	0,404	677 (34%)	219 (47%)	0,88	0,71; 1,07	0,210
chronic kidney disease	61 840 (2%)	245 (2%)	81 (19%)	2,02	1,55; 2,62	<0.001	217 (1%)	79 (15%)	1,73	1,33; 2,25	<0.001	95 (5%)	73 (16%)	1,64	1,25; 2,15	<0.001
chronic pulmonary disease / asthma	192 468 (6%)	848 (7%)	61 (4%)	0,98	0,75; 1,30	0,911	815 (5%)	61 (11%)	0,84	0,64; 1,11	0,216	244 (12%)	58 (13%)	0,74	0,56; 0,98	0,038
Tuberculosis																
never tuberculosis	3 121 133 (90%)	11 370 (91%)	363 (83%)	Ref					Ref			1772 (89%)	399 (86%)	Ref		
previous tuberculosis	287 449 (8%)	990 (8%)	57 (13%)	1,41	1,05; 1,90	0,024	942 (6%)	55 (10%)	1,24	0,91; 1,68	0,168	154 (8%)	48 (10%)	1,25	0,90; 1,73	0,168
current tuberculosis	47 671 (1%)	162 (1%)	15 (3%)	2,58	1,53; 4,37	<0.001	163 (1%)	17 (3%)	1,64	0,99; 2,71	0,053	73 (4%)	16 (3%)	1,11	0,66; 1,87	0,695
HIV																
negative	2 906 904 (84%)	10,249 (82%)	356 (82%)	Ref			13,199 (85%)	446 (83%)	Ref			1618 (81%)	384 (83%)	Ref		
positive	536 392 (16%)	2 273 (18%)	79 (18%)	2,75	2,09; 3,61	<0.001	2247 (15%)	86 (17%)	1,78	1,38; 2,29	<0.001	381 (19%)	79 (17%)	1,28	0,98; 1,67	0,070
well on ART[§]	293 376 (55%)	1 558 (69%)	52 (66%)	3,04	2,21; 4,18	<0.001	1,449 (64%)	59 (69%)	1.68	1.26; 2.25	<0.001	238 (62%)	57 (72%)	1.38	1.04; 1.84	0.026
ART, not confirmed suppressed	151 312 (28%)	409 (18%)	11 (14%)	1,70	0,91; 3,16	0,096	404 (18%)	9 (10%)	1.93	0.96; 3.87	0.065	67 (18%)	7 (9%)	1.25	0.59; 2.68	0.559
never ART	91 704 (17%)	306 (13%)	16 (20%)	2,98	1,79; 4,94	<0.001	394 (18%)	18 (21%)	2.07	1.28; 3.34	0.003	76 (20%)	15 (19%)	1.35	0.80; 2.28	0.255

*Proportions of patients with different values of HbA1c are reported only for diabetic patients; $Reference category for hazard ratio is HIV negative; adjusted for all other variables listed in this table in a different model that included the listed categories of HIV viral load and antiretroviral therapy (ART) instead of the binary variable HIV positive vs. negative; the effect of the other variables on mortality was similar in this model and are not shown; "well on ART" = most recent viral load <1000 copies/ml within the last 3 years AND ART dispensed in the last year, or most recent viral load <1000 copies/ml within the last 18 months if no record of ART dispensed the last year; HR hazard ratio; CI confidence interval; HbA1c glycosylated haemoglobin; VL viral load; ART antiretroviral therapy

i



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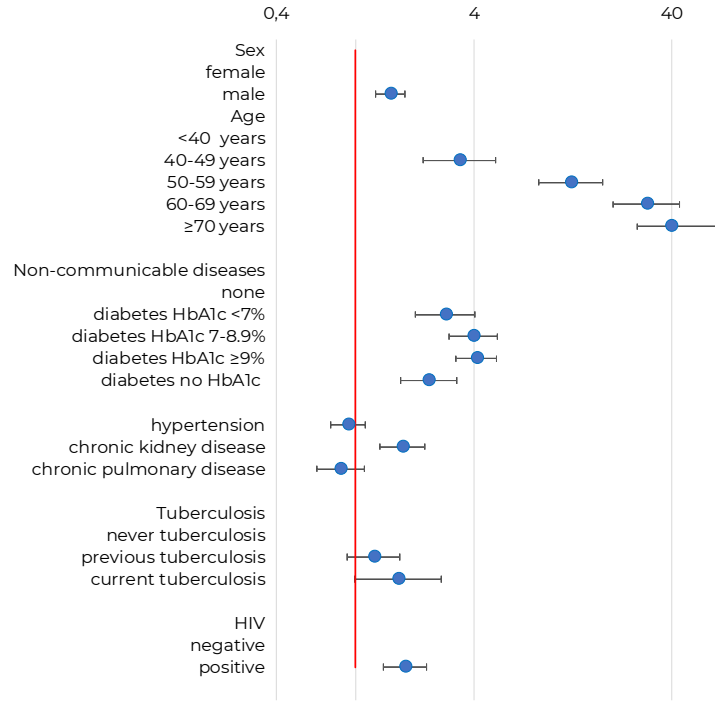

