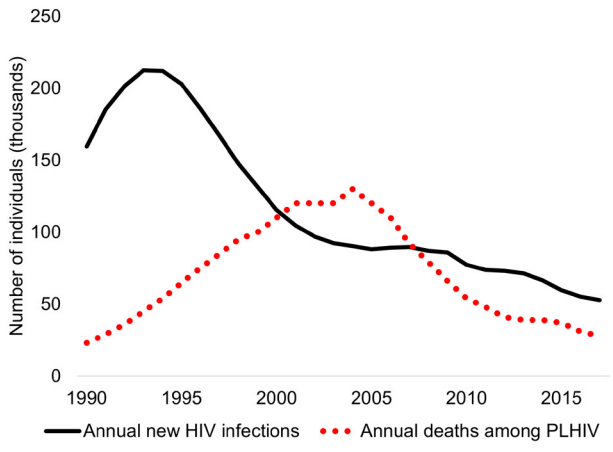
MINISTRY OF HEALTH

Mortuary and Hospital-Based Surveillance of HIV-Associated Mortality in Kisumu County



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NASCOP

COUNTY GOVERNMENT OF KISUMU
HARBOUR OF PROSPERITY

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Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies.

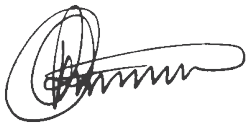
Foreword

High-quality data about the number of deaths and its causes helps inform policy, resource allocation, and evidence-based programming. However, Kenya and other African countries do not have such vital statistics at the national and sub-national levels. From 2010 to 2016, a multi-country study showed that African averaged at 8.3 percent for mortality data accuracy and completeness, compared to a global average of 46.9 percent for the same period.

This mortuary surveillance study in Kisumu County is a key step to identifying Kenya's gaps in meeting 2016, United Nations member states commitment of reducing HIV-associated deaths by 75% between 2010 to 2020. By the end of 2019, Kenya was yet to achieve this target. Approximately 770,000 people died from AIDS-related illnesses worldwide in 2018, a drastic reduction from 1.7 million in 2004, the peak year for HIV-associated mortality. In 2017, Kenya reported 28,214 AIDS-related deaths, of which 23,902 were adults aged 15+ years and 4,312 children aged 0-14 years. Given the burden of HIV disease in the country, approximately 1.3 million adults living with HIV, it is essential for HIV programs to understand overall mortality among HIV positive individuals and in particular, HIV-associated mortality.

In 2015, NASCOP conducted a mortuary surveillance study among adolescent and adult (15 years and above) decedents in Nairobi City and Kenyatta National Hospital (KNH) mortuaries. The study found an overall HIV positivity of 19.5%. It was evident through this study that HIV remained a significant contributor to mortality, with 16% of all deaths in Nairobi county attributable to HIV and 65.7% of deaths among HIV-infected decedents directly attributed to HIV. The 2019 Kisumu mortuary surveillance study expanded the collection of much-needed data to describe the dynamics of mortality in a high HIV burden setting, and to identify innovative methods of measuring mortality as the country continues to improve its' civil and vital statistics registration systems.

We hope that this report will provide much-needed data to guide HIV program implementation and practice. Further, with these data, we will inform guidance for innovative solutions for HIV mortality surveillance and improvements in the country's vital statistics registration processes and systems.



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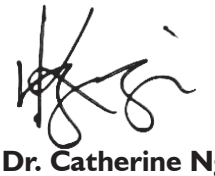
Acknowledgments

Reliable and timely information on HIV cause-specific mortality is fundamental for informing the national HIV program development, implementation, and evaluation of health policy agenda. Kenya has yet to establish a complete vital registration system for its 47 million population. To date, the program relies on mathematical modeling estimates supported by NACC for decision-making. It is on this background that the NASCOP, CDC, UCSF and Kisumu County developed and implemented a Mortuary Surveillance Study to provide empirical estimates of mortality indicators for monitoring the impact of HIV on mortality rates and inform on HIV intervention services in Kisumu county. The report follows a similar one for Nairobi county in 2016.

We have compiled this report on Mortuary, and Hospital-Based Surveillance of HIV-Associated Mortality in Kisumu County through the collaborative effort of several institutions. We wish to acknowledge the commitment and support of the various institutions, partners and stakeholders: Kisumu county government through the Kisumu county health management team, Jaramogi Oginga Odinga Teaching, and Referral Hospital (JOOTRH) and Kisumu County Referral Hospital (KCRH) for their technical support and input during the data collection, sample analysis and report writing. At the national level, we would like to recognize the National AIDS and STI Control Programme (NASCOP), the University of California, San Francisco (UCSF), and the U.S Centers for Disease Control and Prevention (CDC)-Kenya for their technical input, guidance, coordination and report writing. Further, we would want to recognize Kenya Medical Research Institute's (KEMRI) HIV Research Laboratory for conducting serological and molecular testing and the US President's Emergency Plan for AIDS Relief (PEPFAR) through U.S CDC-Kenya for financial support.

Other institutes collaborating in the implementation of this study included the Kisumu East Civil Registry Department, which provided access and support for the civil registry data abstraction and interpretation of civil registry data analysis outputs; and the Kisumu county KEMRI/CDC Community Advisory Board. Finally, we thank the mortuary staff, nurses, individual health records information to staff, and study personnel who devoted their time to support study implementation.

Special recognition to for Dr. Lilly Nyaga (MoH), Leonard Kingwara (NASCOP), Wanjiru Waruiru (UCSF), and Dr. Antony Waruru (CDC) for the coordination of the document development.



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Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ANACoD	Analysing mortality levels and causes of death
ART	Antiretroviral therapy
ARV	Antiretrovirals
CAB	Community Advisory Board
CCC	Comprehensive Care Center
CDC	U.S Centers for Disease Control and Prevention
CI	Confidence interval
COD	Cause of death
CRC	Clinical Research Center
DBS	Dried blood spot
DGHT	Division of Global HIV and Tuberculosis
EDTA	Ethyldeacetamine acid
ELISAs	Enzyme-linked immunosorbent assays
ERC	Ethics Review Committee
GCLP	Good Clinical Laboratory Practice
HDSS	Health and Demographic Surveillance System
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HTC	HIV Testing and Counselling
HTS	HIV Testing Services
ICD-10	International Statistical Classification of Diseases and Related Health Problems 10th Revision
IMR	Infant Mortality Rate
JOOTRH	Jaramogi Oginga Odinga Teaching and Referral Hospital
KCRH	Kisumu County Referral Hospital
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
MOH	Ministry of Health
NASCOP	National AIDS and STI Control Program
NPV	Negative Predictive Value
ORT	Oral Rapid Testing

PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PI	Principal Investigator
PPE	Personal Protective Equipment
PPV	Positive Predictive Value
QC	Quality Control
RNA	Ribonucleic acid
RVD	Retroviral Disease
SOP	Standard Operating Procedures
TB	Tuberculosis
UCSF	University of California San Francisco
VA	Verbal Autopsy
VL	Viral Load

Definition of Terms

HIV-associated deaths: HIV-associated deaths were defined as, decedents whose HIV serological test result were positive or the decedents' HIV infections were documented in medical records.

Death due to HIV/AIDS: A death is considered to be due to HIV if the underlying cause of death is attributed to HIV as defined by International Classification of Diseases, version 10 (ICD-10) rules (ICD-10 codes B20-B24) and the decedent's HIV serological test result was positive or the decedents' HIV infection was documented in medical records.

All-cause mortality rate (crude mortality rate): Number of deaths (expressed per 100,000 population) due to all causes of death in the population. The numerator is the number of deaths attributed to all causes. The denominator is the mid-year (midpoint) size of the population of Kisumu (i.e., on 30 June 2016).

Cause-specific mortality rate: Number of deaths (expressed per 100,000 population) due to a specified cause in the population. The numerator is the annual number of deaths attributed to a specific cause. The denominator is the mid-year size of the population of Kisumu.

Infant mortality rate (IMR): The number of deaths of children under one year of age at time of death per 1,000 live births. The numerator is the annualized number of deaths of children aged <1 year derived from the observed cases. The denominator is the estimated total number of live births for the specific year in Kisumu.

Viral suppression. Viral suppression is defined as a viral load less than 1,000 copies/ml. Viral suppression does not necessarily imply the person was taking antiretrovirals; rather, it indicated that their viral load was below the threshold of 1 000 copies/ml.

Executive Summary

Whereas Kenya has a national civil registration system which captures births and deaths, there are still gaps in incomplete death registration and inaccurate ascertainment of the causes of death, including HIV-associated deaths. This study is part of the Ministry of Health's (MOH) vision of having a comprehensive surveillance system for deaths associated with HIV. The purpose of this study was to better understand HIV-associated mortality in Kisumu county through mortuary and hospital-based surveillance. The surveillance activity sought to determine HIV infection among decedents, determine viral load (VL) count among those that were HIV-infected at two of the largest mortuaries in Kisumu County, JOOTRH and KCRH. In the study, system-level issues, such as documentation of HIV status among the dead in hospital medical files, quality of certification for the cause of deaths and the efficiency of death notification in the County were assessed. The cause of death was abstracted, reviewed, tabulated and analysed from the two mortuaries, during the study period and for the Kisumu East Department of Civil Registration during calendar year 2017. Between April and July 2019, an evaluation of the feasibility of using oral fluids-based HIV testing kits with the decedents was conducted.

KEY FINDINGS:

Study Enrolment

- The total number of decedents admitted into the two mortuaries during the study period was 1,004; 697 (69.4%) from JOOTRH and 307 (30.6%) from KCRH. Of these, 851 were eligible for the study with males comprising 439 (51.6%) of the decedents.
- The majority 555 (65.2%) of the eligible decedents had died at the two participating hospitals (JOOTRH and KCRH) while the rest were brought in dead (BID).
- Approximately 161 (19%) of the eligible decedents were under 15 years of age; 94 (58.4%) of these were less than 18 months of age.
- Blood specimens were collected from 659 (77.5%) of the eligible decedents whose HIV status was not documented.

HIV Infection and Viral Load Suppression

- Overall, of the 851 eligible decedents, 241 (28.3%) had HIV infection. This was a combination of those that had their HIV diagnosis documented in their medical records (n=119) and those who were confirmed to be HIV infected after sample analysis in the laboratory (n=122).
- The HIV infection rate was higher among female (31.3%) compared to male decedents (25.5%).
- Those aged 35 – 44 years had the highest HIV infection (60.7%) followed by those 45 – 54 years old (50.6%).

- Between the ages of 10 - 34 years, female decedents had higher prevalence of HIV infection. This trend was reversed in the 35 - 55-year-old age group where male decedents had higher HIV infection rate.
- Higher HIV infection rate (31.0%) was observed among those who had died in hospitals compared to who died outside a hospital (23.3%).
- Of the 122 decedents found to have HIV infection through laboratory, 116 were tested for viral load. Half of these decedents were virally suppressed (<1,000 copies/ml).
- Viral suppression was higher among males (57.8%) compared to females (40.4%) with the highest being those aged over 55 years and none of the decedents under 15 years (n=11) were virally suppressed.

ART Uptake

- Among the 119 deaths in hospital with documented HIV infection, 89 (74.8%) had ART usage documented of which 70 (58.8%) were on ART and 19 (16.0%) not on ART.

Cause of death (COD)

- Medical charts were retrieved for 456 (82.2%) out of the 555 hospital-based deaths for certification of COD by the panel.
- The highest proportion 51 (11.2%) of decedents whose COD was certified were children aged under 1 year.
- Slightly more than half 241 (52.9%) of certified deaths were females.
- HIV/AIDS was the underlying COD in nearly a quarter (23.1%) of the certified deaths.
- The majority of those whose underlying COD was HIV/AIDS were females 59 (57.8%).
- Communicable diseases including HIV/AIDS accounted for 47.8%, non-communicable for 47.1% and injuries for 5.2% of deaths.

Mortality

- All-cause mortality rate in Kisumu County was 1,086 per 100,000 population per year.
- Non-communicable diseases contributed to the highest cause-specific mortality (516 per 100,000 population per year).
- HIV associated mortality was 312 per 100,000 population per year.
- Mortality due to HIV/AIDS was 251 per 100,000 population per year.

OraQuick® sub-Study

- The enrolled decedents with matched pre- and post-embalming oral samples were 132 out of which 117 (88.6%) were aged 15 years and above at death; 57 (43%) were female.
- The sensitivity of OraQuick® for both pre and post-embalmed sample was 92.6%.
- The specificity was higher for pre-embalmed (97.1%) compared to post-embalmed (95.7%) samples. The difference was not significant.

HIV/AIDS is still the leading cause of deaths among patients who died in hospital and in the county as a whole. The proportions of deaths due to communicable compared to non-communicable diseases were similar. However this does not reflect data from similar settings where the ratio is 2:3 [1], indicating that HIV contributes substantially to the burden of communicable diseases in Kisumu. Efforts to reduce morbidity and mortality in the population using multiple interventions should be scaled-up with focus on preventing mortality among infants and children, cardiovascular diseases among the aging population and reducing injuries among the younger males.

1.0 Introduction

1.1 Background

Globally, around 770,000 people died from AIDS-related illnesses worldwide in 2018, compared to 800,000 in 2017 and 1.7 million in 2004, the peak year for HIV-associated mortality. In 2017, there were 28,214 annual AIDS-related deaths in Kenya, of which 23,902 (84.7%) were adults aged 15+ years and 4,312 HIV-related deaths in children aged 0-14 years [2]. Kisumu County had 1,679 (7%) deaths out of which 369 (8.6%) occurred among children aged 0-14 years [2].

Population level all-cause and cause-specific death rates are important indicators of health status [3,4]. HIV-associated mortality is one of the ways of evaluating HIV interventions. Routine monitoring of these indicators is necessary for monitoring trends in population health, strategic planning and political advocacy and for documenting the impact of diseases on health [5,6]. Studies have highlighted the need to strengthen mortality surveillance globally [7,8]; yet, only an estimated half of deaths are registered with information on cause of death [9]. In all low- and two thirds of middle-income countries where health and civil registration infrastructure are often poor [10,11] or deaths are not registered at all, [9] quantification of causes of death (COD) is not systematically recorded [10,12–15], and where death records are available, the quality of data is unreliable [13]. Kenya, for instance, has an incomplete death registration system and inaccuracy in the ascertainment of the COD, including HIV. According to 2015 civil registration and vital statistics, death registration coverage was 46% for the period 2010-2014 [16].

A direct approach to measuring HIV-associated and AIDS-related mortality is to conduct surveillance at mortuaries [17]. Mortuary surveillance has been conducted among adult decedents in sub-Saharan Africa in Côte d'Ivoire [13] and Kenya [18]. There are few data among infants and children, yet mortuary-based surveillance offers a valuable alternative method of obtaining information about COD among adolescents, adults and children in the absence of an active vital registration system.

In 2015, NASCOP, the University of California, San Francisco (UCSF) and the U.S. Centers for Disease Control and Prevention (CDC) Kenya conducted a pilot mortuary surveillance study among adolescent and adult (15 years and above) decedents in the two largest mortuaries in Nairobi: Nairobi City and Kenyatta National Hospital (KNH) mortuaries. The study found an overall HIV positivity of 19.5% (119 out of the 610 eligible decedents), while COD was documented in only 375 (46.5%) of the 807 cases [13]. Additionally, 65.7% of deaths among HIV-infected decedents were directly attributed to HIV. The study further found that HIV mortuary surveillance is a feasible, low-cost activity that can provide valuable information on HIV-associated mortality and made several suggestions including expansion of the surveillance system to multiple sentinel sites to allow comparisons across regions [19–21].

As a follow-up to the Nairobi study, the Ministry of Health through National AIDS and STI Programme (NASCOP), Kisumu Department of Health CDOH and the UCSF and US CDC-Kenya in collaboration with the Kenya Medical Research Institute (KEMRI) conducted a mortuary and

hospital-based study at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) and the Kisumu County Referral Hospital (KCRH) between April and July 2019. This study was carried out to better understand HIV-associated mortality in a high HIV burden region in Kenya, Kisumu County.

1.2 Goal

The overall goal of this study was to estimate HIV-associated mortality in a high HIV-burden county in Kenya and provide information on how to systematically develop a standard, routine data source for HIV-associated mortality surveillance in Kenya.

1.3 Objectives

1.3.1 Main Objective

To establish appropriate procedures for measuring HIV-associated mortality in Kenya.

1.3.2 Specific Objectives

- To determine the positivity rate of HIV infection among decedents at two mortuaries in Kisumu County
- To determine annual county level all-cause and HIV-specific mortality rates for Kisumu County
- To assess quality of the certification of COD (obtained through death notification, medical records or autopsy reports) in Kisumu county
- To assess the efficiency of death notification process in Kisumu county
- To determine viral load (VL) among HIV-infected decedents admitted at JOOTRH and KCRH mortuaries in Kisumu County on post-mortem samples
- To assess documentation of HIV status among the dead at JOOTRH and KCRH
- To assess the feasibility of using non-invasive rapid HIV antibody testing using oral fluid obtained from decedents

2.0 Study Design and Methodology

2.1 Study Setting

Kisumu County had 15 mortuaries that reported deaths to Kisumu East Department of Civil Registration by September 2015, with JOOTRH and KCRH mortuaries reporting the largest volume of deaths. In the same month, the two mortuaries recorded 288 deaths, corresponding to 73% of total deceased persons reported in Kisumu County in 2014, with JOOTRH mortuary reporting more deaths than KCRH mortuary. In 2019, the capacity to hold bodies at JOOTRH and KCRH mortuaries was 99 and 46, respectively. The two mortuaries receive bodies from both internal (also referred to as brought in dead (BID) and external sources. Approximately 30% of the bodies are received from external sources.

