BMJ Public Health

Leveraging remnant viral load samples for SARS-CoV-2 antibody seroprevalence trends among PLHIV in Kenya, February 2021–October 2022: a cross-sectional surveillance survey

Helen Chun ,[1] Anthony Waruru,[2] Rose Wafula,[3] Ernest Makokha,[2] Erastus Cheti,[4] Valarie Sarah Opollo ,[5] Rachael Joseph ,[2] Emilio Dirlikov ,[6] Marc Bulterys,[2] Hetal Patel ,[1] Muthoni Junghae,[2] John Kiiru,[5] Dominic Kariuki,[5] Rebecca Achieng ,[5] Martha Wezuma,[5] Ann Maina,[4] Elvis Kirui,[4] Noel Odhiambo,[4] Jane Y Carter ,[4] Mary Schmitz,[2] Rashid Aman ,[3] Nancy Bowen,[3] Leonard Kingwara,[3] Mamo Umuro,[3] Denis Wanyama,[4] Kenneth Ouma Ndiege,[4] Appolonia Aoko ,[2] Ray Shiraishi [1]

To cite: Chun H, Waruru A, Wafula R, *et al*. Leveraging remnant viral load samples for SARS-CoV-2 antibody seroprevalence trends among PLHIV in Kenya, February 2021–October 2022: a cross-sectional surveillance survey. *BMJ Public Health* 2026;**4**:e004713. doi:10.1136/bmjph-2025-004713

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjph-2025-004713).

HC and AW contributed equally.

Received 9 December 2025
Accepted 1 May 2026

For numbered affiliations see end of article.

Correspondence to
Dr Helen Chun; vgi2@cdc.gov

ABSTRACT

Introduction People living with HIV (PLHIV) are at increased risk of COVID-19-related mortality. However, the burden of and immune response to SARS-CoV-2 infection among PLHIV, particularly in sub-Saharan Africa, remains poorly understood.

Methods We conducted a four-round serial cross-sectional surveillance survey using HIV viral load testing remnant samples from PLHIV on antiretroviral treatment (ART) in Kenya to assess trends in SARS-CoV-2 antibody seroprevalence from February 2021 to October 2022. SARS-CoV-2 IgG antibodies were detected using a validated two-assay ELISA serial algorithm. Samples with ELISA-positive or borderline result samples were further tested using a multiplex bead assay (MBA) to distinguish potential infection and/or vaccination status.

Results National SARS-CoV-2 antibody seroprevalence among PLHIV on ART increased from 16.1% in round 1 to 91.7% in round 4: round 1: 16.1% (95% CI 6.9% to 33.1%), round 2: 29.6% (95% CI 13.7% to 52.7%), round 3: 84.2% (95% CI 67.7% to 93.1%) and round 4: 91.7% (95% CI 86.5% to 95.0%). These estimates corresponded to approximately 186 891 (95% CI 38 639 to 3 35 143), 363 590 (95% CI 114 267 to 612 913), 1 072 496 (95% CI 914 449 to 1 230 452) and 1 173 399 (95% CI 1 120 224 to 1 226 574) PLHIV on ART with SARS-CoV-2 antibodies across the four rounds. MBA testing of ELISA-positive and borderline samples showed that 97% had evidence of probable infection and/or vaccination while 3% tested negative by MBA.

Conclusions Monitoring SARS-CoV-2 infection in PLHIV is essential. Seroprevalence among PLHIV on ART in Kenya increased substantially during 2021–2022, reflecting both infection and vaccination. Protecting the health of PLHIV through sustained prevention, treatment and vaccination strategies remains critical in mitigating the threat of COVID-19.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Seroepidemiological surveys have been widely used to estimate SARS-CoV-2 burden and track epidemic dynamics. Among people living with HIV (PLHIV), published seroprevalence data from sub-Saharan Africa remain limited, and few studies have assessed trends using routinely collected remnant clinical samples.

WHAT THIS STUDY ADDS

⇒ This is one of the largest studies assessing SARS-CoV-2 antibody seroprevalence among PLHIV in Sub-Saharan Africa. Using viral load testing remnant samples, we assessed seroprevalence trends by age, sex, antiretroviral therapy (ART) regimen, ART duration, year of ART initiation, and HIV viral load test result. From February 2021 to October 2022, SARS-CoV-2 antibody seroprevalence among PLHIV increased from 16.1% to 91.7%. By extrapolating seroprevalence to estimated number of PLHIV on ART, we estimated approximately 1 173 399 (95% CI 1 120 224 to 1 226 574) PLHIV on ART had SARS-CoV-2 antibodies by the end of the study period, reflecting potential SARS-CoV-2 infection, vaccination or both.

INTRODUCTION

Between March 2020 and November 2022, Kenya experienced seven waves of COVID-19, caused by SARS-CoV-2. During 13 March 2020–1 November 2022, there were 339 147 laboratory-confirmed cases (6331 confirmed cases per million) and 5678 reported (105.1 deaths per million).[1] The highest monthly number of reported COVID-19 cases occurred

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These findings support the value of leveraging remnant clinical samples for ongoing surveillance of emerging and epidemic-prone diseases. This efficient approach can complement routine case surveillance, monitor population-level exposure over time, and inform targeted public health action. Future work to refine serologic tools for surveillance, distinguish infection and vaccine-derived responses, and clarify the correlates and durability of protection in PLHIV is needed.

in December 2021, with a test positivity rate exceeding 35%.