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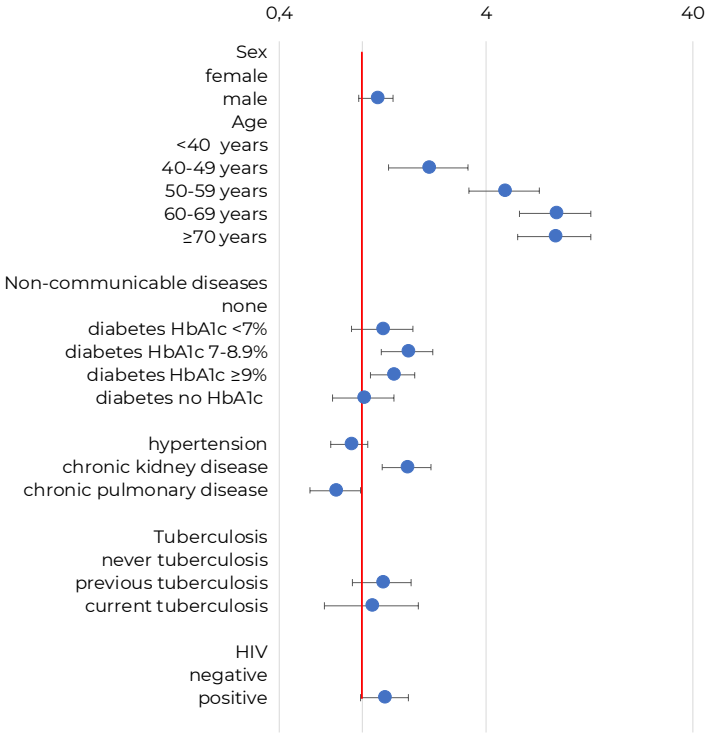

Figure 1. Associations with mortality using Cox-proportional hazards regression among (i) Western Cape Province, South Africa, active public sector patients ≥20 years of age according to COVID-19 outcome (ii) COVID-19 cases diagnosed in the public sector and (iii) hospitalized COVID-19 cases diagnosed in the public sector

In the public sector population patient cohort, COVID-19 death was associated with male sex, increasing age and diabetes mellitus (with higher risk with elevated HbA1c), hypertension and chronic kidney disease, as well as previous and current tuberculosis. After adjusting for

these factors, there was an increased hazard of COVID-19 death in PLWH compared to HIV-negative patients (adjusted hazard ratio [aHR]: 2.75; 95% confidence interval [CI]: 2.09; 3.61). The increased mortality risk was similar in PLWH who were "well on ART" as compared to those who previously started ART but without documented recent viral suppression, or those who had never started ART.

There were 15,978 COVID-19 cases diagnosed in the public sector. This is greater than the number of COVID-19 cases among "active" public sector patients as some of these COVID-19 cases diagnosed in the public sector had not visited a public sector facility in the previous 3 years. Among diagnosed COVID-19 cases, there was an increased mortality in men and older patients. Although the increased risk of death associated with all comorbidities was attenuated when restricting to COVID-19 cases compared to the population analysis, PLWH still had an increased hazard of death compared to HIV negative COVID-19 cases (aHR: 1.78; 95% CI: 1.38-2.29) (Table 1, Figure 1). When restricting the analysis to hospitalized COVID-19 cases the effects of age, male sex and all comorbidities, including HIV, on COVID-19 death were attenuated (Table 1 and Figure 1).

To assess whether the association between HIV and COVID-19 mortality could be due to unmeasured confounding e.g. by socio-economic status or raised BMI, we calculated the E-value for an unmeasured confounder for both above analyses. The E-value is an indication of how strong the association between a confounder (HIV) and the outcome (COVID-19 death) would need to be to account for all of the association between HIV and COVID-19 death. The E-value for the analysis among all public sector patients is 4.94 (and 3.60 for the lower bound of the CI), suggesting that there would need to be a strong association between both HIV and low socio-economic status (or another confounder such as raised BMI), and COVID-19 death to account for all of the observed association between HIV and COVID-19 death.