2.2 Population, Inclusion and Exclusion Criteria

A cross sectional study was conducted in which decedents were enrolled in 2019.

Population: The study population consisted of all decedents admitted to JOOTRH and KCRH mortuaries from April through July 2019.

Inclusion Criteria: All intact decedents of children 0 months and older, adolescents and adult decedents admitted to JOOTRH and KCRH mortuaries during the study period.

Exclusion Criteria: Decedents from which blood could not be collected due to deterioration, burns, embalming and still births or when the person had been dead for ≥48 hours.

2.3 Sample size

The sample size for the mortuary component of this study was set to allow estimation of HIV positivity among decedents aged ≥15 years with a margin of error of ±2%. After increasing the sample size to account for a 20% anticipated loss of specimen, the final target sample size was 545/0.80 = 680, which was further rounded up to 690 decedents. The proportion of deaths under age 15 at the two participating mortuaries was about 20% based on mortuary reports. Therefore, it was anticipated that up to 170 children would be admitted at the two mortuaries during the enrolment period.

For oral sample testing for HIV, a purposive sample of specimen from 120 bodies (adolescents, adults and children ≥ 18 months old) was considered. Factoring in a loss of 10% of specimens, the total sample for oral sample testing was 132 bodies.

2.4 OraQuick® Sub-Study

The objective of the OraQuick® sub-study was to determine the specificity and sensitivity of oral fluids testing using OraQuick® rapid HIV-1/2 test kit (Orasure Technologies, Bethlehem, PA) in HIV diagnosis on non-preserved and preserved decedents compared to HIV testing of blood using the Kenya National Rapid HIV testing algorithm for HIV diagnosis as the gold standard [22], (Appendix 4).

To validate the OraQuick® rapid HIV-1/2 test kit, sample size calculation was based on Clinical and Laboratory Sciences Institute guidelines for validation of a test kit which requires a minimum of 120 samples to be tested [23]. Due to logistical issues, this was only carried out at JOOTRH, and 132 decedents aged >18 months at death were tested. Matched whole-blood samples and pre- and post-preservation oral swabs from the same decedents were collected until the sample size of 132 decedents was obtained. The laboratory technologists testing HIV on blood were blinded from the Oraquick® test results.

2.5 Data Collection at Mortuaries and Hospitals

Consecutive samples of all eligible decedents admitted to the two mortuaries were included during the study period. The duration of sampling was the same at both mortuaries in order to ensure a proportionate sample (expected to be 2:1, JOOTRH: KCRH mortuaries) based on the admission rate in each mortuary. Enrolment continued until the target sample size (690 decedents with blood samples) was reached among adolescents and adults (aged ≥15 years old) at both facilities. All the decedents enrolled in the two mortuaries and aged <15 years at death were included.

2.5.1 Training for Data Collection

All research assistants (RAs) conducting data collection were trainied on protocol-specific procedures and field implementation operating procedures. Training modules included data collection tools and processes, data quality checks, data submission and preparation of weekly study updates. Further, the RAs received training on ethical considerations when conducting human subjects research.

2.5.2 Data Collection at Mortuaries

The decedents admitted in the mortuaries were either hospital deaths (all deaths occurring in the hospital wards or outpatient department); brought in dead (BID), i.e. occurring elsewhere including those who died outside of hospitals and those who died in other hospitals that transferred their decedents; and police cases (BID cases or hospital deaths that required a post-mortem for legal reasons are designated as police cases).

At the two mortuaries, data was collected in both paper and electronic formats. A paper M1 register (Appendix 2) was used to capture details of all deaths documented in the two mortuaries during the study period. A second, M2 register (Appendix 3) was used to record details relating to oral HIV testing for all eligible decedents at JOOTRH mortuary. Data from the two registers were abstracted into a tablet based ODK form and submitted to the study database.

2.5.3 Data Collection at Hospitals

The HIV status for all hospital deaths was ascertained upon admission of the decedent to the mortuary. This was done as soon as the decedents were admitted by visiting hospital wards or records office and obtaining their HIV status from medical files. When the HIV status was not documented or indicated that the patient had been uninfected for more than three months prior to death, a blood sample was drawn for HIV testing. Abstraction of hospital deaths data was done on

the Hospital Records Link Sheet (Appendix 10) and subsequently updated onto electronic format. All BIDs also had a blood sample drawn for HIV testing as there were no records to ascertain their HIV status. Additionally, COD for all hospital deaths was directly abstracted from D1 (Appendix 5) or post-mortem records into the study's M3 form (Appendix 12) electronically.

2.5.4 Data Quality Checks

We re-abstracted data and performed quality checks on 10% of randomly selected records; checking for consistency and completeness. The CDC Science office conducted one monitoring visit.

2.6 Specimen Collection

2.6.1 Blood Sample Collection

Cardiac blood was collected as soon as possible upon decedent admission into the mortuary, but no more than 48 hours after death. Inclusion and exclusion criteria for blood sample collection are outlined in Section 2.2. The procedure was performed by mortuary technicians and supervised by a mortuary technologist or the pathologist.

Non-clotted blood specimens of 6 ml or 2 ml/4 ml (for infants) was collected through a percutaneous trans-thoracic needle using a 12 cm needle and transferred it into a sterile ethylenediaminetetraacetic acid (EDTA)-containing venous blood collection tube (Becton, Dickinson and Company, Franklin Lakes, New Jersey, USA). Specimen collection was documented in blood specimen collection register (Appendix 2). Blood samples were triple packaged into a specimen cool box and sent to the Clinical Research Centre (CRC/KEMRI) laboratory within 4 hours of collection.

2.6.2 Oral Swab Specimen Collection and Testing

Oral sample collection occurred only at JOOTRH mortuary. Oral samples were collected sequentially until targeted sample size of 132 decedents with blood samples and matching pre- and post- embalming oral samples was achieved. The OraQuick® HIV test kit was used to collect test samples pre- and post- embalming. Inclusion and exclusion criteria for oral swab collection, are outlined in section 2.4.

Briefly, the swab was placed above the teeth against the outer gum and gently swabbed around the outer gums, both upper and lower, ***one time around*** while ensuring that the roof of the mouth or the inside of the cheek or tongue were ***not*** swabbed. The swab was then inserted into the developer solution vial, the results read between 20 and 40 minutes, and the results interpreted as guided by the manufacturer's instructions. Oral specimen collection was documented in the oral specimen collection registers (Appendix 3).

Figure 1 below illustrates the samples flow and processing procedures for both blood and oral samples.

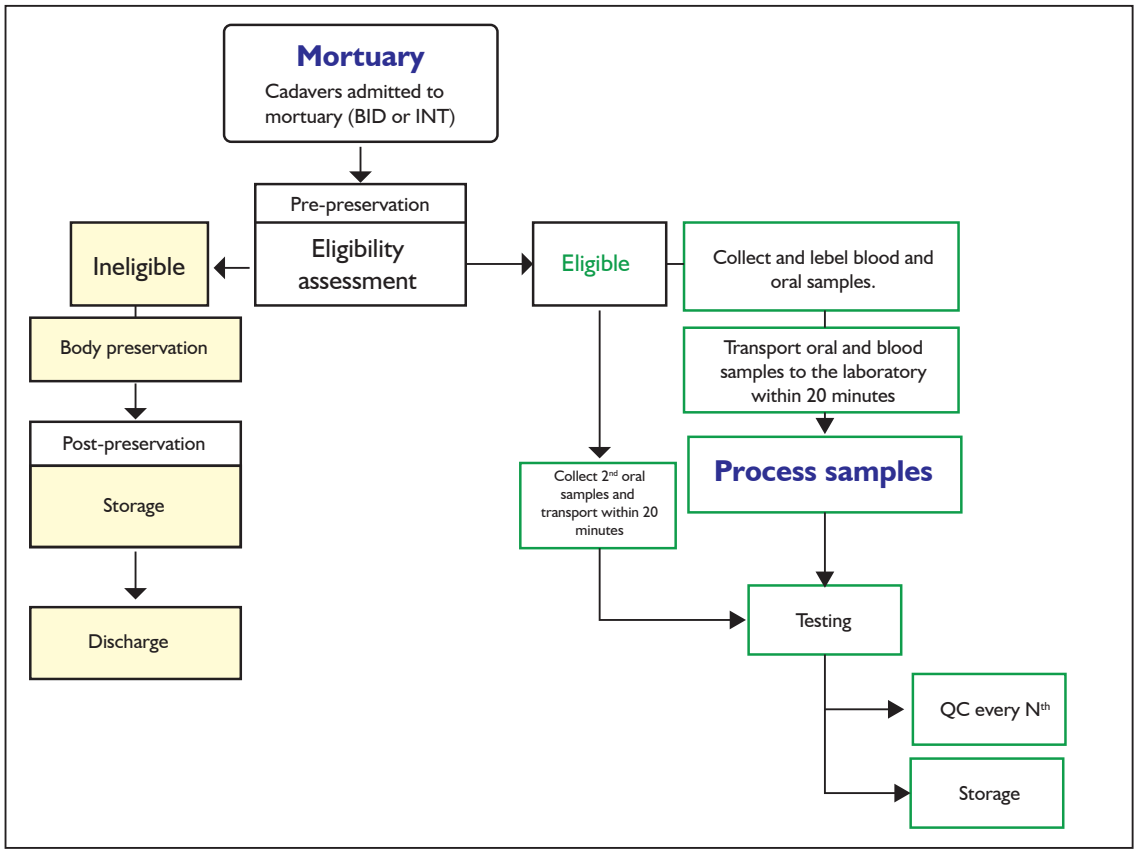

Figure 1: *Sample flow and processing procedures*

2.7 Specimen Management at Laboratory

2.7.1 Blood Specimen Receipt, Preparation and Storage

At the mortuary, a Laboratory Request Form (Appendix 13) for each sample was completed by the RA to accompany the samples to the CRC KEMRI laboratory. A Sample Manifest Form (Appendix 14) was used to track sample transport to the laboratory. Upon receipt of oral specimen at the CRC KEMRI laboratory, staff verified specimen quality against a predefined acceptance criteria. The blood samples were used for dried blood spot (DBS) sample preparation. DBS were prepared by spotting 1-2 drops (~70 μl) of blood drawn from EDTA tubes onto each of 5 spots of two filter papers per specimen (total of 10 spots). DBS cards were placed onto drying racks and left overnight to dry. Once dried, specimens were packed with desiccants and humidity indicator cards and stored at room temperature for up to 30 days prior to testing or at -20^{0}C to -30^{0}C for long term storage. The remaining blood sample was centrifuged, and the plasma obtained stored at 2-8^{0}C for up to 72 hours prior to serological testing. Any plasma that remained after serological testing was put into aliquots of 2ml cryovials, labelled and stored at -80^0 C for future testing such as HIV drug resistance or antiretroviral (ARV) metabolites testing.

2.7.2 Blood Specimen Testing

HIV testing: Polymerase chain reaction (PCR) test was used for HIV diagnosis of all samples from decedents aged <18 months old. Samples from children ≥18 months, as well as those from adolescents and adults (≥15 years) were tested for HIV antibodies as per the NASCOP HIV testing services guidelines [24]. Rapid HIV testing was conducted on plasma as guided by the national HIV testing algorithm with Determine™ HIV-1/HIV-2 (Abbott Diagnostic Division, Hoofddorp, Netherlands) as the screening assay and First Response (Premier Medical Corp. Lt, Daman, India), as the confirmatory test for all reactive results (Appendix 4). Samples yielding reactive on Determine and First Response and reactive on Determine and non-reactive on First Response were considered positive or inconclusive, respectively. These samples with initial inconclusive final HIV result were subjected to a second set of testing (retested), done by a different technician, using the same algorithm. Samples positive in the initial tests and retests were concluded as positive. Samples with inconclusive HIV results on the initial tests that yielded a non-reactive HIV result on the second screening assay (Determine) were considered negative. Samples that were initially positive in the first set of tests (Determine and First Response) and upon retesting with the Determine were non-reactive were considered as inconclusive. Additionally, samples that were initially inconclusive and became inconclusive upon retesting were also considered inconclusive. For samples that yielded inconclusive results, deoxyribonucleic acid polymerase chain reaction (DNA PCR) test was used for tie-breaking to confirm the final HIV status.

VL testing: To determine the level of HIV RNA concentration present in decedent blood, VL (HIV-RNA copies/mL) testing was performed using plasma from all HIV-positive samples. VL testing was conducted using Abbott m2000 system (Abbott Molecular, Inc., Des Plaines, IL). A DBS sample was used where a plasma sample was not available. VL results were reported quantitatively and categorized by viral suppression (copies < 1,000/ml).

Quality control (QC) procedures: The CRC KEMRI laboratory performed QC for HIV serological testing daily by retesting every seventh HIV–negative specimen using the rapid test kits used for the study. The laboratory also participated in a proficiency testing program for both HIV rapid test and VL.

2.7.3 Laboratory Results

Laboratory results were transcribed by laboratory technicians on a paper Laboratory Reporting Form (Appendix 11). HIV results were then abstracted into the electronic data collection tools on ODK and submitted to the study database.

2.8 Cause of Death Data Abstraction and Certification

2.8.1 Sources of Cause of Death Data

Cause of death (COD) data was abstracted at two points:

- **JOOTRH & KCRH Mortuaries:** COD data was abstracted from the death notification D1 form (Appendix 5) for hospital deaths, death notification D2 form (Appendix 6) for BID, or post mortem reports for police cases. The D1 forms are used by health institutions while D2s

are used by registration assistants (chiefs and sub-chiefs) for deaths that occur at home that are not certified by a medical professional.

- **Kisumu East Department of Civil Registration:** All death records for the City of Kisumu are stored in paper format at the Kisumu East Department of Civil Registration. For each death, a copy of the completed D1 or D2 forms are filed and bound in volumes according to year of death. Cause of death was abstracted from available D1 forms for all patients who died at the two hospitals. In order to annualize the COD for Kisumu East and considering both data completeness as well as data entry backlogs, 2017 data was selected. The COD data was abstracted from both D1 and D2 forms at civil registry records, entered into an ODK electronic tool and submitted to the central database [25].

2.8.2 Cause of Death Certification/Re-certification and ICD-10 Coding

Medical Officers (MO) and Health Records Information Officers (HRIO) were trained on COD certification and coding as outlined in the ICD-10 rules [26]. For the hospital deaths data, the MOs abstracted antemortem medical history of illnesses, HIV status and HIV treatment status from the medical charts of the decedents. The causes of death (immediate, antecedent and underlying) were determined and recorded in the COD paper panellist summary form (Appendix 9). HRIOs assigned ICD-10 codes to the documented CODs and entered the CODs and respective ICD-10 codes in an ODK electronic tool, and submitted them to the study database.

2.9 Training and Supervision

Sensitization trainings were done for the Kisumu County Health Management Team (CHMT) and facility nurses at both JOOTRH and KCRH. The study team (mortuary technicians, laboratory technicians, pathologists, research assistants (RAs), MOs and HRIOs) were trained on the study protocol. Training was customized to the staff responsibilities. Additionally, MOs and HRIOs who were certifying and coding the deaths respectively were trained on COD certification and ICD-10 coding.

To ensure scientific integrity of the study as well as the rights and protection of study subjects, monitoring and supervision was conducted on a regular basis by the representative(s) from the different institutions implementing the study. Supervisory visits were done at the participating hospitals' mortuary, laboratory and civil registration offices.

2.10 Data Management and Security

Data collection for this study was relatively complex due to the variety of data sources, format in which data was available and coordination of timing of when data was needed for critical decision making (for example ascertainment of HIV status of decedent from hospital records to determine if a sample was needed prior to embalming). Figure 2 below outlines the different data sources and tools used for this study, and the flow of data from source to study database.