COVID-19 vaccination was introduced in March 2021 and became widely available by March 2022.[2] By 30 October 2022, 14 million (25.9% of the population) had received at least one vaccine dose, 9 861 223 (19.6%) had received two or more doses, and 1 592 647 had received a booster. Overall vaccination uptake reached 36.2% by the end of October 2022.[3]

In 2021, among Kenya's total population of 55 million,[4] an estimated 1.4 (1.2–1.6) million people living with HIV (PLHIV), of whom 1.28 million (93% (83% to >98%)) were receiving antiretroviral therapy (ART).[5] Although PLHIV are not necessarily more likely to acquire SARS-CoV-2 infection, clinical and social determinants may contribute to worse COVID-19 outcomes.[6 7]

Population-based seroepidemiological surveys can estimate the proportion of a population exposed with evidence of SARS-CoV-2 antibodies and the proportion potentially still susceptible. However, systematically collected data to estimate the burden of SARS-CoV-2 infection among PLHIV, particularly in sub-Saharan Africa, remain limited.[8–11] To address this gap, we assessed trends in SARS-CoV-2 antibody seroprevalence among PLHIV on ART in Kenya from February 2021 to October 2022.

METHODS

Study design

We conducted four nationally representative cross-sectional SARS-CoV-2 serologic surveys using a multistage cluster survey design. Surveys used remnant samples collected for routine HIV viral load (VL) testing among PLHIV on ART in Kenya between 12 February 2021 and 21 October 2022. Per national guidelines, PLHIV on ART are routinely monitored via VL testing, primarily using plasma sample type, with samples sent from health facilities to one of ten VL testing laboratories in the country. In the first stage, five of Kenya's 47 counties were selected using probability proportional to size (PPS) sampling with replacement. The size was determined based on PLHIV on PEPFAR-supported ART during the quarter ending 31 March 2020. In the second stage, approximately 500 remnant VL samples were selected using systematic sampling from within the laboratories of each of the five selected counties. The sampling interval was calculated as the number of available VL samples divided by 500 and the frame for the VL samples consisted of remnant samples collected for routine HIV VL testing during the month of the survey round (round 1: 22 February–19 March 2021; round 2: 31 May–29 June 2021; round 3: 31 May–26 June 2022; round 4: 26 September–24 October 2022). When fewer than 500 remnant VL samples were available at the time of sampling, a take-all approach was used.

Sampling deviated from our initial approach only in survey round 2 because of logistical challenges in retrieving samples. During round 2, for Nairobi County, one laboratory was selected with certainty (selection probability=1.0) in stage 2 due to its small size, and two of five additional laboratories were selected using PPS with replacement, where size was based on the number of monthly samples. All the laboratories serving the four remaining counties were selected with certainty. In stage three, approximately 500 remnant VL samples were then selected using systematic sampling from within each of the five selected counties.

Sampling weights were calculated as the inverse of the product of the stage one and two selection probabilities, and for survey round 2, the inverse of the product of the stage one, two, and three selection probabilities. Sampling weights were then adjusted for non-response, where non-response included stored samples that could not be located or retested for SARS-CoV-2, as well as undercoverage. Undercoverage occurred when the number of available remnant samples was less than the number of samples tested during the month. Poststratification was conducted by age (ie, <1, 1–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, ≥50 years) and sex, aligning with fiscal year 2023 (October 2022-September 2023) PEPFAR monitoring, evaluation, and reporting data for PLHIV on ART during the fiscal-year quarter of each survey round,[12] so that the weighted sample reflected the age-sex distribution of PLHIV on ART at the time of sampling.

SARS-CoV-2 laboratory testing

Remnant plasma samples were tested at the Kenya Medical Research Institute, Centre for Global Health Research, HIV Research Laboratory, Kisumu. SARS-CoV-2 IgG antibodies were detected using a validated two-assay ELISA serial algorithm (online supplemental figure 1a). Initial screening used the *InBios* SCoV-2 Detect IgG ELISA (InBios International, Seattle, Washington, USA), a qualitative indirect ELISA for the detection of IgG antibodies that targets epitopes derived from SARS-CoV-2, with manufacturer-reported sensitivity of 97.8% and specificity of 98.9%.[13] Positive samples were tested in duplicate using the confirmatory test, EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) (EuroImmun US, New Jersey, USA), which uses an antigen against the S1 domain of the spike protein of SARS-CoV-2, and

Table 1 Baseline characteristics of PLHIV on ART in Kenya by sample round tested for SARS-CoV-2 antibodies