Among all public and private sector laboratory-diagnosed COVID-19 cases, there were 97 deaths among an estimated ~520 000 PLWH in the province (187 deaths/million) and 573 deaths among 6.36 million people without HIV (90 deaths/million). The SMR for COVID-19 mortality in PLWH, relative to the HIV-negative population, was 2.33 (95% CI: 1.83-2.91) and the attributable fraction of COVID-19 deaths due to HIV was 8.2% (95% CI: 5.3-11.2%).

DISCUSSION

In this analysis of nearly 3.5 million adults in South Africa including nearly 13 000 COVID-19 cases and 435 deaths, we found approximately twice the risk of COVID-19 death in people with HIV irrespective of viral suppression or ART use. This increased risk is modest in comparison to the increased risk of COVID-19 death associated with other risk factors such as older age or diabetes. While this risk may be over-estimated if there is residual confounding due to socio-economic status or comorbidities not routinely recorded in public sector patients, our results suggest that patients with HIV may be at moderately elevated risk of severe COVID-19, irrespective of viral suppression. Nonetheless, despite a high burden of HIV in the province (16% PLWH in active public sector patients), we have not seen

large numbers of patients with advanced HIV and severe COVID-19, and the attributable fraction of all deaths which could be ascribed to HIV is less than 10%.

While most cohort studies of HIV and SARS-CoV-2 co-infection have not shown high risk of poor outcomes in PLWH,[1-3,5-7] cohorts of hospitalized PLWH with COVID-19 in London and New York have reported substantial morbidity and mortality, including patients on suppressive ART.[16,17] A comparison of hospitalized COVID-19 PLWH and people without HIV suggested that COVID-19 outcomes may be worse in PLWH, but the study was small and the differences were not significant.[18] Absence of increased mortality risk in hospitalized patients with comorbidities may be explained by selection bias i.e. risk factors for COVID-19 death may be attenuated by restricting to the subset of hospitalized patients who are already at high risk of mortality.[19] It is therefore expected that for all the comorbidities that we examined, the increased risk of death was progressively attenuated when restricting to cases (i.e. people with sufficiently severe symptoms to be tested) and hospitalized patients.

Several studies have reported a high prevalence of comorbidities among PLWH with severe COVID-19 disease,[3,6,7] and PLWH with COVID-19 have been noted to be younger than their HIV-negative counterparts, attributed to the "aging effect" of HIV[2,7] In the Western Cape, deceased COVID-19 PLWH had a high prevalence of comorbidities and two-thirds were virally suppressed, suggesting that the effect of HIV may at least partly be due to an increased risk of comorbidities. We also found both current and previous tuberculosis to be strongly associated with COVID-19 severity, but since current tuberculosis itself causes death, it is difficult to disentangle the effects of COVID-19 vs. tuberculosis disease on mortality per se.

Strengths of our analysis include its large size using population-level data, laboratory confirmed SARS-CoV-2 diagnoses in all COVID-19 patients, and inclusion of both hospitalized and non-hospitalized cases and deaths. Key limitations are: under-ascertainment of comorbidities in routine administrative data; lack of data on other potential risk factors for poor COVID-19 outcomes, such as socio-economic status and BMI; relatively long gaps since the most recent viral load in many patients on ART; and limited data on CD4 counts prior to COVID-19 diagnosis due to these not being indicated in virologically suppressed patients, so that we could not assess associations with immune function before SARS-CoV-2 infection. While the analysis restricted to confirmed cases may under-estimate the association between co-morbidities (including HIV) and mortality due to selection bias towards patients with more advanced disease, the population-level analysis may over-estimate the effects of HIV and tuberculosis on COVID-19 death due to residual confounding by socio-economic status, especially if transmission has preferentially been in densely populated poorer areas with higher HIV prevalence.

To our knowledge, this is the largest assessment of SARS-CoV-2 and HIV co-infected patients. While our findings may over-estimate the effect of HIV on COVID-19 death due to the presence of residual confounding, people living with HIV should be considered a high-risk group for COVID-19 management with modestly elevated risk of poor outcomes, irrespective of viral suppression, and especially if they have other comorbidities.

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