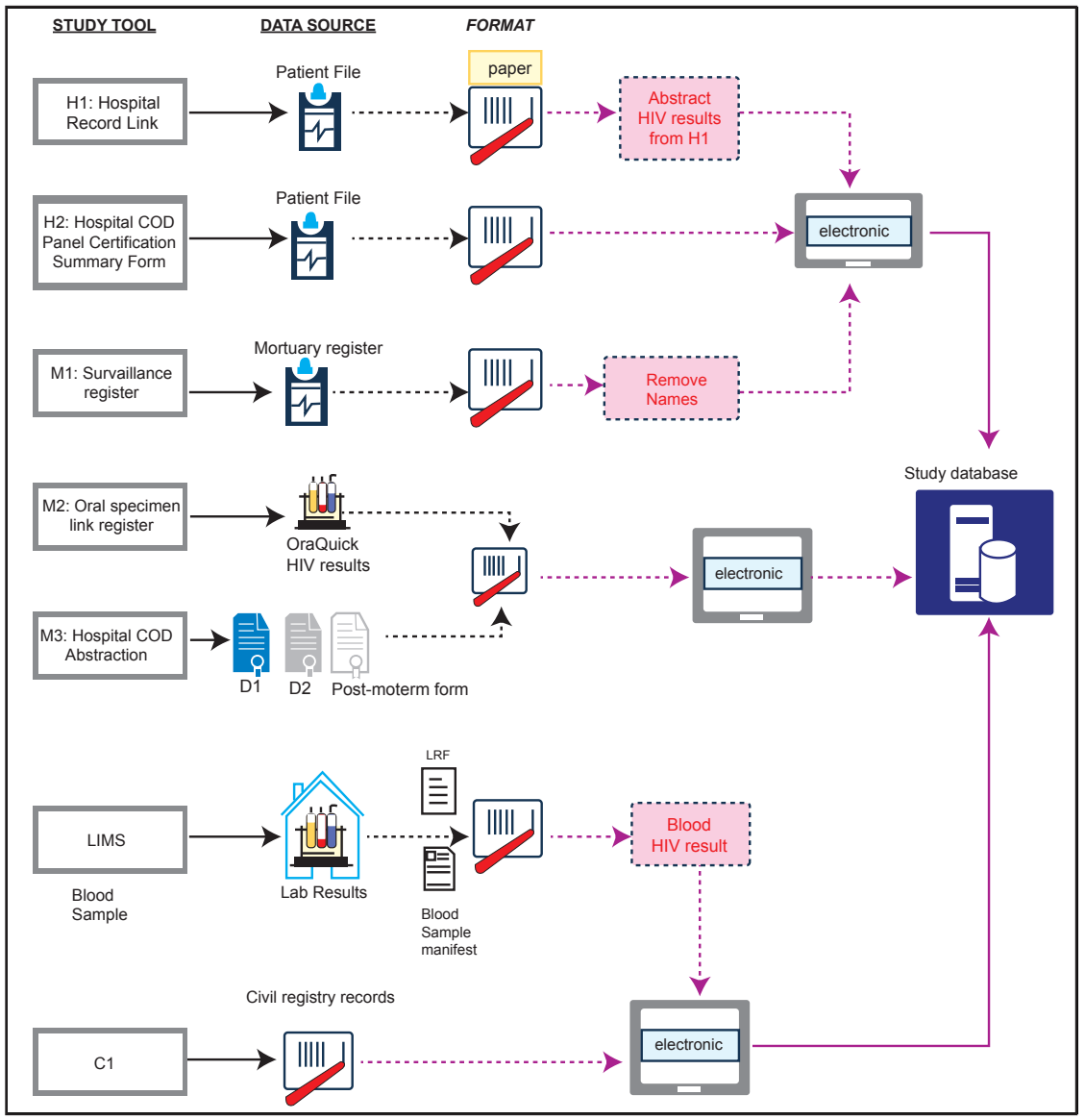

Figure 2: *Data tools and flow*

Manual registers and tools: All study tools were kept in lockable cabinets when not in use. These tools were accessible to study staff during the period of the study for purposes of data cleaning. Archiving of these data sources will be done at the Kisumu County Department of Health for a minimum of 2 years after publication of main study findings.

Electronic data: De-identified raw data was sent to an ODK study server with data quality checks implemented during data capture for data completeness, accuracy and consistency; cleaned and frozen for analysis. These data are accessible upon request from the Kisumu County Department of Health.

Abstracted data: Data quality assessments (DQA) were conducted periodically on 10% of the data from the surveillance mortuary register, COD re-abstraction, laboratory results and civil registry data abstraction during implementation of the study. All variables were re-abstracted from

the source documents and compared with the corresponding variables as recorded in the electronic dataset. The DQA exercises focused on ensuring data completeness, accuracy and overall integrity of the collected data. The findings were discussed amongst the study team and corrective measures put in place to address identified gaps.

COD coding: For cause of death, quality indicators such as proportion of deaths with no cause assigned and proportion of deaths with an invalid cause assigned were used to measure the quality of death certification and coding. A random selection (10%) of entries made at the civil registrar's office were re-abstracted and compared against initial entries. Disagreement rates between the two entries was 2% which was below the set 5% threshold requirement for entire data re-abstraction. For the entries that were discrepant, immediate ascertainment of correct status was done, and the data updated.

2.11 Data Analysis

Data in the study database (originated from data submitted via ODK) was downloaded in CSV format and imported into STATA Version 14. Mortuary, laboratory and medical file review data was cleaned and merged using a unique identifier. Stata syntax was developed to check for outliers, missing or inconsistent values. As part of an ongoing data quality processes, lists of potential errors were generated and given to the study coordinator, and RAs/abstractors for verification against source documents. Data was analysed using STATA Version 14 (STATA Corporation, College Station, TX).

Civil registry data was summarised to calculate the distribution of deaths by demographic and clinical variables. For the civil registry data, deaths which had a missing or invalid cause were excluded. These included deaths where only the mode of death was provided (e.g. cardiopulmonary failure or old age). For hospital deaths, COD was determined by review of the medical records. However, the COD for some hospital deaths could not be determined due to insufficient or inconclusive data.

Grouping and coding of underlying causes of death. The Global Burden of Disease approach to grouping deaths by broad causal categories classifies disease and injury, burden and causes of death into three broad cause groups [27]:

1. Group I-Communicable, perinatal, maternal, and nutritional diseases
2. Group II-Non-communicable diseases
3. Group III-Injuries

Group I was further categorised into HIV-related and non-HIV related causes. Death information was abstracted from D1, D2 forms at the civil registry. Given the large volume of unstructured text that they presented, pattern matching was used to locate deaths that mentioned HIV or a euphemism for HIV such as RVD. These were coded to HIV regardless of the underlying cause.

2.11.1 Mortality and Cause-of-Death Data

COD data was analysed using Analysing mortality levels and Causes-of-Death (ANACoD) tool version 2.0 developed by the WHO in collaboration with the University of Queensland and Health Metrics Network. The freely downloadable (https://www.who.int/healthinfo/anacod/en/) Microsoft® Excel-based tool provided a stepwise approach that enabled the comprehensive analysis of ICD-10 coded data. The mortality data was reviewed for errors, tabulated and the results presented in the form of tables and charts. The tool also classified the underlying causes of death using the Global Burden of Diseases (GBD) categorisation and provided a comparison of findings with those from other countries [28].

2.11.2 OraQuick® Validation

The sensitivity, specificity and positive and negative predictive values of OraQuick® Rapid HIV-1/2 Antibody Test with oral fluid were calculated and compared to the results of the Determine™ HIV-1/HIV-2 (Abbott Diagnostic Division, Hoofddorp, Netherlands) and First Response (Premier Medical Corp. Lt, Daman, India) algorithm. Analyses were done using STATA Version 14 with corresponding 95% confidence intervals (CI) to evaluate the performance of the individual tests for both pre- and post-preservation specimens versus the gold standard blood test results.

2.12 Ethical Considerations

This surveillance activity used specimens from non-living subjects for HIV testing, results of which could not be linked back. A waiver of informed consent was requested since the research involved no more than minimal risk to the subjects, the waiver or alteration did not adversely affect the rights and welfare of the subjects, and the research could not have been practicably carried out without the waiver or alteration. For practicability specifically, time was not sufficient to obtain consent from the subject's next of kin, within the short duration before body embalmment.

Laboratory test results including HIV test results were not provided to next of kin and neither were cause of death results from the study used to update official death notifications.

Support for HIV mortuary surveillance was also sought from the Kisumu Department of Health (Appendix 16). Community sensitization on the surveillance plan was done through the Kisumu County KEMRI Community Advisory Board (CAB). Study progress updates were routinely shared during the monthly Kisumu county KEMRI/CDC community advisory board's meetings.

The study was approved by KEMRI's Science and Ethical Review Unit (KEMRI/RES/7/3/1), JOOTRH ethics committee (ERC.IB/VOL.1/615), CDC's Center for Global Health, Associate Director for Science (2018-256) and the UCSF Committee for Human Research (230355).

3.0 Main Study Results

3.1 Overall Study Findings

3.1.1 Enrolment

In total, 1004 decedents were admitted into the two mortuaries during the study period; 697 (69.4%) were from JOOTRH and 307 (30.6%) from KCRH. Among the admitted decedents, 49 (4.9%) were not available for the study because they were subsequently transferred to other facilities or dispatched for burial before enrolment. Out of the 955 decedents available, 104 (10.9%) were not eligible for the study. The most common reason for ineligibility was stillbirth decedents 66 (63.4%). Among the 851 eligible decedents, 192 (22.5%) had the HIV status documented in the patient file. Of these, 119 (62.0%) were HIV infected. Blood samples were drawn from 659 decedents with undocumented HIV status for analysis in the CRC KEMRI laboratory. Appendix 15 shows a table summarising number of blood draw attempts per decedent . Five samples (0.8%) were rejected in the CRC KEMRI laboratory due to poor quality (clotting, haemolysis, foamy). The remaining 654 (99.2%) were tested for HIV, of which 122 (18.7%) tested positive and were tested for viral load. Results were available for 116 samples (95.1%) while the remaining 6 (4.9%) could not be analysed due to sample quality issues. Figure 3 summarises the enrolment data.

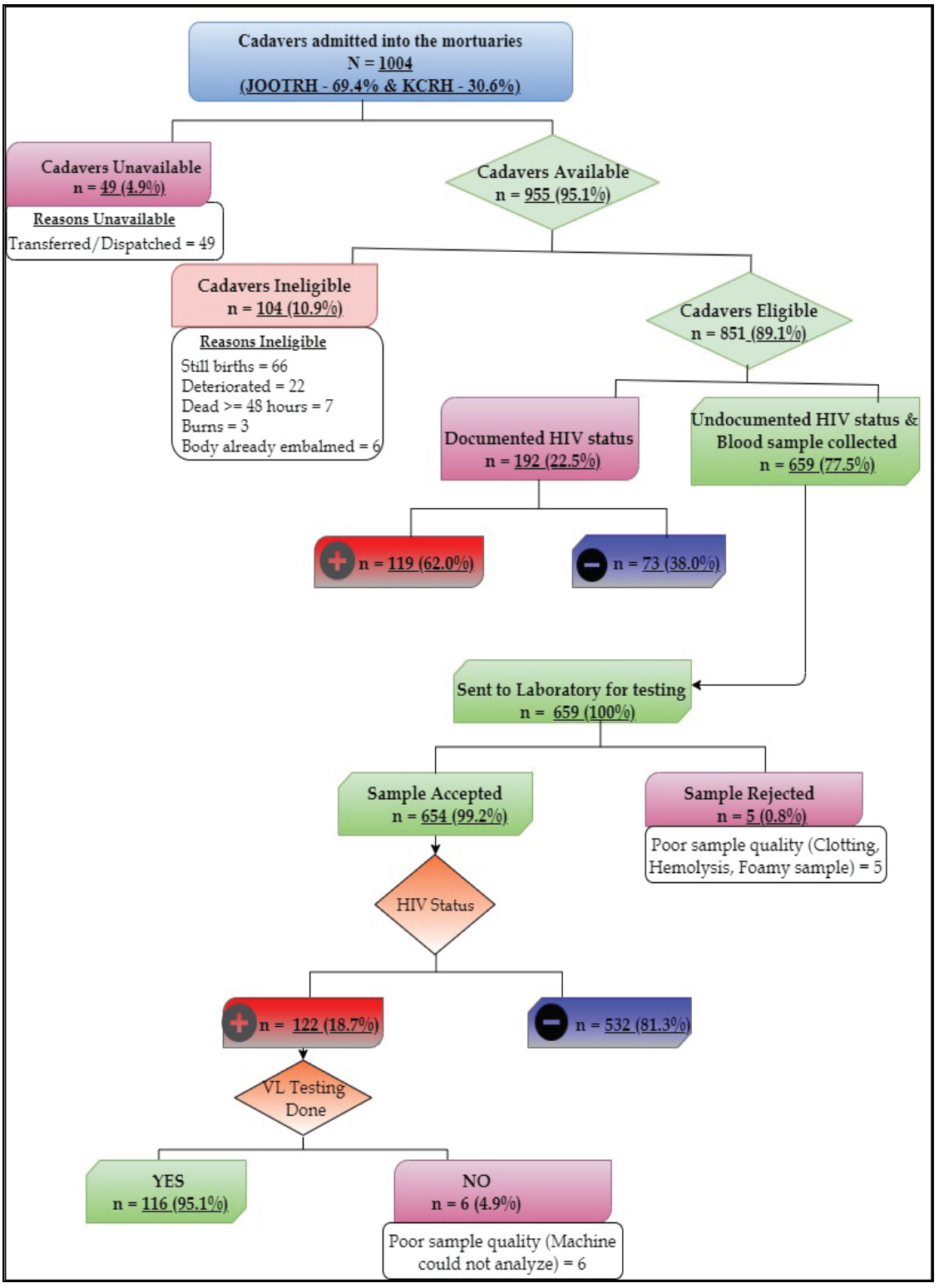

Figure 3: *Enrolment Flow Chart*

3.1.2 General Characteristics of Eligible Decedents

Majority 555 (65.2%) of the eligible decedents were from the two participating hospitals (JOOTRH and KCRH) while the rest were BID, out of which 42 (14.2%) were police cases. Males comprised 439 (51.6%) of the eligible decedents. Approximately 161 (19%) of the eligible decedents were under 15 years, of whom 94 (58.4%) were aged less than 18 months. Among decedents aged 75 years and above, there were twice as many females as males. Table 1 below shows the summary of the general characteristics of the eligible decedents.

Table 1: *General Characteristics of the eligible decedents*

	Total		Male		Female	
	N	**%**	**n**	**%**	**N**	**%**
Age category:						
Under 15 years	**161**	**18.9**	**77**	**17.5**	**84**	**20.4**
Under 18 months	94	11.0	44	10.0	50	12.1
18 months - 9 years	49	5.8	25	5.7	24	5.8
10 - 14 years	18	2.1	8	1.8	10	2.4
15+	**690**	**81.1**	**362**	**82.5**	**328**	**79.6**
15 - 24 years	58	6.8	33	7.5	25	6.1
25 - 34 years	131	15.4	73	16.6	58	14.1
35 - 44 years	117	13.7	74	16.9	43	10.4
45 - 54 years	89	10.5	52	11.8	37	9.0
55 - 64 years	74	8.7	36	8.2	38	9.2
65 - 74 years	89	10.5	47	10.7	42	10.2
75+	132	15.5	47	10.7	85	20.6
Decedent Categories:						
Hospital deaths	555	65.2	259	59.0	296	71.8
Brought in dead*	42	4.9	39	8.9	3	0.7
Brought in dead†	254	29.8	141	32.1	113	27.4
Mortuary:						
JOOTRH	564	66.3	278	63.3	286	69.4
KCRH	287	33.7	161	36.7	126	30.6
Total	**851**		**439**		**412**	

*These include police cases e.g. homicides

†These include community-based deaths, transfers from other mortuaries but exclude police cases

3.1.3 HIV Infection

Of the eligible decedents, 241 (28.3%) had evidence of HIV infection; 119 had a diagnosis of HIV infection recorded in their patient files and 122 had serological evidence of HIV infection upon laboratory testing. The positivity rate of HIV infection was slightly higher among female compared to male decedents (129/412 [31.3%] vs. 112/439 [25.5%]; P value = 0.061).

The 35 – 44 year age group had the highest positivity rate of HIV infection (71/117, 60.7%), followed by those aged 45 – 54 years (45/89, 50.6%). A higher HIV positivity rate was also observed in hospital deaths compared to the brought in dead (172/555 [31.0%] vs. 69/296 [23.3%] P value = 0.018). Table 2 below shows the positivity rates of HIV infection among eligible decedents by sex, age and decedent class.