	Round 1		Round 2		Round 3		Round 4	
	Total		Total		Total		Total	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Age								
<15	129	5.4	160	5.3	202	4.7	122	4.5
15–24	120	7.8	154	7.7	223	7.6	209	7.5
25–44	712	50.3	948	49.6	648	48.2	958	47.9
45+	455	36.5	810	37.4	326	39.6	817	40.1
Total	1416	100.0	2072	100.0	1399	100.0	2106	100.0
Sex								
Female	964	67.0	1382	67.2	934	66.9	1416	66.9
Male	452	33.0	690	32.8	465	33.1	690	33.1
Total	1416	100.0	2072	100.0	1399	100.0	2106	100.0
Current ART regimen								
DTG-based	1112	81.3 (72.0 to 88.1)	1665	88.3 (79.3 to 93.7)	1153	85.6 (78.1 to 90.8)	1847	88.8 (79.8 to 94.1)
NNRTI-based	115	7.7 (5.3 to 11.1)	63	2.7 (0.8 to 8.1)	42	4.3 (2.1 to 8.5)	44	2.0 (0.2 to 15.2)
PI-based	151	9.5 (4.5 to 19.1)	153	7.1 (3.6 to 13.3)	155	7.6 (4.9 to 11.5)	154	6.9 (5.3 to 8.9)
Other	29	1.5 (0.6 to 3.5)	57	2.0 (0.3 to 11.6)	39	2.5 (1.4 to 4.6)	58	2.4 (0.6 to 9.4)
Total	1407	100.0	1938	100.0	1389	100.0	2103	100.0
Most recent VL								
<200	1052	84.3 (78.7 to 88.7)	1719	93.4 (88.4 to 96.4)	1199	88.4 (85.0 to 91.2)	1865	89.9 (85.6 to 93.1)
≥200	207	15.7 (11.3 to 21.3)	122	6.6 (3.6 to 11.6)	196	11.6 (8.8 to 15.0)	213	10.1 (6.9 to 14.4)
Total	1259	100.0	1841	100.0	1395	100.0	2078	100.0
Vaccine validity								
Not documented	371	36.0 (9.3 to 75.4)	560	33.4 (18.3 to 53.0)	559	44.7 (28.5 to 62.1)	693	35.5 (27.3 to 44.7)
Not vaccinated	705	63.9 (24.4 to 90.6)	1132	61.2 (37.7 to 80.4)	160	13.7 (5.4 to 30.5)	64	3.6 (0.6 to 19.7)
Vaccinated	2	0.2 (0.0 to 4.4)	103	5.4 (2.1 to 13.2)	357	41.6 (33.6 to 50.1)	1057	60.9 (49.0 to 71.7)
Total	1078	100.0	1795	100.0	1076	100.0	1814	100.0
Time on ART								
<5 years	434	38.9 (36.6 to 41.3)	618	37.7 (34.7 to 40.7)	378	34.6 (28.4 to 41.4)	521	28.5 (22.9 to 34.9)
≥5 years	643	61.1 (58.7 to 63.4)	1174	62.3 (59.3 to 65.3)	694	65.4 (58.6 to 71.6)	1286	71.5 (65.1 to 77.1)
Total	1077	100.0	1792	100.0	1072	100.0	1807	100.0
ART start year								
<2015	557	53.0 (49.2 to 56.8)	986	51.7 (47.4 to 56.1)	484	46.9 (42.4 to 51.4)	906	49.5 (46.6 to 52.4)
2015 to <2017	183	16.5 (11.9 to 22.4)	301	16.8 (14.5 to 19.4)	171	14.4 (11.5 to 17.8)	308	17.5 (13.3 to 22.7)
≥2017	337	30.5 (28.8 to 32.3)	507	31.4 (25.9 to 37.5)	418	38.7 (32.4 to 45.3)	594	33.0 (26.8 to 39.8)
Total	1077	100.0	1794	100.0	1073	100.0	1808	100.0
SARS-CoV-2								
Borderline	47	3.0 (2.4 to 3.8)	85	3.7 (2.8 to 4.8)	25	1.4 (1.0 to 2.1)	18	0.8 (0.4 to 1.6)
Negative	1169	80.9 (65.4 to 90.5)	1339	66.7 (43.5 to 83.9)	284	14.4 (5.8 to 31.6)	165	7.5 (4.0 to 13.5)
Positive	200	16.1 (6.9 to 33.1)	648	29.7 (13.7 to 52.9)	1090	84.2 (67.7 to 93.1)	1923	91.7 (86.5 to 95.0)
Total	1416	100.0	2072	100.0	1399	100.0	2106	100.0

ART, antiretroviral treatment; DTG, dolutegravir; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PLHIV, people living with HIV; VL, viral load.

has reported sensitivity of 94.4% and specificity of 99.6%.[14] Both assays received the US Food and Drug Administration Emergency Use Authorisation and regulatory approval from the Kenya Pharmacy and Poisons Board. All testing was conducted according to the manufacturer's instructions for use (IFU).

Samples testing positive or borderline on EUROIMMUN were further tested using FlexImmArray 7-Plex

SARS-CoV-2 Human IgG Antibody Test (Tetracore, Rockville, Maryland, USA), a multiplex bead assay (MBA) that has magnetic microspheres coupled with recombinant SARS-CoV-2 antigens to detect IgG antibodies to three SARS-CoV-2 antigen targets: the Receptor Binding Domain (RBD-CoV-2), Nucleocapsid Protein (NP-CoV-2) and RBD-Nucleocapsid Protein hybrid (RBD-NP).[15] Fluorescence intensity was measured using Luminex MagPix equipment (Luminex, Austin, Texas, USA), and initial test results were classified using relative fluorescence intensity (RFI) values as per the IFU (online supplemental figure 1b). MBA test results used the RFI and median fluorescence intensity (RFI and MFI, respectively) for three microspheres for RBD-CoV-2, NP-CoV-2 and RBD-NP to determine potential infection and/or vaccination status using the following logic: Samples with RFI values for any of the three microspheres less than 0.9 were classified as negative; all three greater than 1.2 were classified as positive, and any of the three values between 0.9–1.2 were considered equivocal. Samples testing positive (RFI>1.2) were further classified for potential SARS-CoV-2 infection and/or COVID-19 vaccination status (ie, 'vaccination alone', 'probable infection and vaccination' or 'probable infection') based on RFI and MFI values for RBD-CoV-2, NP-CoV-2 and RBD-NP (online supplemental Table 1).