Table 2: *HIV status among eligible decedents by sex and age*

	Eligible decedents			HIV Positivity Rate		
				Total	Males	Females
	Total	Males	Females	n/N (%)	n/N (%)	n/N (%)
Age category:						
Under 15 years	**161**	**77**	**84**	**20/161 (12.4)**	**10/77 (13.0)**	**10/84 (11.9)**
Under 18 months	94	44	50	6/94 (6.4)	3/44 (6.8)	3/50 (6)
18 months - 9 years	49	25	24	10/49 (20.4)	5/25 (20.0)	5/24 (20.8)
10 - 14 years	18	8	10	4/18 (22.2)	2/8 (25.0)	2/10 (20)
15+	**690**	**362**	**328**	**221/690 (32.0)**	**102 / 362 (28.2)**	**119/328 (36.3)**
15 - 24 years	58	33	25	17/58 (29.3)	7/33 (21.2)	10/25 (40)
25 - 34 years	131	73	58	50/131 (38.2)	16/73 (21.9)	34/58 (58.6)
35 - 44 years	117	74	43	71/117 (60.7)	39/74 (52.7)	32/43 (74.4)
45 - 54 years	89	52	37	45/89 (50.6)	24/52 (46.2)	21/37 (56.8)
55 - 64 years	74	36	38	29/74 (39.2)	11/36 (30.6)	18/38 (47.4)
65 - 74 years	89	47	42	4/89 (4.5)	4/47 (8.5)	0/42 (0)
75+	132	47	85	5/132 (3.8)	1/47 (2.1)	4/85 (4.7)
Source of decedent:						
Hospital deaths	555	259	296	172/555 (31.0)	71/259 (27.4)	101/296 (34.1)
Brought in dead*	42	39	3	11/42 (26.2)	11/39 (28.2)	0/3 (0)
Brought in dead†	254	141	113	58/254 (22.8)	30/141 (21.3)	28/113 (24.8)
Total	**851**	**439**	**412**	**241 / 851 (28.3)**	**112/439 (25.5)**	**129/412 (31.3)**

*These include police cases e.g. homicides

†These include community-based deaths, transfers from other mortuaries but exclude police cases

From Figure 4, HIV positivity rate was higher among female decedents aged 10-34 years 46/93 (49.5%) compared to their male counterparts 25/114 (21.9%) [P value = <0.001]. There was however a higher proportion of HIV-infected male decedents in the 35 – 54 year age category 53/80 (66.3%) group compared to females 63/126 (50.0%), [P value = 0.022].

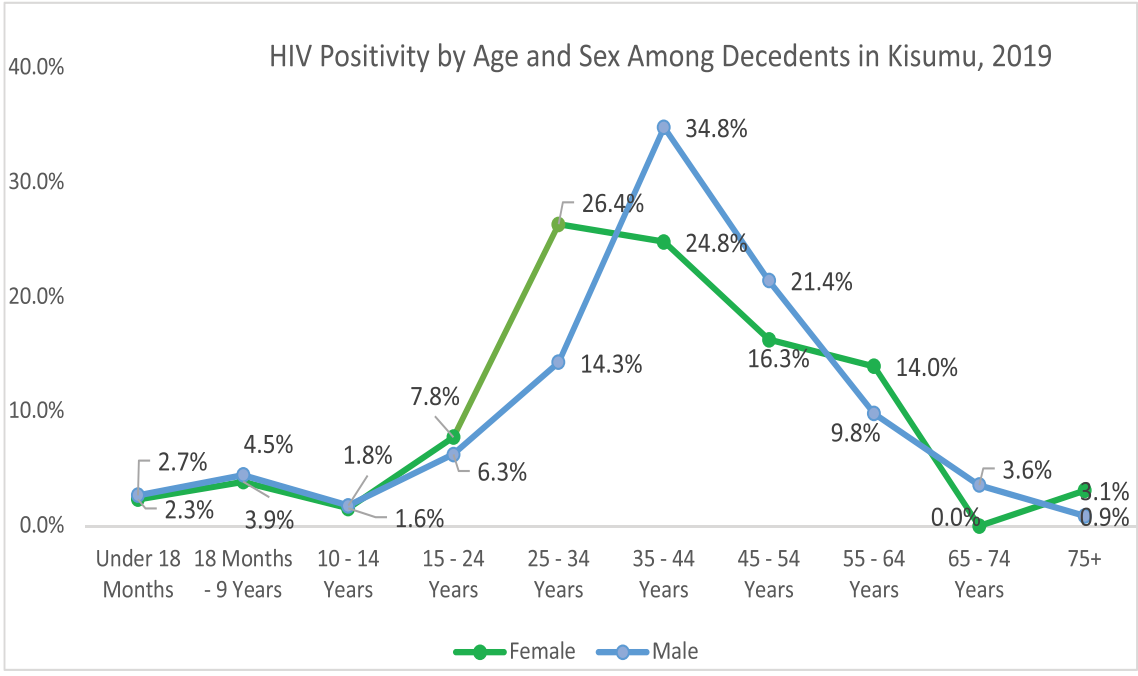

Figure 4: *Distribution of HIV-infected cases by age and sex, JOOTRH and KCRH Mortuaries, 2019*

Among the hospital deaths more female decedents had their HIV status documented as compared to males although not statistically significant. Figure 5 below shows HIV positivity rate by decedent class and sex.

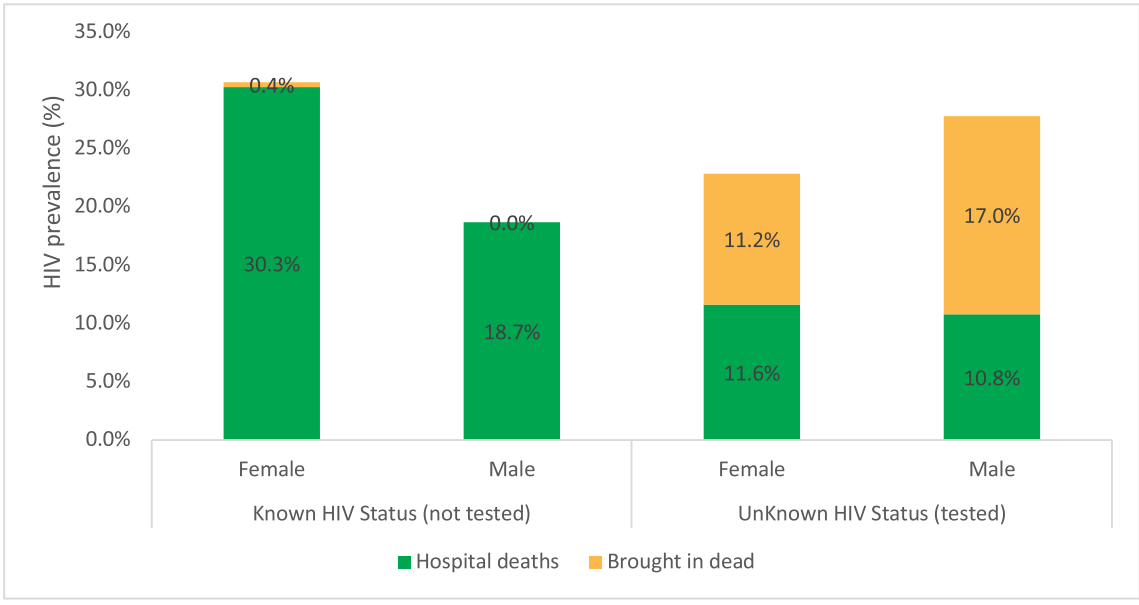

Figure 5: *Contribution to HIV Positivity by decedent class and sex*

3.1.4 Anti-retroviral Treatment Status

Documentation of ART uptake was assessed in the 119 hospital deaths whose medical records had documented HIV infection. Of these 89 (74.8%) decedents had ART usage status documented in their files with 70 (58.8%) documented to be on ART and 19 (16.0%) not on ART (Figure 6). The remaining 30 (25.2%) decedents had no documentation of ART, either because their files were not available for abstraction 19 (16.0%) or their files contained no information about ART use 11 (9.2%). Figure 6 below summarises the ART status among those with documented HIV infection.

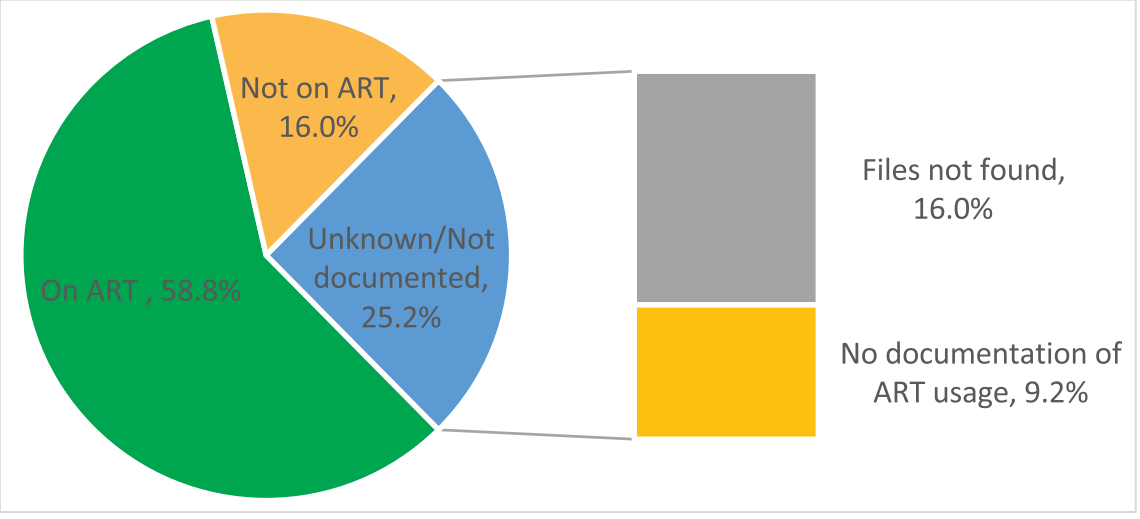

Figure 6: *ART status among those with documented HIV infection*

3.1.5 Viral Suppression Rates in HIV-infected Decedents

Of the 122 decedents found to have HIV infection through laboratory, 116 were tested for viral load. Half of these decedents were virally suppressed (<1,000 copies/ml) and viral load suppression (<1,000 copies/ml) was highest amongst those aged over 55 years. None of the decedents under 15 years (n=11) were virally suppressed. The viral load suppression rate was 57.8% among males and 40.4% among females. Table 3 below shows viral suppression rates among HIV positive decedents by age, sex and mortuary.

Table 3: *Viral suppression rates in laboratory-confirmed HIV infected decedents*

	<1000 copies/ml		≥1000 copies/ml		Total
	N	%	N	%	N
Age category:					
Under 15 years	0	0.0	11	100	11
15+	58	55.2	47	44.8	105
15 - 24 years	1	16.7	5	83.3	6
25 - 34 years	8	50.0	8	50.0	16
35 - 44 years	25	62.5	15	37.5	40
45 - 54 years	10	47.6	11	52.4	21
55+	14	63.6	8	36.4	22
Sex:					
Male	37	57.8	27	42.2	64
Female	21	40.4	31	59.6	52
Mortuary:					
JOOTRH	37	64.0	31	53.0	68
KCRH	21	36.0	27	47.0	48
Total	**58**		**58**		**116**

3.2 Causes of Death for Hospital-Based Deaths

3.2.1 Causes of Death as Certified

Medical charts were retrieved for 456 (82.2%) out of the 555 hospital-based deaths for JOOTRH and KCRH for certification of COD by the panel (Table 4).

Children aged under 1 year had the highest proportion of decedents whose COD was certified 51 (11.2%) followed by those above 80 years of age 42 (9.2%). Slightly over half 241 (52.9%) of the decedents with a certified COD were female. Males accounted for 13 (68.4%) of adolescents aged 15 to 19 years, 29 (56.9%) of children aged under 1 year and 9 (56.3%) of children aged 1 to 4 years whose CODs were certified. Table 4 and Figure 7 below shows the distribution of deaths by age and sex.

Table 4: *Distribution of deaths by age and sex, in hospital deaths with certified cause of death, Kisumu, 2019*

Age-group (years)	Total (%)*	Male (%)#	Female (%)#
All	**456**	**215 (47.1)**	**241 (52.9)**
Under one year	51 (11.2)	29 (56.9)	22 (43.1)
1-4	16 (3.5)	9 (56.3)	7 (43.8)
5-9	20 (4.4)	9 (45.0)	11 (55.0)
10-14	12 (2.6)	6 (50.0)	6 (50.0)
15-19	19 (4.2)	13 (68.4)	6 (31.6)
20-24	12 (2.6)	6 (50.0)	6 (50.0)
25-29	37 (8.1)	17 (45.9)	20 (54.1)
30-34	41 (9)	16 (39.0)	25 (61.0)
35-39	29 (6.4)	14 (48.3)	15 (51.7)
40-44	24 (5.3)	14 (58.3)	10 (41.7)
45-49	25 (5.5)	10 (40.0)	15 (60.0)
50-54	18 (3.9)	8 (44.4)	10 (55.6)
55-59	18 (3.9)	10 (55.6)	8 (44.4)
60-64	25 (5.5)	11 (44.0)	14 (56.0)
65-69	15 (3.3)	7 (46.7)	8 (53.3)
70-74	29 (6.4)	13 (44.8)	16 (55.2)
75-79	19 (4.2)	8 (42.1)	11 (57.9)
80+	42 (9.2)	13 (31.0)	29 (69.0)

*Column percentage

#Row percentage

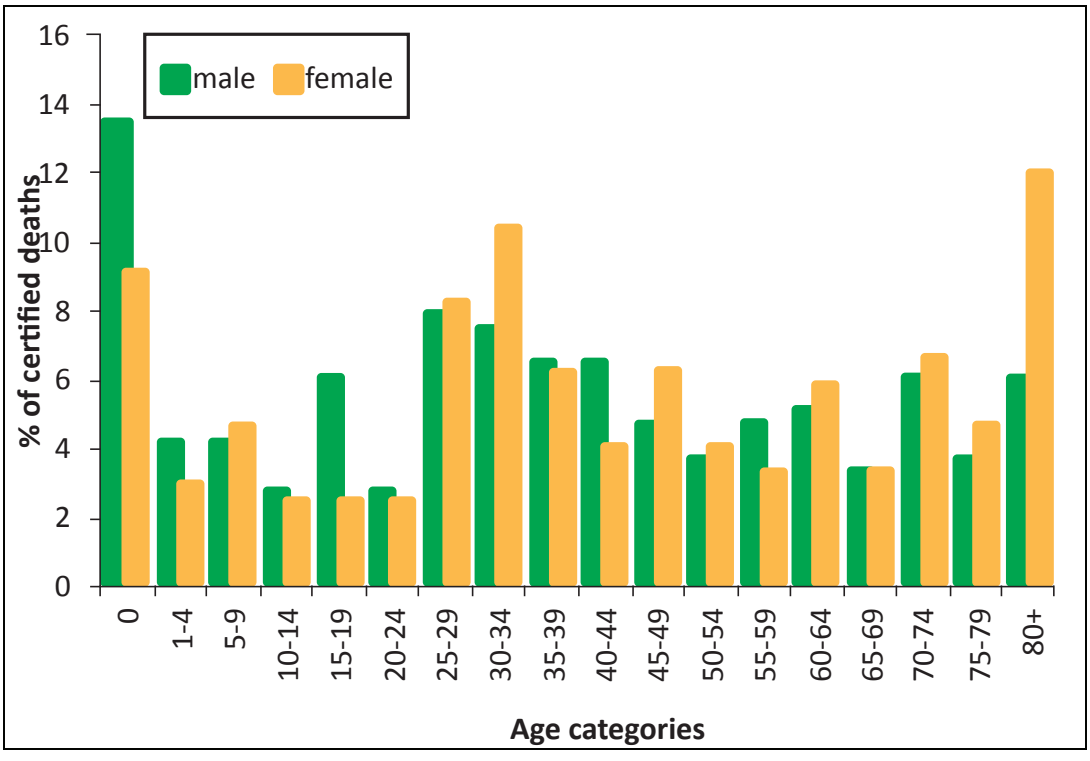

Figure 7: *Percentage of certified deaths by sex and age group, Kisumu, 2019*

3.2.2 *HIV Associated Mortality*

Of the 456 hospital deaths with a re-certified COD, 152 (33.3%) were determined to be HIV-associated. Among these, HIV was the underlying COD in 102 (67.1%), and HIV/AIDS was listed as other significant condition in an additional 50 (32.9%) decedents (Figure 8).

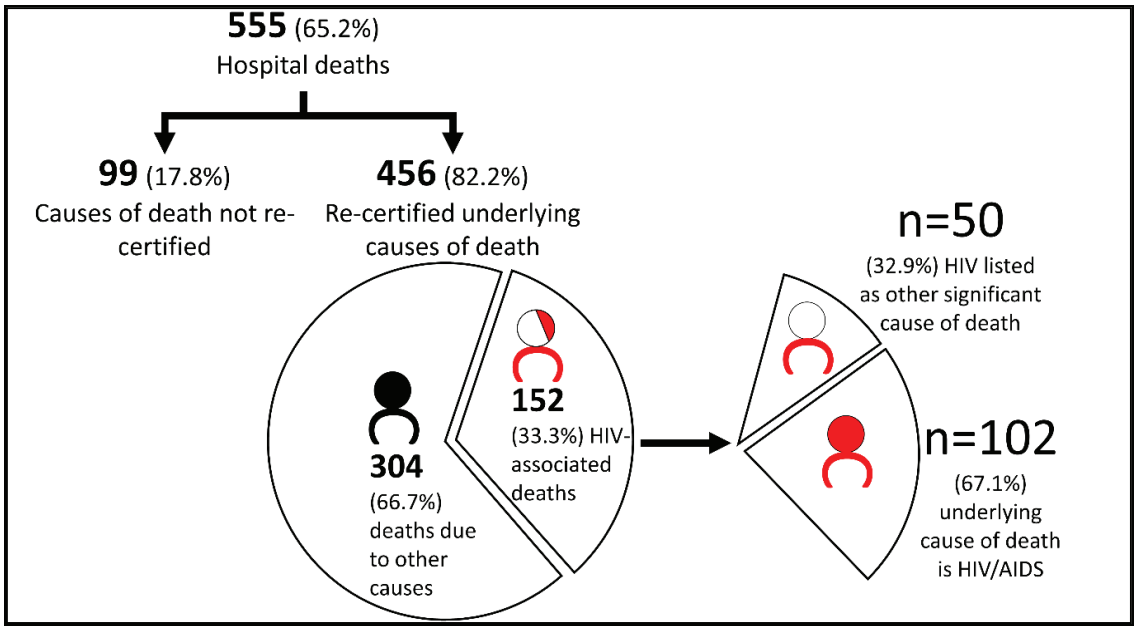

Figure 8: *Proportion of deaths due to HIV with laboratory confirmation of HIV status or documented HIV infection in medical chart, reported at JOOTRH and KCRH mortuaries, Kisumu, 2019*

3.2.3 *Causes of Death using Global Burden of Disease Classification*

Of the 456 entries with certified COD, 14 entries were excluded in the analysis using Global Burden of Disease classification because the COD could not be determined. HIV/AIDS was the underlying COD in 102 (23.1%) of the deaths (Table 5). Majority of those whose underlying COD was HIV/AIDS were female 59 (57.8%). Of the 23 deaths resulting from injuries, males were disproportionately affected 18 (78.3%). For both males and females non-communicable diseases accounted for the highest proportion of COD (42.1% and 51.5%, respectively) (Figure 9).

Table 5: *Cause of death by Global Burden of Disease (GBD) category and by sex, JOOTRH and KCRH Mortuaries, Kisumu, 2019*

GBD category	n (%)*	Male (%)#	Female (%)#
Group I†	211 (47.8)	103 (48.8)	108 (51.2)
HIV**	102 (23.1)	43 (42.2)	59 (57.8)
All other Group I causes	109 (24.7)	60 (55.0)	49 (45.0)
Group II‡	208 (47.1)	88 (42.3)	120 (57.7)
Group III§	23 (5.2)	18 (78.3)	5 (21.7)
Total	442 (100)	209 (47.3)	233 (52.7)

*Column percentage

#Row percentage

**HIV – when HIV status was documented in medical records or through laboratory testing and was assigned as underlying COD

†Group I - Communicable, perinatal, maternal and nutritional

‡Group II - Non-communicable diseases

§Group III - Injuries

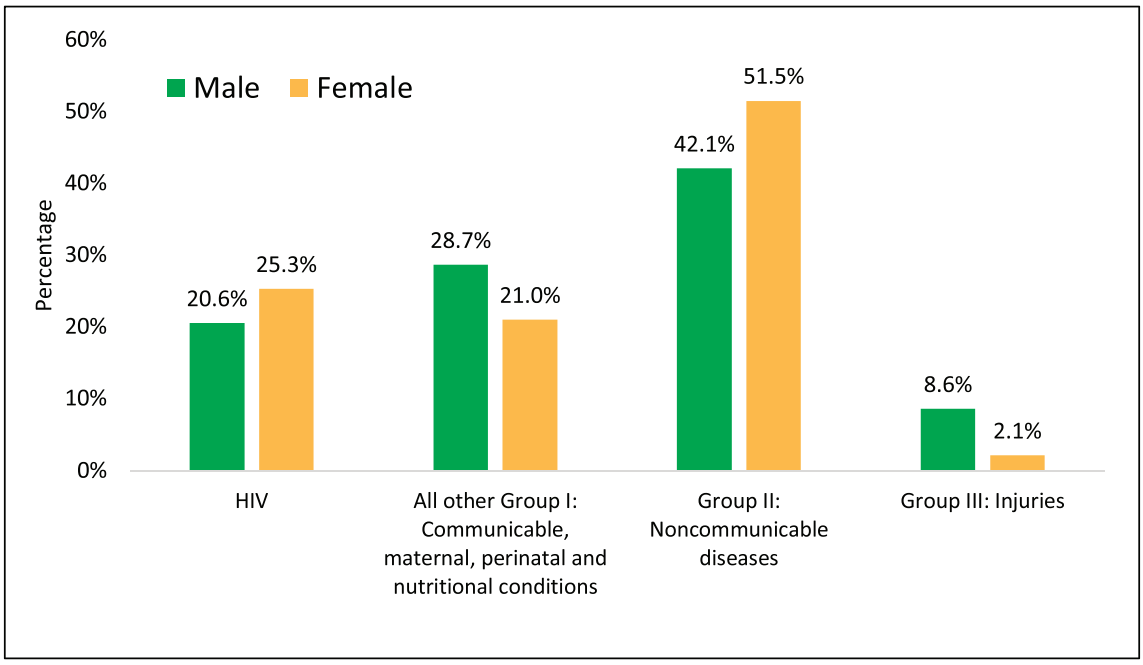

Figure 9: *Distribution of Global Burden of Disease (GBD) category among males and females, JOOTRH and KCRH Mortuaries, Kisumu, 2019*

The proportion of deaths due to HIV/AIDS increased with increase in age group with a peak at age 35 to 44 years among males and females (Figure 10). HIV/AIDS accounted for 7 (22.3%) among the 31 deaths in adolescents and young people (aged 15 to 24 years). For children aged 0-14 years, other communicable, perinatal, maternal and nutritional diseases were the most prevalent CODs for both males and females (Figure 10). In general the HIV positivity for non-communicable disease as a COD increased with age.

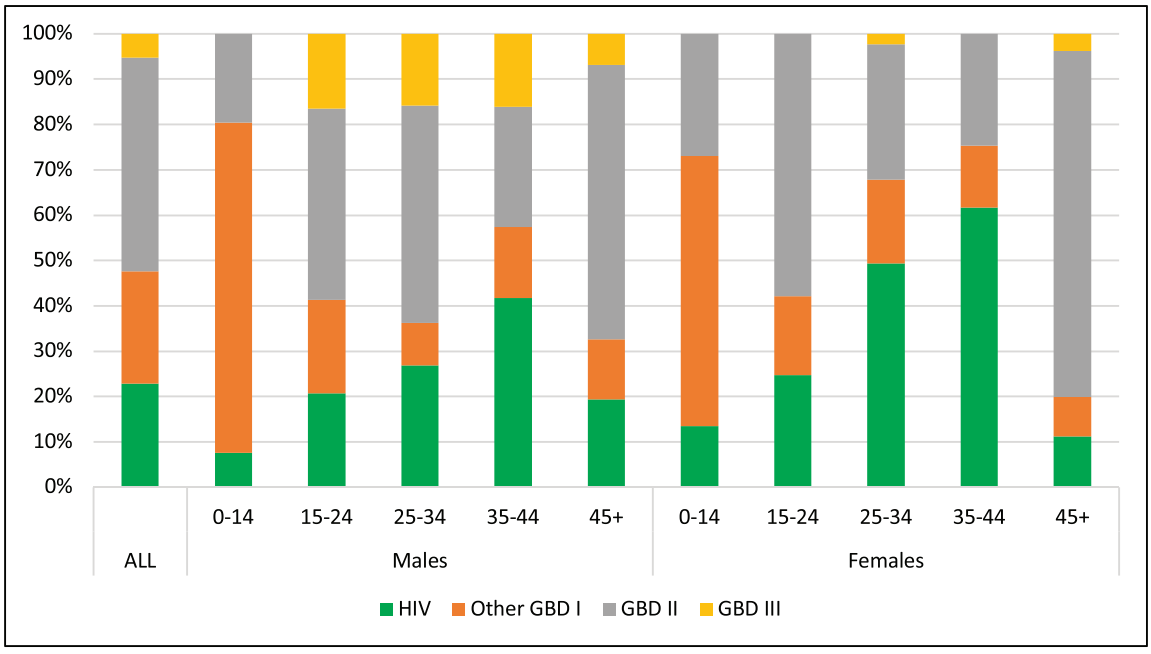

Figure 10: *Distribution of COD by GBD categories, age and sex JOOTRH and KCRH Mortuaries, Kisumu, 2019*

3.2.4 Leading Underlying Causes of Death

The leading underlying COD at the two mortuaries were HIV 102 (22.4%), hypertensive disease 41 (9.0%) and other cardiovascular diseases 23 (5.0%) (Figure 11). Perinatal conditions and malnutrition accounted for 7.0% and 1.3% of underlying COD respectively while 3% of underlying COD were ill defined. All 11 decedents whose underlying COD was road traffic accidents were males. Infectious and parasitic diseases (140) were more common among females 76 (54.2%) compared to males 64 (45.8%) (Figure 11).

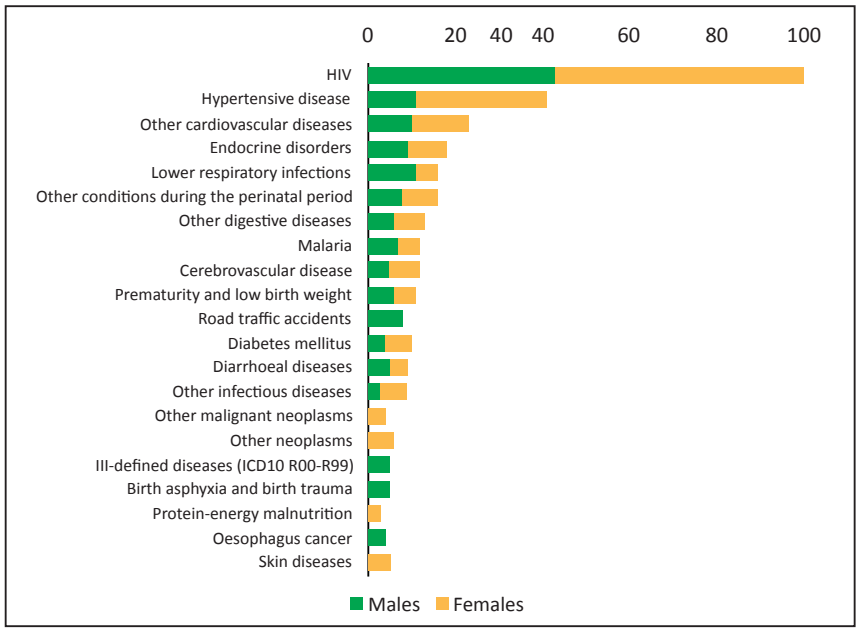

Figure 11: *Top 20 leading causes of death at JOOTRH and KCRH Mortuaries, 2019*

3.2.5 Viral Suppression among those with Certified COD

Out of the 116 decedents for whom we got the viral load results, 52 were from hospital based deaths, 53 BID's and 11 police cases. Of the 52 hospital based decedents, 45 had the cause of death certified by the panel of experts. Of these 45 (51.1%) deaths were due to HIV/AIDS and 48.9% were due to other causes where HIV was listed as another significant COD. Viral load suppression was slightly lower among those whose deaths was not directly due to HIV/AIDS (50.0%) compared to those whose underlying cause COD due to HIV/AIDS (60.9%) [P value=0.69] (Figure 12) though not statistically significant.

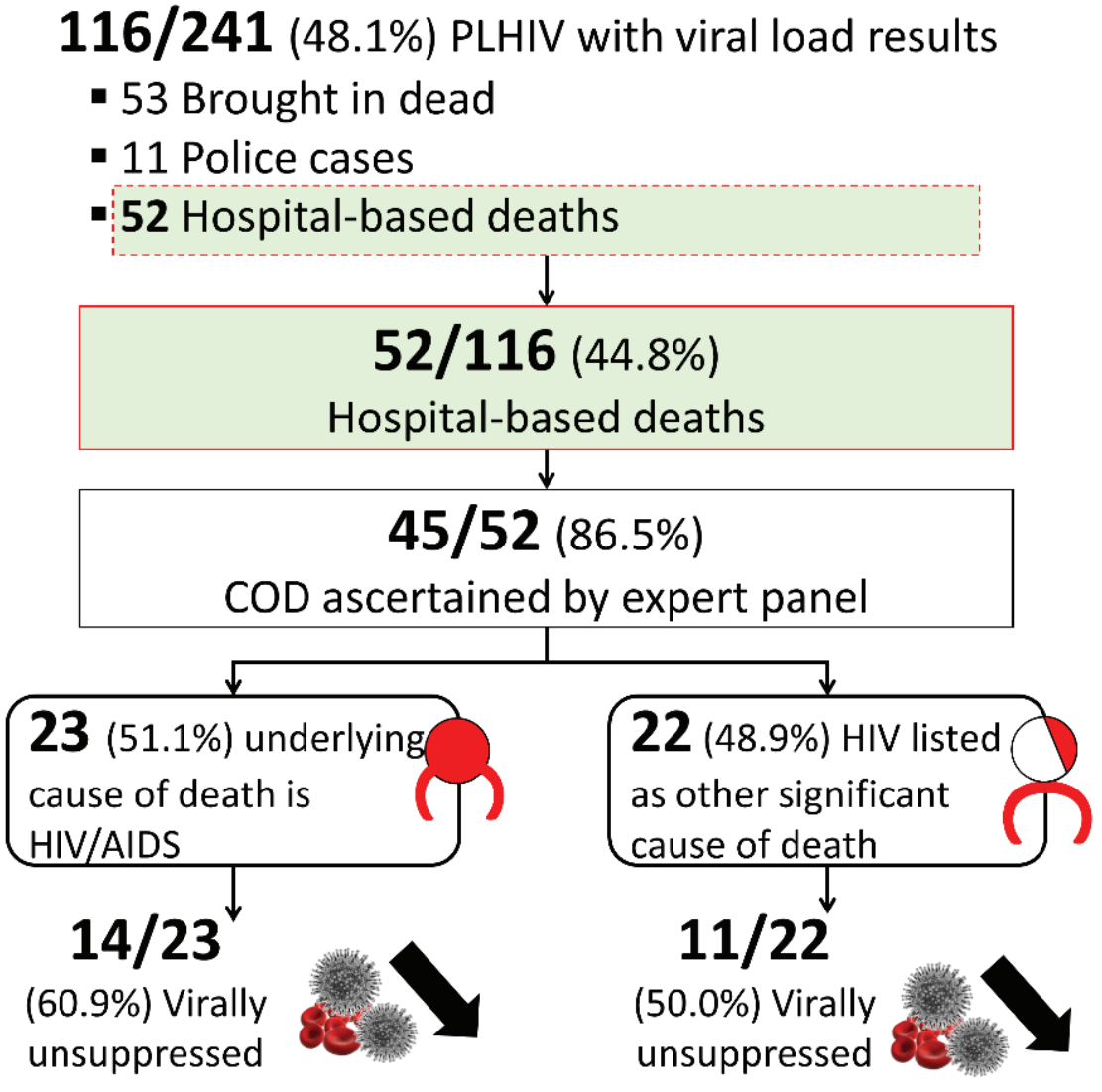

Figure 12: *Viral load suppression rates for deaths due to HIV compared to other causes among PLHIV, Kisumu, 2019*

3.2.6 Quality Of COD Documentation in Hospital D1 Forms

The COD for 236 records which had both D1 and a COD certification by the expert panel were compared. Out of the 236 matched records, 167 (70.8%) had a discrepant underlying COD in the comparison exercise. The reasons for discrepancies were incorrect assignment of COD in the D1 (87.4%) or incorrect sequencing (12.6%), e.g. the underlying COD was documented in the D1 either as an antecedent or an immediate COD.

3.3 Causes of Death at Kisumu East Civil Registry

3.3.1 Notifications of Deaths to the Civil Registry

Kisumu County has three civil registries situated in Nyando, Kisumu West and Kisumu East. Out of the 17,159 expected death notifications in Kisumu County in 2017, only 7,761 (45.2%) were notified to the registrar of births and deaths. Kisumu East registry recorded 3,739 (48.2%) of the reported deaths. Of the notified deaths at the Kisumu East registry in 2017, 3,277 (87.6%) were abstracted. Over three quarters, that is 76.6% (2,511) of these were deaths notified from hospitals using D1 forms. The remaining 766 (23.4%) were notified from the community using D2 forms.

During the study period, both study facilities admitted 938 decedents (excluding stillbirths). For the first six months of 2019, 1,700 death notifications were reported from all facilities in the sub-county. We projected that for both JOOTRH and KCRH, the deaths would be 3,938 for an entire year.

3.3.2 COD Obtained from the Civil Registry and COD certification

In comparing the top 20 underlying COD from the expert panel certification and the 2017 civil registry, HIV/AIDS was the leading cause of mortality for deaths reported at the civil registry; accounting for 6.7% of deaths (Table 6). Though the years and dataset compared are different, this is about one third of the reported 22.4% we found among the hospital-based deaths. Data quality at the civil registry was also suboptimal as 12 of the top 20 CODs in the certification exercise were absent in CODs abstracted from the civil registry notifications.