Patient data

Patient data were extracted from the VL laboratory information system (National AIDS/STD Control Programme VL-early infant diagnosis (NASCOP VL-EID)) and electronic patient records in the National Data Warehouse (NDW), a centralised data warehouse of routinely reported data from facility electronic medical record systems. Available COVID-19 vaccination data were also obtained from the NDW and linked to NASCOP VL data through unique patient numbers. MBA test results and vaccination documentation data were merged. Vaccination status was determined for samples with non-equivocal MBA results by comparing the documented COVID-19 vaccination date with the date the sample was received by the VL testing laboratory. Vaccine validity was defined using three categories: not documented, not vaccinated or vaccinated. Not documented was defined as having no record of COVID-19 vaccine receipt in the patient's file. Not vaccinated was defined as having received a COVID-19 vaccine after the date of sample receipt by the VL testing laboratory. Vaccinated was defined as having had at least one COVID-19 vaccine dose prior to the date of VL sample receipt by the VL testing laboratory. Additionally, vaccination status was classified as fully or partially vaccinated by clinicians, based on the number of doses and vaccine type. Quality checks and cleaning were conducted prior to merging serosurvey, clinical, and vaccination data.

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting, or dissemination of this research. The research questions and outcome measures were developed by the study investigators based on programmatic priorities and existing literature available at the time. No direct patient recruitment was undertaken as this study used secondary data analysis and remnant samples.

Statistical analysis

Analyses were conducted using Stata V.17.0 (StataCorp., 2021. Stata Statistical Software: Release 17.0, StataCorp) and accounted for the multistage cluster survey design, including weighting and clustering. We estimated SARS-CoV-2 antibody seroprevalence as the proportion of individuals with detectable anti-SARS-CoV-2 IgG antibodies, with the denominator comprising all samples tested via ELISA. We also estimated SARS-CoV-2 antibody seroprevalence stratified by demographic and clinical characteristics, including age, sex, ART regimen (ie, integrase strand transfer inhibitor, dolutegravir (DTG), non-nucleoside reverse transcriptase inhibitor or protease inhibitor (PI)-containing ART), ART duration, HIV VL result, COVID-19 vaccination status, whether vaccination was received at or prior to the date of the VL sample receipt by the VL laboratory, and round of VL sample collection. Statistical testing for differences in seroprevalence across various demographic and clinical factors was conducted using a Rao-Scott χ^2 test. We used seroprevalence estimates to project the number of PLHIV on ART with SARS-CoV-2 antibodies by applying the estimates to the total number of PLHIV on ART reported at the end of each survey quarter.

Additionally, we analysed the distribution of antibody response by final classification for samples tested using MBA, final MBA classifications by survey round, and the relationship between ELISA ratio values and final MBA classifications across rounds.

RESULTS

Between February 2021 and October 2022, 6993 (87.3%) of 8007 sampled remnant VL samples, representing 80.1% of the expected sample size, were retrieved and tested for SARS-CoV-2 antibodies. Sample sizes by survey round ranged from 1399 to 2106: round 1—1416; round 2—2072; round 3—1399; round 4—2106 (online supplemental figure 2). All 6993 samples were tested using ELISA, with 3861 (55.2%) testing positive, 175 (2.5%) borderline and 2957 (42.3%) negative.

Characteristics of PLHIV among selected remnants were similar across survey rounds, approximately 67% were female, 47.9%–50.3% were aged 25–44 years, 61.1%–71.5% were on ART for more than 5 years, 81.3%–88.8% were on DTG-based regimens, and 84.3%–93.4% were virally suppressed (<200 copies/mL) (table 1). Among those with available vaccination documentation, the proportion with ≥1 COVID-19 vaccine dose before VL sample collection increased across rounds: 0.0% in round 1, 14.6% in round 2, 72.0% in round 3 and 94.2% in round 4. The percentage with full vaccination status

Table 2 Trends in SARS-CoV-2 antibody seroprevalence among PLHIV on ART in Kenya by demographic and clinical characteristics between March 2021 and October 2022

	Round 1		Round 2		Round 3		Round 4	
	n/N	Seroprevalence (%) (95% CI)	n/N	Seroprevalence (%) (95% CI)	n/N	Seroprevalence (%) (95% CI)	n/N	Seroprevalence (%) (95% CI)
Overall	200/1416	16.1 (6.9 to 33.1)	648/2072	29.7 (13.7 to 52.9)	1090/1399	84.2 (67.7 to 93.1)	1923/2106	91.7 (86.5 to 95.0)
Age								
<15	9/129	8.2 (4.7 to 13.8)	23/160	11.4 (3.5 to 31.6)	139/202	66.1 (38.9 to 85.7)	100/122	83.8 (69.1 to 92.3)
15–24	15/120	14.2 (5.1 to 33.7)	45/154	28.8 (9.5 to 60.9)	170/223	83.7 (52.9 to 95.9)	192/209	90.5 (83.5 to 94.7)
25–44	101/712	16.3 (6.4 to 35.5)	300/948	28.9 (10.6 to 58.2)	504/648	83.0 (60.4 to 94.0)	871/958	91.3 (86.2 to 94.7)
45+	75/455	17.4 (8.0 to 34.0)	280/810	33.5 (21.0 to 48.8)	277/326	87.8 (77.2 to 93.9)	760/817	93.2 (86.0 to 96.9)
Sex								
Female	141/964	16.1 (7.5 to 31.4)	456/1382	31.5 (14.0 to 56.6)	731/934	84.9 (68.3 to 93.6)	1312/1416	93.1 (90.3 to 95.1)
Male	59/452	16.1 (5.7 to 37.8)	192/690	25.9 (12.5 to 46.1)	359/465	82.8 (65.1 to 92.6)	611/690	88.8 (76.9 to 95.0)
DTG-based	171/1112	17.2 (7.8 to 33.7)	512/1665	29.1 (13.6 to 51.6)	904/1153	84.4 (66.8 to 93.5)	1690/1847	91.9 (87.3 to 94.9)
NNRTI-based	14/115	16.1 (5.4 to 38.9)	22/63	33.1 (5.9 to 79.6)	33/42	86.3 (66.4 to 95.3)	44/44	100.0
PI-based	11/151	7.9 (2.7 to 20.9)	45/153	31.0 (15.4 to 52.6)	120/155	83.5 (76.5 to 88.8)	136/154	88.6 (80.2 to 93.7)
Other	4/29	14.5 (5.9 to 31.5)	21/57	47.2 (27.1 to 68.2)	27/39	79.2 (42.4 to 95.2)	51/58	87.9 (51.1 to 98.1)
Most recent VL								
<200	146/1052	15.1 (8.0 to 26.6)	516/1719	27.9 (15.1 to 45.6)	956/1199	85.4 (67.5 to 94.3)	1720/1865	92.5 (87.8 to 95.5)
≥200	22/207	12.4 (6.8 to 21.5)	22/122	17.2 (11.7 to 24.5)	130/196	74.6 (58.6 to 85.9)	178/213	84.9 (76.1 to 90.9)
Vaccine validity								
Not documented	57/371	19.1 (7.7 to 39.8)	167/560	29.7 (13.5 to 53.2)	421/559	81.9 (59.5 to 93.3)	620/693	90.1 (79.2 to 95.6)
Not vaccinated	98/705	14.8 (10.8 to 19.9)	341/1132	27.8 (13.3 to 49.2)	115/160	76.3 (66.6 to 83.8)	60/64	94.8 (36.6 to 99.8)
Vaccinated	0/2	0.0	62/103	56.3 (48.8 to 63.5)	299/357	87.7 (69.7 to 95.7)	988/1057	93.2 (89.5 to 95.7)
Time on ART								
<5 years	62/434	15.8 (8.3 to 28.0)	163/618	24.6 (11.8 to 44.3)	278/378	77.0 (61.2 to 87.7)	458/521	88.4 (74.6 to 95.2)
≥5 years	92/643	16.4 (8.9 to 28.3)	406/1174	33.1 (15.9 to 56.5)	553/694	86.9 (68.4 to 95.3)	1203/1286	93.6 (90.8 to 95.6)
ART start year								
<2015	78/557	16.1 (8.1 to 29.6)	336/986	32.9 (15.7 to 56.3)	393/484	87.4 (69.4 to 95.5)	846/906	93.4 (91.5 to 95.0)
2015 to <2017	25/183	15.0 (7.0 to 29.3)	103/301	30.7 (13.0 to 56.8)	128/171	85.9 (59.9 to 96.1)	287/308	93.5 (86.8 to 97.0)
≥2017	51/337	16.8 (8.9 to 29.6)	130/507	24.6 (11.7 to 44.4)	311/418	77.9 (61.3 to 88.7)	529/594	89.5 (76.4 to 95.8)

ART, antiretroviral treatment; DTG, dolutegravir; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PLHIV, people living with HIV; VL, viral load.