Table 6: *Leading underlying causes of death, Kisumu, 2019*

20 leading underlying causes of death	Notified (D1) (%)	Hospital (panel) (%)
HIV	6.7	22.4
Hypertensive disease	3.2	9.0
Other cardiovascular diseases		5.0
Endocrine disorders	3.1	3.9
Lower respiratory infections	3.9	3.5
Other conditions arising during the perinatal period	1.5	3.5
Other digestive diseases		2.9
Malaria	3.0	2.6
Cerebrovascular disease	2.3	2.6
Prematurity and low birth weight	2.1	2.4
Road traffic accidents		2.4
Diabetes mellitus	1.9	2.2
Diarrheal diseases		2.0
Other infectious diseases		2.0
Other malignant neoplasms		1.5
Other neoplasms		1.5
Ill-defined diseases (ICD10 R00-R99)		1.5
Birth asphyxia and birth trauma		1.3
Protein-energy malnutrition		1.3
Oesophagus cancer		1.3
Skin diseases		1.3

3.4 Mortality Rates in Kisumu County

The all-cause mortality rate was 1,086 per 100,000 population. Non-communicable diseases contributed to the highest cause-specific mortality (516 per 100,000 population) followed by HIV-associated mortality (513 per 100,000 population) while estimated mortality due to HIV/AIDS was (251 per 100,000 population). Table 7 below shows the mortality rates per 100, 000 population.

Table 7: *Mortality rates*

Mortality rate	Per 100,000 population
All-cause specific mortality rate	1,086
Cause specific mortality rate	
Due to HIV/AIDS	251
GBD I	513
GBD II	516
GBD III	56
HIV associated mortality	312

4.0 OraQuick® Validation Sub-Study Results

4.1 Samples

Of the 697 decedents admitted into JOOTRH, 564 (80.9%) were eligible for the study, and among these, 421 (74.6%) were eligible for blood and oral fluid sample collection (Figure 13). Samples from 267 (63.4%) of the eligible decedents were not collected from the analysis due to presence of blood in the oral cavity. Of the remaining 154 decedents, a total of 132 had matched pre-embalming and post-embalmed samples.

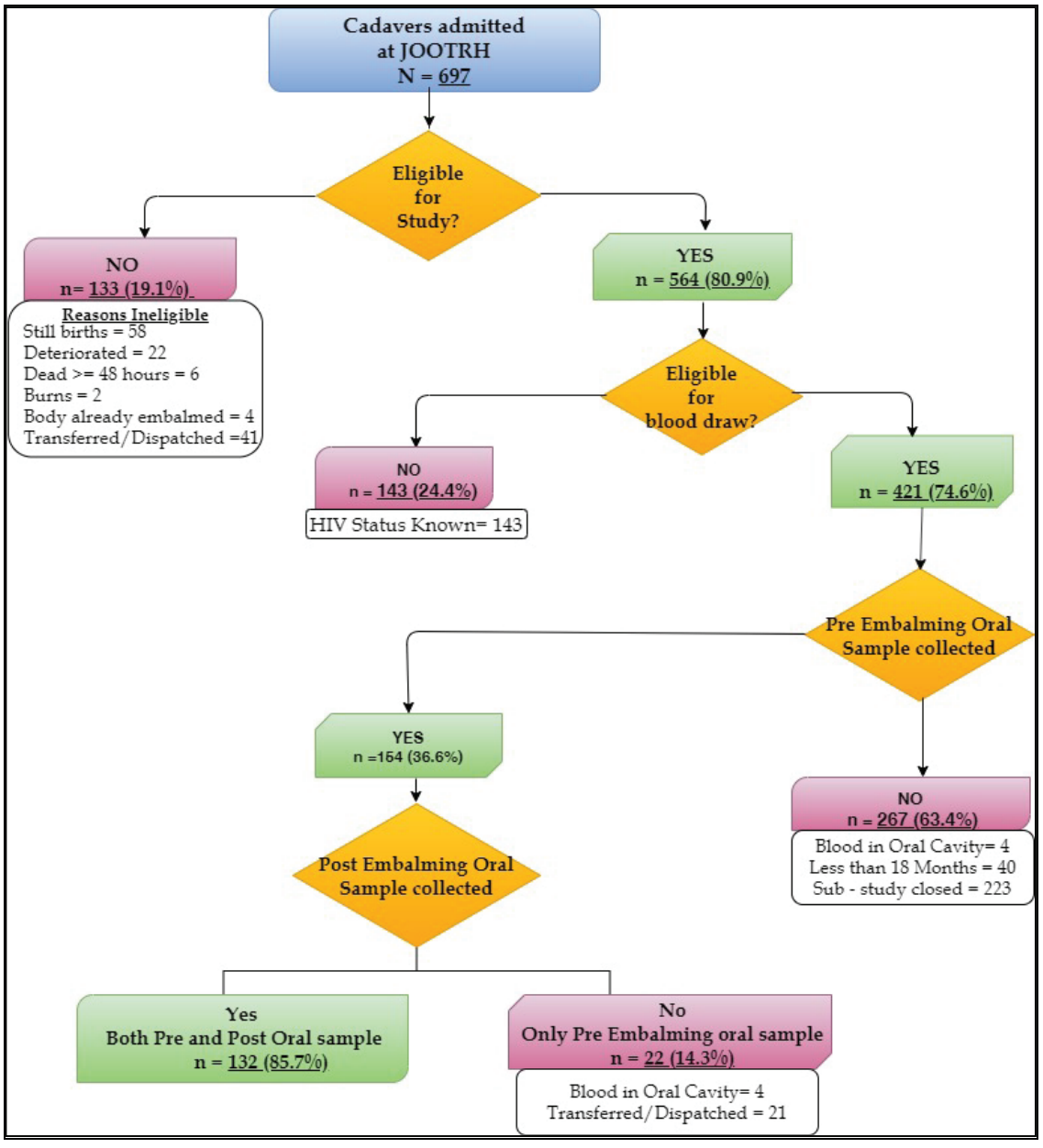

Figure 13: Flow chart enrolment to OraQuick® sub-study

4.2 Demographics

Demographic characteristics of decedents that were enrolled in the OraQuick sub-study are presented in Table 8. Of the 132 decedents enrolled, 117 (88.6%) were 15 years and above; 57 (43%) were female and the median age was 46 years [18 months – 105 years] with 71 (53.4%) having died in the hospital.

Table 8: *Demographic characteristics of the enrolled decedents with both the pre and post preservation oral sample, Kisumu*

	Total	
	N	**%**
Age category:		
Under 15 years	**15**	**11.4**
18 months - 9 years	11	8.0
10 - 14 years	4	3.0
15+	**117**	**88.6**
15 - 24 years	8	6.1
25 - 34 years	22	16.7
35 - 44 years	19	14.4
45 - 54 years	14	10.6
55 - 64 years	13	9.8
65 - 74 years	19	14.4
75+	22	16.7
Sex:		
Male	75	56.8
Female	57	43.2
Decedent Category:		
Hospital deaths	71	53.8
Brought in dead*	10	7.6
Brought in dead†	51	38.6
N	**132**	

*These include police cases e.g. homicides

†These include community-based deaths, transfers from other mortuaries but exclude police cases

4.3 HIV Positivity on OraQuick®

4.3.1 Pre-embalming Performance of OraQuick®

The overall HIV positivity rate among the 132 decedents as determined using the gold standard algorithm was 20.5% (95% CI, 13.9%-28.4%). OraQuick® detected a total of 28 positives of which 25 were true positives; thus, the sensitivity and positive predictive value (PPV) were 92.6% (95% CI, 75.7%-99.1%) and 89.3%, (95% CI, 71.8%-97.7%) respectively for pre-preservation samples. Of the 105 negative samples confirmed by the gold standard, 104 samples tested negative by OraQuick®. Specificity and negative predictive value (NPV) were 97.1% (91.9%, 99.4%) and 98.1% (95% CI, 93.2%-99.8%) respectively. The performance of OraQuick® rapid test against the gold standard for pre-embalmed samples is illustrated in table 9 below.

Table 9: *Pre-embalming Performance of OraQuick® Rapid HIV-1/2 against the gold standard, Kisumu*

	Gold standard (national HIV diagnostic algorithm)			
		Positive (%)	**Negative (%)**	**Total (%)**
OraQuick® results	Positive	25 (89.3)	3 (10.7)	28 (21.2)
	Negative	2 (1.9)	102 (98.1)	104 (78.8)
	Total	**27 (20.5)**	**105 (79.5)**	**132**

4.3.2 Post-embalming Performance of OraQuick®

Post embalmment, OraQuick® detected a total of 30 positives of which 25 were true positives; thus, giving sensitivity and PPV of 92.6% (95% CI, 75.7%-99.1%) and 83.3%, (95% CI, 65.3% -94.4%), respectively. Of the 105 negative samples confirmed by the gold standard, 102 samples were detected negative by OraQuick®. Specificity and NPV were 95.7% (95% CI, 89.2% -98.4%) and 98.0% (95% CI, 93.1%-99.8%) respectively. Table 10 below shows the performance of OraQuick® rapid test against the gold standard for post-embalmed samples.

Table 10: *Post-embalming Performance of OraQuick® Rapid HIV-1/2 against the gold standard, Kisumu*

	Gold standard (national HIV diagnostic algorithm)		
	Positive (%)	**Negative (%)**	**Total (%)**
Positive	25 (83.3)	5 (16.7)[‡]	30 (22.7)
Negative	2 (2.0)[§]	100 (98.0)	102 (77.3)
Total	**27 (20.5)**	**105 (79.5)**	**132**

Based on final HIV result on pre-embalming whole blood. If Determine® was reactive, a First Response® confirmatory test was performed. The final HIV status was positive if the First Response was reactive, otherwise if First Response was negative it was based on a positive DNA PCR test as tiebreaker.

[‡]False positives/false detection rate

[§]False negatives/false omission rate

5.0 Summary, Limitations and Recommendations

5.1 Summary

Although widespread access to ART has reduced HIV-related mortality in high-income countries [29,30], HIV is still the leading cause of death among HIV-infected persons in this study. Nearly a quarter (23.1%) of the certified deaths were due to HIV/AIDS. It was not clear whether these deaths were due to recent or long-standing infection. Among deaths due to HIV/AIDS, fewer than 10% had TB/HIV co-infection. The majority (57.8%) of those whose underlying COD was HIV/AIDS were female. Deaths due to injuries were four times higher among males compared to females. The proportions of deaths due to communicable compared to non-communicable diseases were similar. This is not comparable to other similar settings where the ratio is 2:3 [1], indicating that HIV contributes substantially to the burden of communicable diseases in Kisumu and therefore premature mortality. Other infectious diseases contributed to more deaths among children than among adults.

Implementation of the Kisumu study incorporated lessons learnt from the Nairobi mortuary study. The study included two additional components that were missing in the Nairobi study, i.e., inclusion of children (0-15 years) and the OraQuick® sub-study. The study found it was feasible to collect sufficient blood volumes from children decedents, and the OraQuick® sub-study showed that it is feasible to collect oral swabs and test for HIV using OraQuick® both pre- and post-embalming. Working successfully within mortuary settings was made possible through integration of mortuary staff in the study and coordination of body movement, hospital record abstraction and sample collection with hospital personnel. However, retrieval of hospital records was not always feasible. Coordination with the testing laboratory was also critical due to time limits from sample collection to testing.

Overall, this study was successful in accomplishing its objectives. Below are some of the study limitations to take into consideration when interpreting the findings as well as the recommendations for implementation by the country.

5.2 Limitations

This study had some limitations

- Medical history was only available for hospital-based deaths and in this case the Research Assistants were not able to locate 17.8% of the inpatient files.
- While the current study reports the HIV positivity of 28.3%, a comparison with the prevalence for Kisumu County in the 2018 Kenya HIV estimates (16.3%) cannot be drawn despite the majority of deaths being hospital-based deaths who were likely to be severely ill.
- Documented use of ART in the medical files was relied on to estimate ART use. Given a quarter of the known HIV-infected decedents had no documentation of ART usage in their records, there is a likely underestimation of this indicator.

- Further, the lack of data on ART use limited our ability to interpret some findings such as establishing whether a high viral load was due to treatment failure, poor adherence or lack of treatment.

- While there were 555 hospital deaths, 192 had documented HIV status thus no samples were drawn for both HIV & VL testing (for those that could have tested HIV positive). The study only processed the samples for those decedents that had undocumented HIV status, out of which VL was done for the HIV positives. However, considering that no samples were collected from decedents whose HIV status was documented in the patient charts , VL tests could equally not be done. The VL suppression presented herein is only for a subset of the eligible decedents whose VL was done.

- While the protocols stated that the HIV status was not documented or indicated that the patient had been uninfected for more than three months prior to death, a blood sample was drawn for HIV testing. However, in the analysis all these were considered as undocumented and thus samples were drawn from such decedents.

- The reported number of still births may not be representative of the true incidence of stillbirth in the study population and is not necessarily a reflection of quality of antenatal care at these facilities.

5.3 Recommendations

5.3.1 Data Quality

- Improve documentation in medical files for more accurate surveillance data

  - HIV status was documented in 22.5% of the patient files that were retrieved. Further, a quarter of the known HIV-infected patients who died in hospital had no documentation of ART usage. This documentation is a critical element in optimum diagnosis and patient management therefore, clinicians should be encouraged to inquire and document the diagnosis of HIV infection and ART use as part of standard practice for hospitalized patients.

  - Synchronization of patients records at comprehensive care centre (CCC) and inpatient files should be optimized to ensure detailed patients history as captured in their respective CCC files is available for clinical management upon admission.

- Almost three-quarters of notified deaths at JOOTRH and KCRH had the wrong underlying COD assigned.

  - Capacity building for medical staff on proper completion of D1 forms, correct death certification and timely submission of D1 forms is urgently needed.

- An update of the current D1 & D2 form to include additional WHO-recommended data elements would enhance classification of deaths.

- There is need for concerted effort to improve classification and reporting of deaths occurring in the community including a standardised verbal autopsy tool.
- Data completeness and data entry backlogs were a hindrance while striving to annualize the most current COD for Kisumu East thus, the 2017 civil registry data was selected.
- There is need to standardize and avail data capture tools (for admission and discharge of decedents and autopsy reports) across mortuaries.

5.3.2 HIV Care and Treatment Programme

- The HIV programme should optimize evaluation of the coverage and practice of the treatment and care programme especially in other service delivery points such as inpatient files that equally need the patient information stored at the CCC.
    - ➢ Of those with ART documentation, 20% of HIV-infected decedents were not on ART.
    - ➢ None of the 11 samples for decedents under 15 years of age were virally suppressed. This highlights the need to strengthen PMTCT programming including Early Infant Diagnosis (EID) and ART initiation and other initiatives that aim at improving outcomes for infected children and adolescents.
    - ➢ Mortality reviews should be conducted by clinicians prior to death certification.

To improve on current analysis and estimates, it is recommended that HIV-positive samples be tested for ARV metabolites in the future.

5.3.3 Performance of OraQuick®

- OraQuick® showed high sensitivity and specificity to detect HIV in decedents. The sensitivity of OraQuick®, found through our study is 92.6% at both pre- and post-embalming. These findings are consistent with other evaluations which were done in living subjects [31,32].
- While the sensitivity is lower than WHO minimum requirement for clinical diagnostic testing, OraQuick® is a feasible practical solution for mortuary-based surveillance: minimally invasive, requires minimal training, is conducted on site and relatively inexpensive due to reduced needs for additonal supplies which would be needed to maintain cold-chain during sample transportation to a testing laboratory.

5.3.4 Maternal and Child Health

The most common reason for ineligibility was found to be still births. Identification of still birth was done using patient files of mothers obtained from the wards while others were through oral confirmation by nurses. There is need for further investigation to identify reasons for these still births by strengthening infant mortality audits and developing interventions based on findings. However, it is worth noting that both JOOTRH and KCRH are referral hospitals where complicated and high-risk maternal cases are referred.

5.3.5 Mortuary Surveillance Systems

A formal surveillance evaluation was conducted after the Nairobi mortuary study [20] using the CDC guidelines for evaluating public health surveillance systems [33]. The evaluation showed that implementation of a mortuary study is feasible; however, in spite of being a low-cost system, the sustainability of the mortuary surveillance system was reliant on external funding, as it was not yet incorporated into the national HIV surveillance. In implementing the Kisumu study, lessons learnt from the Nairobi mortuary study were incorporated, including two additional components that were missing in the Nairobi study, i.e., inclusion of children (0-15 years) and the OraQuick® sub-study.

- The study showed it was feasible to collect sufficient blood volumes from paediatric decedents.
- There is need for systems that can accommodate additional processing times for samples beyond regular business hours.
- OraQuick® is a practical, low-cost and minimally invasive alternative to blood sample-based testing for future HIV-associated mortality surveillance activities in the country.
- Findings from the Nairobi and Kisumu studies can serve as foundations for developing policy documents on mortuary and hospital-based surveillance of HIV-associated mortality in Kenya.
- Although conducting mortuary studies is feasible, they are not part of the current surveillance systems and, thus, require additional resources and commitment. Sentinel surveillance (every 2-5 years) at selected mortuaries can be considered as an alternative.

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Appendix 2: Blood Collection Register (M1)

MORTALITY SURVEILLANCE REGISTER

M1

☐ **Participating Mortuary:** 1-Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) 2-Kisumu County Referral Hospital (KCRH)

Study ID	Date of death	Time of death	Date of admission into the mortuary	RA Initials	Time of admission into the mortuary	Cadaver Classification	Cadaver number	Ward No.	Name			Age	Sex	Availability of Cadaver	Eligibity of Cadaver	Reason (s) In-eligible* /unavailable	If cadaver is available and eligible	Blood				Submission Status Tick if data is entered	Cause of Death (CoD) Tracking		Comments
																		For cadavers whose HIV results are not known					Entered	Source	
Code format J-xxxxx for JOOTRH OR K-xxxx for Kisumu County Ref. Hosp. [stick barcode]	Date: DD/MM/YYYY	HH:MM (tick if AM or PM)	Date: DD/MM/YYYY	RA Initials	HH:MM (tick if AM or PM)	Brought in dead [1] Police Case [2] Inpatient [3] Outpatient [4]			First	Middle	Last	Specify: Years [Y], Months [M], Weeks [W], OR Days [D]	Male [M] Female [F] Unknown [UK]	Yes [Y] No [N]	Yes [Y] =Eligible No [N] = Not Eligible	1. Transfered /discharged 2. Burns 3. Deteriorated 4. Still birth 5. dead for ≥48 hours 6. Legal reasons 7. Cannot be found 8. Other (Specify)	**HIV Results known?** Yes -Y/No-N If Yes, Do NOT collect sample If No, collect sample	BL ID Stick barcode	Date Collected DD/MM/YY YY	Time Collected HH : MM (tick if AM or PM)	No. of blood draw attempts (indicate the number in the box and tick the status)	H1	Yes [Y] No [N]	D1 [1] Post Mortem[2] Both [3]	
☐	__/__ /__	☐☐:☐☐ AM [] PM [] Unknown []	__/__ /__		☐☐:☐☐ AM [] PM [] Unknown []	☐	ADM ☐ IPN ☐ INT ☐	☐				☐ ☐	☐	☐	☐	☐	☐	☐	__/__ /__	☐☐:☐☐ AM [] PM []	☐ Successful [ ] Not Successful[ ]	☐	☐	☐	
☐	__/__ /__	☐☐:☐☐ AM [] PM [] Unknown []	__/__ /__		☐☐:☐☐ AM [] PM [] Unknown []	☐	ADM ☐ IPN ☐ INT ☐	☐				☐ ☐	☐	☐	☐	☐	☐	☐	__/__ /__	☐☐:☐☐ AM [] PM []	☐ Successful [ ] Not Successful[ ]	☐	☐	☐	
☐	__/__ /__	☐☐:☐☐ AM [] PM [] Unknown []	__/__ /__		☐☐:☐☐ AM [] PM [] Unknown []	☐	ADM ☐ IPN ☐ INT ☐	☐				☐ ☐	☐	☐	☐	☐	☐	☐	__/__ /__	☐☐:☐☐ AM [] PM []	☐ Successful [ ] Not Successful[ ]	☐	☐	☐	
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☐	__/__ /__	☐☐:☐☐ AM [] PM [] Unknown []	__/__ /__		☐☐:☐☐ AM [] PM [] Unknown []	☐	ADM ☐ IPN ☐ INT ☐	☐				☐ ☐	☐	☐	☐	☐	☐	☐	__/__ /__	☐☐:☐☐ AM [] PM []	☐ Successful [ ] Not Successful[ ]	☐	☐	☐	
☐	__/__ /__	☐☐:☐☐ AM [] PM [] Unknown []	__/__ /__		☐☐:☐☐ AM [] PM [] Unknown []	☐	ADM ☐ IPN ☐ INT ☐	☐				☐ ☐	☐	☐	☐	☐	☐	☐	__/__ /__	☐☐:☐☐ AM [] PM []	☐ Successful [ ] Not Successful[ ]	☐	☐	☐	
☐	__/__ /__	☐☐:☐☐ AM [] PM [] Unknown []	__/__ /__		☐☐:☐☐ AM [] PM [] Unknown []	☐	ADM ☐ IPN ☐ INN ☐	☐				☐ ☐	☐	☐	☐	☐	☐	☐	__/__ /__	☐☐:☐☐ AM [] PM []	☐ Successful [ ] Not Successful[ ]	☐	☐	☐	

Appendix 3: Oral Fluid Collection Register (M2)

M2

MORTALITY SURVEILLANCE ORAL SAMPLE REGISTER

Participating Mortuary: Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH)

Study ID	Cadaver Number	Age	Sex	Pre - embalming sample		Oral [Pre]					Embalming		Post - embalming sample		Oral [Post]					ODK Results Submission Status	Comments
				Pre Sample collected	Reason (s) for not collecting Oral Specimen								Post Sample collected	Reason (s) for not collecting Oral Specimen							
Stick Barcode		Specify: Years [Y], Months [M], Weeks [W], OR Days [D]	Male [M] Female [F] Unknown [UK]	Yes [Y] No [N]	1. Transferred / discharged 2. Burns 3. Deteriorated 4. Still birth 5. Legal reasons 6. Blood in oral cavity 9. Other (specify)	PR ID Stick barcode	Date Collected DD/MM/YYYY	Time Collected HH:MM (tick if AM or PM)	HIV Results Positive[P] Negative [N] Invalid [I] If invalid, repeat test	HIV Results Positive[P] Negative [N] Invalid [I]	Date embalming ended DD/MM/YYYY	Time embalming ended HH:MM (tick if AM or PM)	Yes [Y] No [N]	1. Transferred / discharged 2. Burns 3. Deteriorated 4. Still birth 5. Legal reasons 6. Blood in oral cavity 9. Other(specify)	PS ID Stick barcode	Date Collected DD/MM/YYYY	Time Collected HH : MM (tick if AM or PM)	HIV Results Positive[P] Negative [N] Invalid [I] If invalid, repeat test	HIV Results Positive[P] Negative [N] Invalid [I]	Yes [Y] No [N]	
☐	ADM ☐ IPN ☐ INT ☐	☐ ☐	☐	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	__/__/__	☐☐:☐☐ AM [] PM [] Unknown []	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	☐	
☐	ADM ☐ IPN ☐ INT ☐	☐ ☐	☐	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	__/__/__	☐☐:☐☐ AM [] PM [] Not available []	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	☐	
☐	ADM ☐ IPN ☐ INT ☐	☐ ☐	☐	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	__/__/__	☐☐:☐☐ AM [] PM [] Unknown []	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	☐	
☐	ADM ☐ IPN ☐ INT ☐	☐ ☐	☐	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	__/__/__	☐☐:☐☐ AM [] PM [] Unknown []	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	☐	
☐	ADM ☐ IPN ☐ INT ☐	☐ ☐	☐	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	__/__/__	☐☐:☐☐ AM [] PM [] Unknown []	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	☐	
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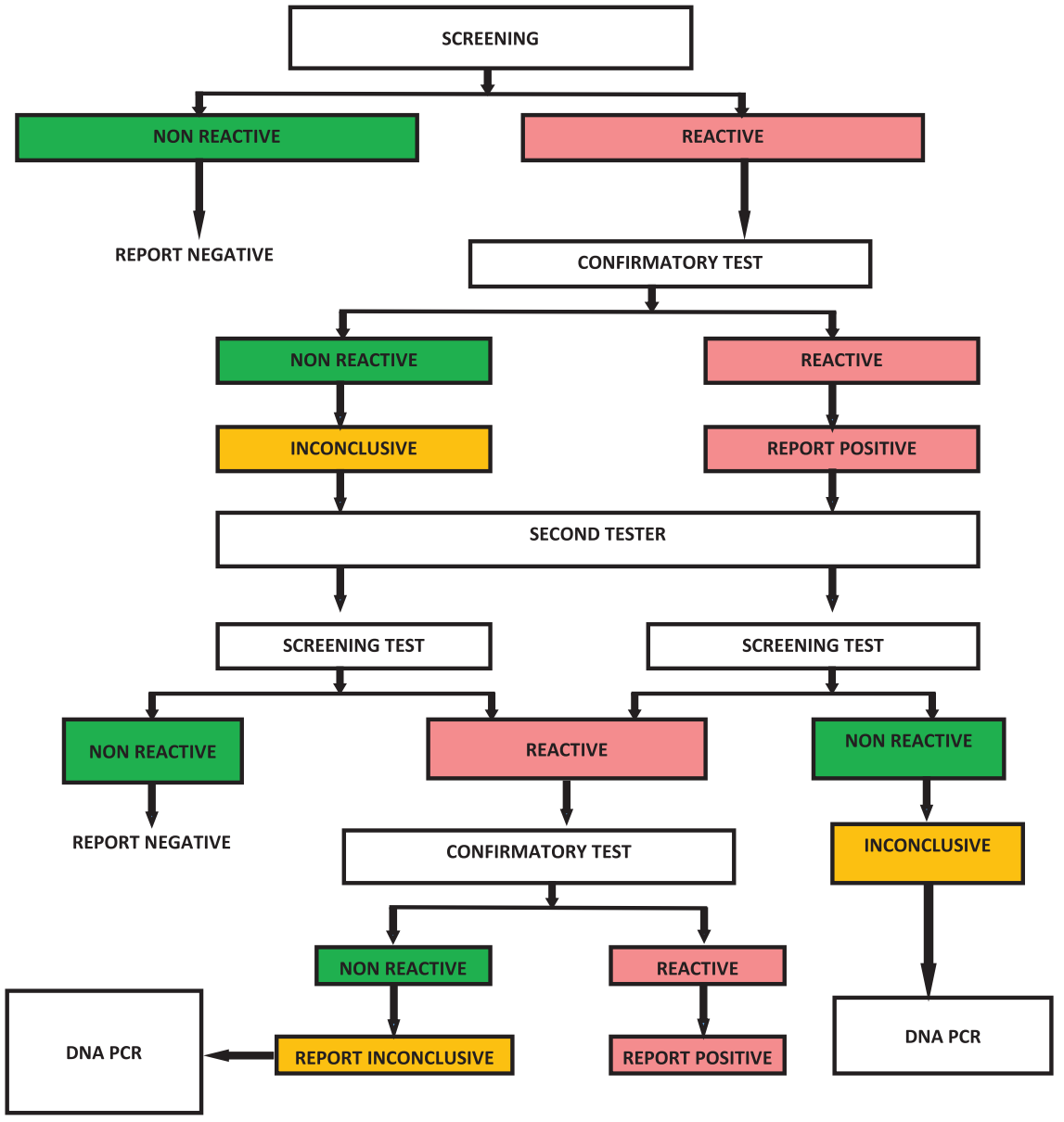
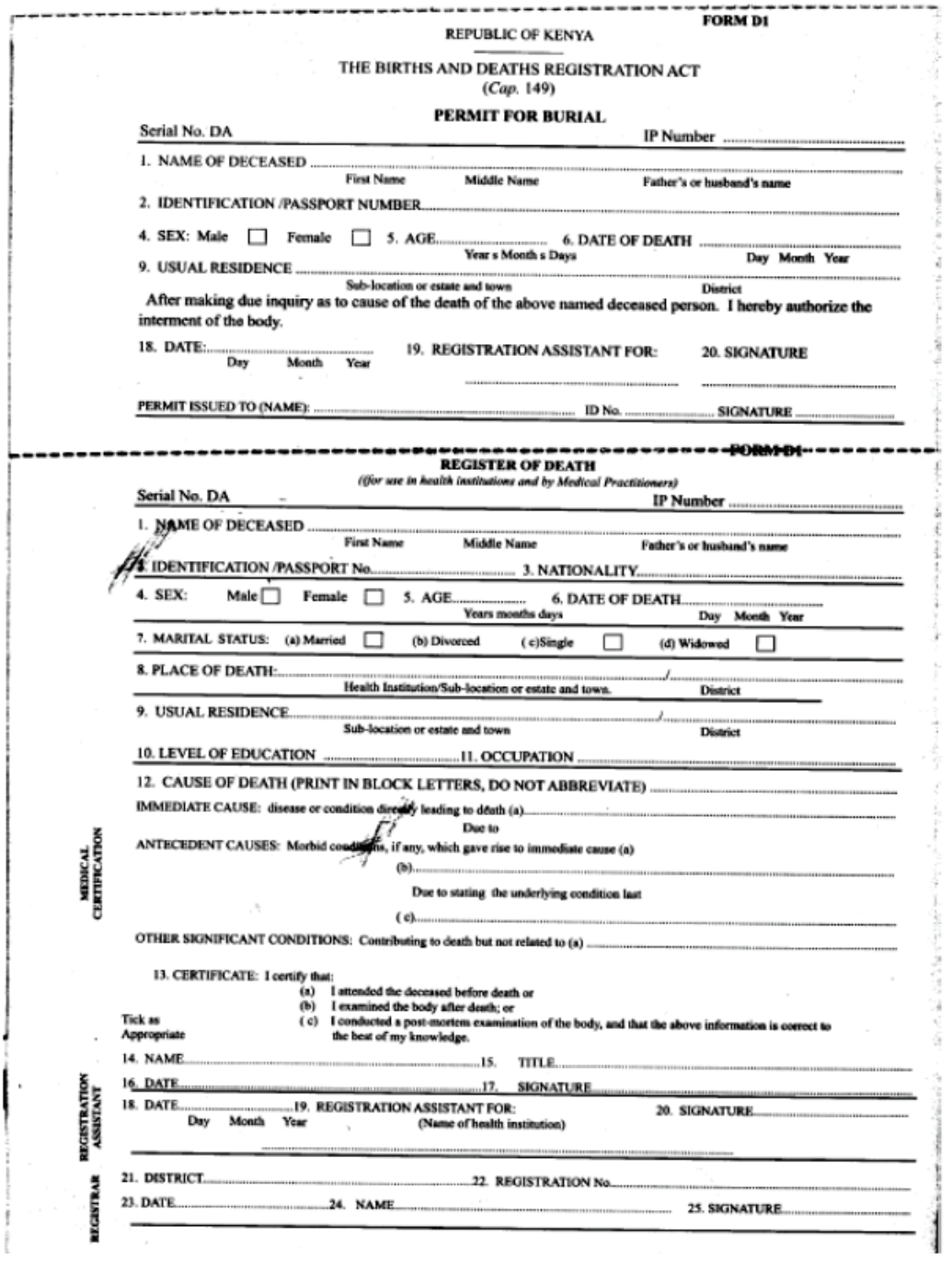
☐	ADM ☐ IPN ☐ INT ☐	☐ ☐	☐	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	__/__/__	☐☐:☐☐ AM [] PM [] Unknown []	☐	☐	☐	__/__/__	☐☐:☐☐ AM [] PM []	☐	☐	☐	

Appendix 4: National HIV Testing Algorithm



Appendix 5: Death Notification Form (D1)



FORM D1

REPUBLIC OF KENYA

THE BIRTHS AND DEATHS REGISTRATION ACT
(*Cap.* 149)

PERMIT FOR BURIAL

Serial No. DA _____ IP Number _____

1. NAME OF DECEASED _____
First Name Middle Name Father's or husband's name

2. IDENTIFICATION /PASSPORT NUMBER _____

4. SEX: Male ☐ Female ☐ 5. AGE _____ 6. DATE OF DEATH _____
Year s Month s Days Day Month Year

9. USUAL RESIDENCE _____
Sub-location or estate and town District

After making due inquiry as to cause of the death of the above named deceased person. I hereby authorize the interment of the body.

18. DATE: _____ 19. REGISTRATION ASSISTANT FOR: 20. SIGNATURE
Day Month Year

PERMIT ISSUED TO (NAME): _____ ID No. _____ SIGNATURE _____

FORM D1

REGISTER OF DEATH
(for use in health institutions and by Medical Practitioners)

Serial No. DA _____ IP Number _____

1. NAME OF DECEASED _____
First Name Middle Name Father's or husband's name

2. IDENTIFICATION /PASSPORT No. _____ 3. NATIONALITY _____

4. SEX: Male ☐ Female ☐ 5. AGE _____ 6. DATE OF DEATH _____
Years months days Day Month Year

7. MARITAL STATUS: (a) Married ☐ (b) Divorced ☐ (c)Single ☐ (d) Widowed ☐

8. PLACE OF DEATH: _____
Health Institution/Sub-location or estate and town. District

9. USUAL RESIDENCE _____
Sub-location or estate and town District

10. LEVEL OF EDUCATION _____ 11. OCCUPATION _____

12. CAUSE OF DEATH (PRINT IN BLOCK LETTERS, DO NOT ABBREVIATE) _____

MEDICAL CERTIFICATION

IMMEDIATE CAUSE: disease or condition directly leading to death (a) _____
Due to

ANTECEDENT CAUSES: Morbid conditions, if any, which gave rise to immediate cause (a)
(b) _____
Due to stating the underlying condition last
(c) _____

OTHER SIGNIFICANT CONDITIONS: Contributing to death but not related to (a) _____

13. CERTIFICATE: I certify that:
(a) I attended the deceased before death or
(b) I examined the body after death; or
Tick as Appropriate
(c) I conducted a post-mortem examination of the body, and that the above information is correct to the best of my knowledge.