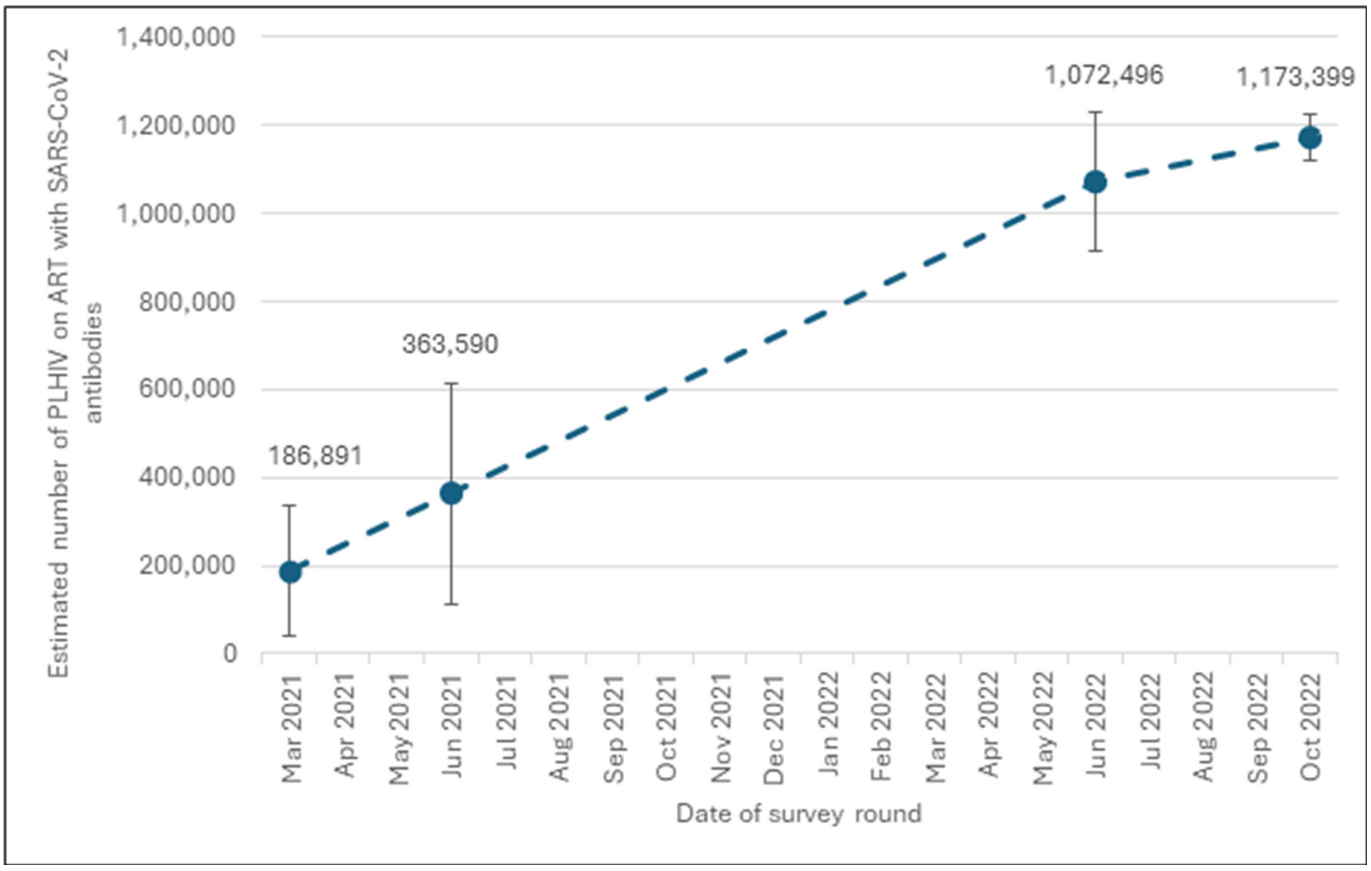

Figure 1 Trends in estimated PLHIV on ART with SARS-CoV-2 antibodies in Kenya, March 2021–October 2022. ART, antiretroviral treatment; PLHIV, people living with HIV.

also increased from 0.0 to 2.0%, 62.8% and 87.7% over rounds 1–4, respectively (online supplemental Table 2).

National SARS-CoV-2 seroprevalence rose markedly over time: round 1: 16.1% (95% CI 6.9% to 33.1%); round 2: 29.7% (95% CI 13.7% to 52.9%); round 3: 84.2% (95% CI 67.7% to 93.1%) and round 4: 91.7% (95% CI 86.5% to 95.0%) (table 2). These seroprevalence estimates translated to an estimated 186 891 (95% CI 38 639 to 335 143) PLHIV on ART with SARS-CoV-2 antibodies in round 1, 363 590 (95% CI 114 267 to 612 913) PLHIV on ART with SARS-CoV-2 antibodies in round 2, 1 072 496 (95% CI 9 14 449 to 1 230 452) PLHIV on ART with SARS-CoV-2 antibodies in round 3, and 1 173 399 (95% CI 1 120 224 to 1 226 574) PLHIV on ART with SARS-CoV-2 antibodies in round 4 (figure 1). Few differences in seroprevalence by age, sex, current ART regimen, most recent VL result, vaccine validity, ART duration and ART initiation year were observed across rounds (table 2).

We conducted an unweighted subanalysis of MBA results among the 4036 samples that were ELISA positive or borderline (online supplemental figure 2). Of these, 236 (5.9%) were classified as equivocal. Among the remaining 3795, 1591 (42%) were classified as probable infection, 1155 (30%) as probable infection and vaccination, 929 (24%) as probable vaccination and 120 (3%) as negative. Vaccination data were available for 2044 (53.9%) of MBA-tested samples. Among 1917 (93.8%) samples with definitive MBA results (ie, negative or positive) and vaccination documentation, 1312 (68.4%) were reported to have received ≥1 COVID-19 vaccine dose before sample collection (vaccinated), and 605 (32%) were not vaccinated (ie, received their first dose of COVID-19 vaccine after the sample collection). Of the 1312 samples with vaccination status determined by a clinician using the number of vaccine doses and vaccine type, 1158 (88.3%) were fully vaccinated and 154 (11.7%) were partially vaccinated.

MBA antibody response patterns by final classification showed higher RBD-CoV-2 responses among individuals classified as probable infection and vaccination than among those classified as probable infection alone or probable vaccination alone, and higher NP-CoV-2 responses among those classified as probable infection (online supplemental figure 3). The distribution of final antibody response classification by MBA showed that the proportion of seronegative declined across rounds, while the proportions of probable vaccination only and probable infection and vaccination increased (online supplemental Table 3). Because the EUROIMMUN assay detects anti-spike IgG, positive results could reflect prior infection, vaccination, or both. MBA classification therefore provided additional context by incorporating response patterns to RBD and nucleocapsid targets; higher EUROIMMUN ratios were generally observed in

specimens classified by MBA as probable infection, probable infection and vaccination, or probable vaccination only, whereas MBA-negative specimens remained low across rounds (online supplemental figure 4). Overall, increasing SARS-CoV-2 antibody seroprevalence was observed alongside increasing vaccination uptake among PLHIV during the study period (online supplemental figure 5).

DISCUSSION

By the end of 2022, most PLHIV in Kenya on ART had SARS-CoV-2 antibodies, indicating substantial cumulative immunologic exposure to infection, vaccination or both. The largest increase in seroprevalence occurred between round 2 and round 3, paralleling Kenya's successive epidemic waves and expansion of vaccine uptake (online supplemental figure 5), suggesting that both infection and vaccination contributed to antibody prevalence. Continued serologic surveillance using remnant VL samples may provide valuable data on undiagnosed and unreported cases and inform vaccination and public health planning. Because seropositivity does not directly measure neutralising capacity, durability of protection, or risk of onward transmission, these findings should be interpreted as evidence of prior exposure rather than protective immunity.

Additional studies are needed to assess the durability and correlates of vaccine-induced and hybrid immunity in PLHIV, including how antibody responses vary by immunologic status.[16–18] We observed a strong association between SARS-CoV-2 seroprevalence and vaccination coverage, suggesting that antibodies detected were partly vaccine-induced. Maintaining ART continuity, virologic suppression, management of comorbidities and access to COVID-19 vaccination and treatment remain important for reducing the risk of severe outcomes in PLHIV.[19–22]

Serosurveys are critical to understanding the spread of COVID-19 and guiding public health policy and disease control strategies. This study leveraged Kenya's routine VL monitoring infrastructure and remnant VL samples, enabling cost-effective, longitudinal surveillance, while the high VL coverage among PLHIV strengthened the reliability of the data. The 20-month statistical sampling design allowed for analysis of seroprevalence trends across the different waves of the pandemic and periods of vaccine rollout. Vaccination data, from utilisation of available electronic medical record data, also demonstrated the feasibility of this approach for future passive disease surveillance.

This study had several limitations. It focused on PLHIV on ART who had VL testing from selected counties, limiting generalisability. In rounds three and four, three laboratories were excluded due to logistical issues, and one small county's samples were inconsistently tested. ELISA was not always able to distinguish between vaccine-induced and infection-induced antibodies, particularly as vaccine availability was limited during earlier rounds, with antibodies likely reflecting infection. Factors such as waning antibodies, timing of infection, variant-specific differences in assay performance or cross-reactivity may have underestimated seroprevalence. COVID-19 vaccination data, which were based on self-report and provider documentation, may have been subject to recall bias. While MBA testing improved differentiation between infection and vaccination, 6% of results were equivocal but not retested due to resource constraints. Further analyses were limited due to incomplete linkage with the NDW, which, however, lacks COVID-19 symptom, hospitalisation and mortality data. Pandemic disruptions in the supply chain also affected the study timeline and data completeness.

Despite these limitations and the evolving understanding of immune response to SARS-CoV-2, this study provides important national data on SARS-CoV-2 antibody seroprevalence among PLHIV on ART in Kenya, a population at heightened risk for severe COVID-19. This study is one of the largest seroprevalence studies in PLHIV in sub-Saharan Africa, which is home to 66% of the global PLHIV population.[23] Our findings are consistent with other serosurveillance data from Kenya and broader standardised seroprevalence syntheses showing substantial increases in SARS-CoV-2 antibody seroprevalence during 2021–2022.[24–26] Leveraging VL testing and electronic medical records systems for ongoing surveillance offers a scalable, efficient model for monitoring public health threats, identifying intervention gaps and informing future epidemic preparedness.

Author affiliations
[1]Centers for Disease Control and Prevention Global Health Center, Atlanta, Georgia, USA
[2]Centers for Disease Control and Prevention Global Health Center, Nairobi, Kenya
[3]Kenya Ministry of Health, Nairobi, Nairobi County, Kenya
[4]Amref Health Africa, Nairobi, Nairobi County, Kenya
[5]Kenya Medical Research Institute, Kisumu, Nyanza, Kenya
[6]Centers for Disease Control and Prevention Global Health Center, Maputo, Mozambique

Acknowledgements We thank the Kenyan Ministry of Health, the National AIDS and STIs Control Programme, viral load laboratories, implementing partners and patients. This work was supported by the American Rescue Plan Act of 2021 (ARPA) and the President's Emergency Plan for AIDS Relief (PEPFAR) through the US Centers for Disease Control and Prevention (CDC) under cooperative agreement #GH00285.

Contributors HC conceptualised the study. HC, RS, MS, HP and ED developed the methodology. DK, RA and MW performed the testing. AM collected the data. RS and AM curated the data. RS and HC conducted the formal analysis. RS, HC, AW and AM accessed and verified the data. HC, RS, AW, EM and ED drafted the original manuscript. All authors critically reviewed, revised and approved the final manuscript. HC and AW as first co-authors are the guarantors. CDC AI tools was used to edit for clarity and concision.

Funding This project has been supported by the American Rescue Plan Act of 2021 (ARPA) and the President's Emergency Plan for AIDS Relief (PEPFAR) through the US Centers for Disease Control and Prevention (CDC) under cooperative agreement #GH00285.

Disclaimer The study funder had no role in the study design, data collection, analysis, interpretation, or writing. The first and senior authors had full access to all the data. The first three authors and the senior authors had final responsibility for the decision to submit for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This activity was reviewed by Amref Health Africa, Ethical and Scientific Review Committee and the CDC in accordance with human protection procedures and was determined to be non-research.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Other than SARS-CoV-2 antibody testing, no new primary data were collected for this study. Data from this study are owned by the Kenyan Ministry of Health, and requests for additional use may be directed to the National Coordinator, National AIDs and STIs Control Programme (NASCOP) (Head@nascop.or.ke).

ORCID iDs
Helen Chun https://orcid.org/0000-0002-1050-7361
Valarie Sarah Opollo https://orcid.org/0000-0002-5931-1685
Rachael Joseph https://orcid.org/0000-0003-4644-1568
Emilio Dirlikov https://orcid.org/0000-0003-4631-2643
Hetal Patel https://orcid.org/0000-0002-5468-2591
Rebecca Achieng https://orcid.org/0009-0004-1406-5275
Jane Y Carter https://orcid.org/0000-0003-4671-3519
Rashid Aman https://orcid.org/0000-0002-7296-5608
Appolonia Aoko https://orcid.org/0000-0001-6597-607X
Ray Shiraishi https://orcid.org/0000-0001-7640-0666

REFERENCES

1 Mathieu E, Ritchie H, Rodés-Guirao L, *et al*. COVID-19 pandemic. 2020. Available: https://ourworldindata.org/coronavirus
2 Our World in Data. COVID-19 vaccination policy. 2022. Available: https://ourworldindata.org/grapher/covid-vaccination-policy?time=2022-03-10&ion=Africa&country=~VUT
3 Ministry of Health Kenya. COVID-19 outbreak in Kenya: daily situation report - 958. 2022.
4 World Population View. Kenya population. 2022. Available: https://worldpopulationreview.com/countries/kenya-population
5 United Nations Joint Programme on HIV/AIDS (UNAIDS). AIDSinfo. UNAIDS data 2022. 2022. Available: https://www.unaids.org/en/resources/documents/2023/2022_unaids_data
6 Del Amo J, Polo R, Moreno S, *et al*. SARS-CoV-2 infection and coronavirus disease 2019 severity in persons with HIV on antiretroviral treatment. *AIDS* 2022;36:161–8.
7 Park LS, McGinnis KA, Gordon KS, *et al*. SARS-CoV-2 Testing and Positivity Among Persons With and Without HIV in 6 US Cohorts. *J Acquir Immune Defic Syndr* 2022;90:249–55.
8 Dutschke A, Wejse C, Nanque JP, *et al*. SARS-CoV-2 seroprevalence among people living with HIV in Guinea-Bissau. *Public Health (Fairfax)* 2022;209:36–8.
9 Kwedi Nolna S, Niba M, Djadda C, *et al*. Seroprevalence of anti-SARS-CoV-2 IgG antibodies in HIV-positive and HIV-negative patients in clinical settings in Douala, Cameroon. *Front Epidemiol* 2023;3:1212220.
10 Moyo S, Simbayi LC, Zuma K, *et al*. Seroprevalence Survey of Anti-SARS-CoV-2 Antibody and Associated Factors in South Africa: Findings of the 2020–2021 Population-Based Household Survey. *PLOS Glob Public Heal* 2023;3:e0002358.
11 Spinelli MA, Lynch KL, Yun C, *et al*. SARS-CoV-2 seroprevalence, and IgG concentration and pseudovirus neutralising antibody titres after infection, compared by HIV status: a matched case-control observational study. *Lancet HIV* 2021;8:e334–41.
12 US. President's Emergency Plan for AIDS Relief. Monitoring, evaluation, and reporting indicator reference guide. MER 2.0 (version 2.5). 2020. Available: https://help.datim.org/hc/article_attachments/360071630231
13 InBios International Inc. InBios scov-2 detecttm igG ELISA: instructions for use. 2021. Available: https://inbios.com/wp-content/uploads/2021/05/LBL-0113-03-EUA-CE-SCoV-2-Detect-IgG-ELISA-product-insert-English.pdf
14 Medizinische Labordiagnostika AG. Anti-SARS-CoV-2 ELISA (IgG): Instruction for use. 2019;18.
15 Tetracore Inc. Tetracore: instructions for use. 2020.1–12.
16 Chun HM, Milligan K, Agyemang E, *et al*. A Systematic Review of COVID-19 Vaccine Antibody Responses in People With HIV. *Open Forum Infect Dis* 2022;9.
17 Brown LB, Spinelli MA, Gandhi M. The interplay between HIV and COVID-19: summary of the data and responses to date. *Curr Opin HIV AIDS* 2021;16:63–73.
18 Wang Y, Xie Y, Hu S, *et al*. Systematic Review and Meta-Analyses of The Interaction Between HIV Infection And COVID-19: Two Years' Evidence Summary. *Front Immunol* 2022;13:1–8.
19 Bertagnolio S, Thwin SS, Silva R, *et al*. Clinical features of, and risk factors for, severe or fatal COVID-19 among people living with HIV admitted to hospital: analysis of data from the WHO Global Clinical Platform of COVID-19. *Lancet HIV* 2022;9:e486–95.
20 Nomah DK, Reyes-Urueña J, Díaz Y, *et al*. Sociodemographic, clinical, and immunological factors associated with SARS-CoV-2 diagnosis and severe COVID-19 outcomes in people living with HIV: a retrospective cohort study. *Lancet HIV* 2021;8:e701–10.
21 Shapiro AE, Bender Ignacio RA, Whitney BM, *et al*. Factors Associated With Severity of COVID-19 Disease in a Multicenter Cohort of People With HIV in the United States, March-December 2020. *J Acquir Immune Defic Syndr* 2022;90:369–76.
22 Mirzaei H, McFarland W, Karamouzian M, *et al*. COVID-19 Among People Living with HIV: A Systematic Review. *AIDS Behav* 2021;25:85–92.
23 World Health Organization. Epidemiological fact sheet: HIV statistics, globally and by WHO region, 2023. *Who* 2023;1–8.
24 Uyoga S, Adetifa IMO, Otiende M, *et al*. Prevalence of SARS-CoV-2 Antibodies From a National Serosurveillance of Kenyan Blood Donors, January-March 2021. *JAMA* 2021;326:1436–8.
25 Kagucia EW, Ziraba AK, Nyagwange J, *et al*. SARS-CoV-2 seroprevalence and implications for population immunity: Evidence from two Health and Demographic Surveillance System sites in Kenya, February-December 2022. *Influenza Other Respir Viruses* 2023;17:e13173.
26 Bergeri I, Whelan MG, Ware H, *et al*. Global SARS-CoV-2 seroprevalence from January 2020 to April 2022: A systematic review and meta-analysis of standardized population-based studies. *PLoS Med* 2022;19:e1004107.