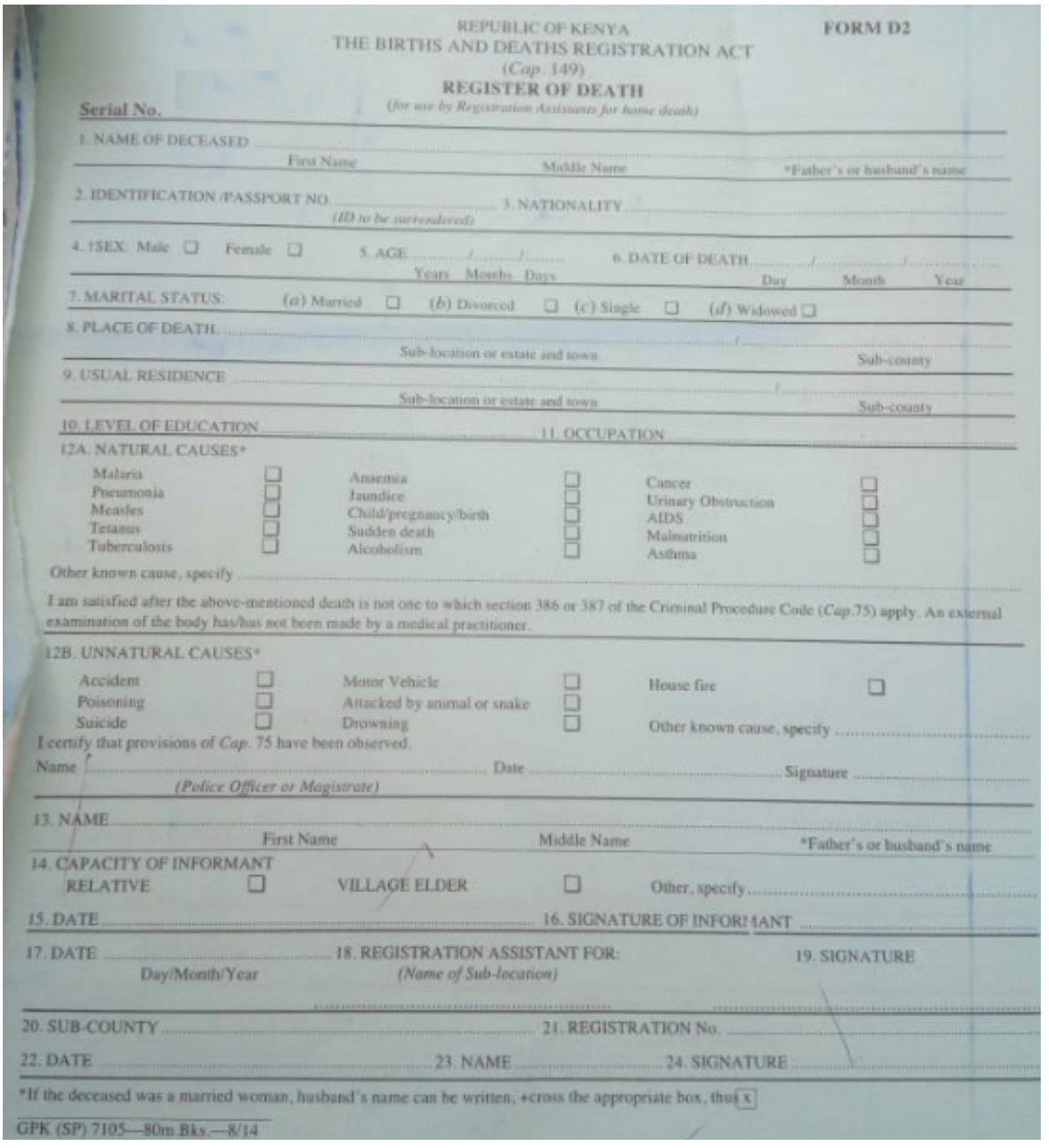
REGISTRATION ASSISTANT

14. NAME _____ 15. TITLE _____
16. DATE _____ 17. SIGNATURE _____
18. DATE _____ 19. REGISTRATION ASSISTANT FOR: 20. SIGNATURE _____
Day Month Year (Name of health institution)

REGISTRAR

21. DISTRICT _____ 22. REGISTRATION No. _____
23. DATE _____ 24. NAME _____ 25. SIGNATURE _____

Appendix 6: Death Notification Form (D2)



REPUBLIC OF KENYA

THE BIRTHS AND DEATHS REGISTRATION ACT

(*Cap*. 149)

FORM D2

REGISTER OF DEATH

(for use by Registration Assistants for home death)

Serial No. _____

1. NAME OF DECEASED _____
First Name Middle Name *Father's or husband's name

2. IDENTIFICATION /PASSPORT NO. _____ 3. NATIONALITY _____
(ID to be surrendered)

4. †SEX: Male ☐ Female ☐ 5. AGE ____/____/____ 6. DATE OF DEATH ____/____/____
Years Months Days Day Month Year

7. MARITAL STATUS: (*a*) Married ☐ (*b*) Divorced ☐ (*c*) Single ☐ (*d*) Widowed ☐

8. PLACE OF DEATH _____/_____
Sub-location or estate and town Sub-county

9. USUAL RESIDENCE _____/_____
Sub-location or estate and town Sub-county

10. LEVEL OF EDUCATION _____ 11. OCCUPATION _____

12A. NATURAL CAUSES*

Malaria	☐	Anaemia	☐	Cancer	☐
Pneumonia	☐	Jaundice	☐	Urinary Obstruction	☐
Measles	☐	Child/pregnancy/birth	☐	AIDS	☐
Tetanus	☐	Sudden death	☐	Malnutrition	☐
Tuberculosis	☐	Alcoholism	☐	Asthma	☐

Other known cause, specify _____

I am satisfied after the above-mentioned death is not one to which section 386 or 387 of the Criminal Procedure Code (*Cap*.75) apply. An external examination of the body has/has not been made by a medical practitioner.

12B. UNNATURAL CAUSES*

Accident	☐	Motor Vehicle	☐	House fire	☐
Poisoning	☐	Attacked by animal or snake	☐		
Suicide	☐	Drowning	☐	Other known cause, specify	_____

I certify that provisions of *Cap*. 75 have been observed.

Name _____ Date _____ Signature _____
(Police Officer or Magistrate)

13. NAME _____
First Name Middle Name *Father's or husband's name

14. CAPACITY OF INFORMANT
RELATIVE ☐ VILLAGE ELDER ☐ Other, specify _____

15. DATE _____ 16. SIGNATURE OF INFORMANT _____

17. DATE _____ 18. REGISTRATION ASSISTANT FOR: 19. SIGNATURE
Day/Month/Year *(Name of Sub-location)*

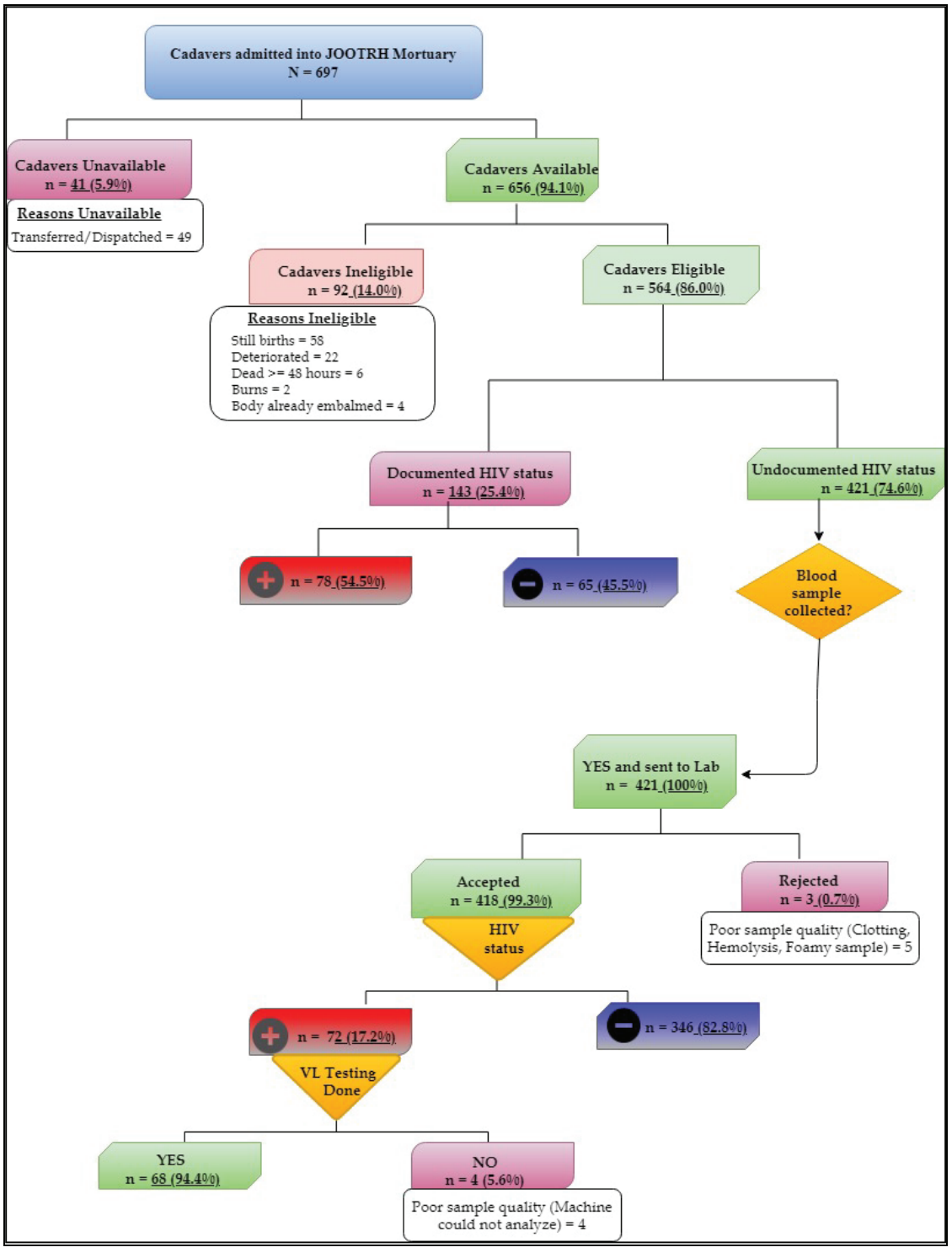
20. SUB-COUNTY _____ 21. REGISTRATION No. _____

22. DATE _____ 23. NAME _____ 24. SIGNATURE _____

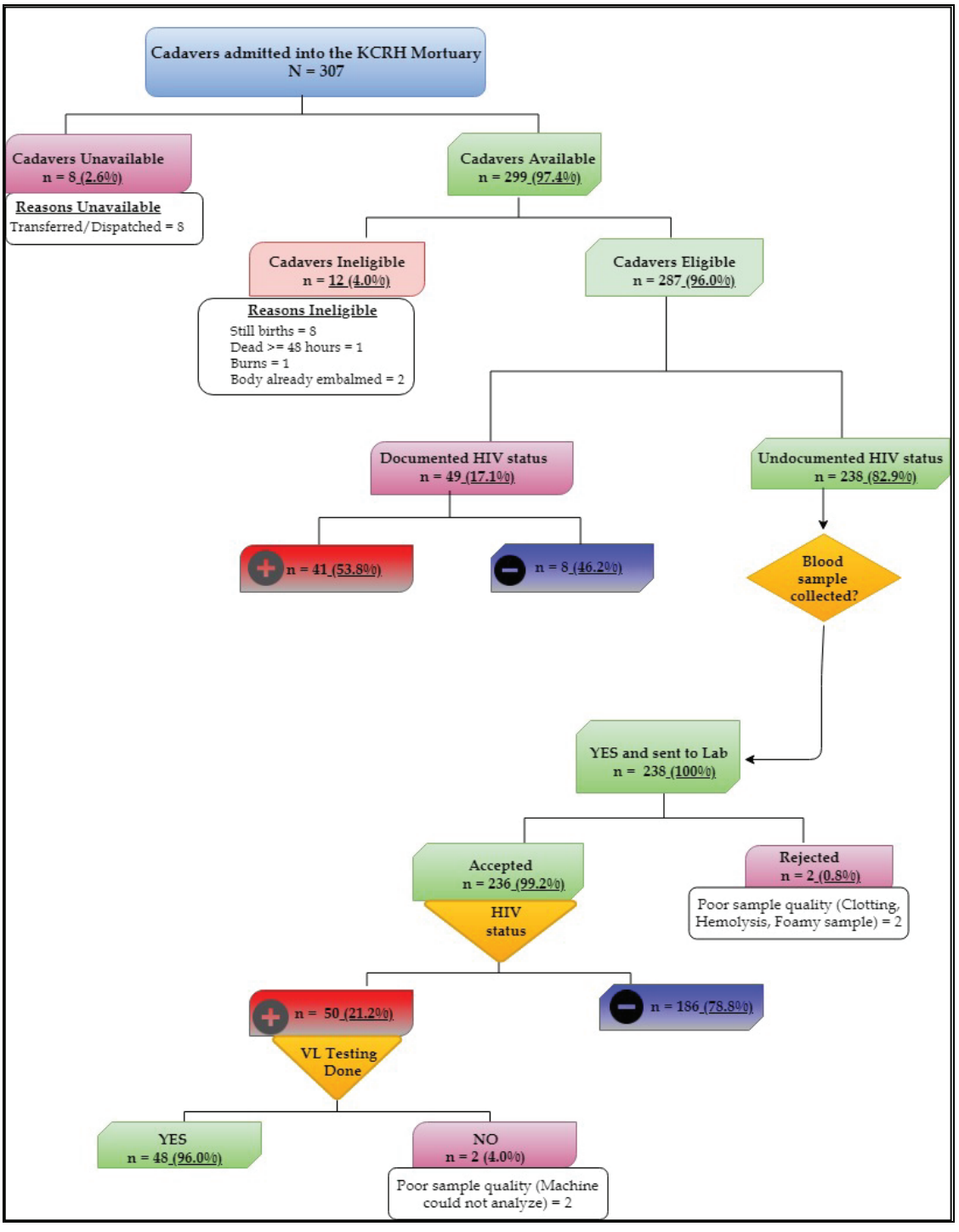
*If the deceased was a married woman, husband's name can be written, +cross the appropriate box, thus [x]

GPK (SP) 7105—80m Bks.—8/14

Appendix 7: Flow Chart for JOOTRH



Appendix 8: Flow Chart for KCRH



Appendix 9: COD Panelist Summary Form

Part A: COD Panelist Summary Form

[Comprised of Parts A-1 to A-6 to be Completed by Individual Panelist/Panel]

Review type: O Initial O For QC O Panel Discussion

Facility (Circle or Check Appropriately):

O JOOTRH

O Kisumu County Referral Hospital

A-1: Case Summary

Study ID:	[ ][ ][ ][ ] *from tagged file (format **J###** or **K###**)*
Sex:	O Male O Female O Unknown
Age at death	_____ (tick; years [Y], months [M] or days [D])
Date of death	_____
Date of most recent hospitalization before death: _____	
If date of hospitalization is missing, approximate days/months hospitalized: _____	

A-2: Summary of Conditions, Medical History and Diagnosis Before Death

Summarize the case as if writing a discharge or death note for a patient's chart.

A-2 (i): *Presenting complaints, HPI, pre-existing conditions and developments while admitted. (Please include comments on peculiarities or special aspects about the chart)*

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.....
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.....

A-2 (ii) *Laboratory and Radiological Investigations Dates and Findings (start with most recent).*

Include post mortem HIV and VL test results:

Date	Investigation	Findings

A-3: HIV Status Documentation and Association with Mortality

A-3 (i) HIV Status Documentation

1	Known positive at time of hospitalization		O Yes O No (if Yes, go to 4: if No, go to 2)
2	If No, tested for HIV during this hospitalization?		O Yes O No *(No here means HIV status unknown)* (if No, go to A-3)
3	If tested, HIV test result		O Positive O Negative O Unknown If negative go to A-3 (iv)
4	On HAART (at or during hospitalization)?	O Yes O No	If yes, current regimen…… …… …..…… Duration on HAART? |__|__|__|__|__| O Duration unknown (tick; years [Y], months [M] or days [D])
5	Are most recent viral load results available?	O Yes O No	…… Copies/ml or …… LDL/Undetectable

A-3 (ii) HIV Symptoms Documentation in Patient Chart

Conditions where a presumptive diagnosis can be made based on clinical signs or simple investigations

QN	Sign/symptom/illness/opportunistic infections	Documented?
1	HIV wasting syndrome	Yes O No O
2	Pneumocystis pneumonia	Yes O No O
3	Recurrent severe or radiological bacterial pneumonia	Yes O No O
4	Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration)	Yes O No O
5	Oesophageal candidiasis	Yes O No O
6	Extrapulmonary TB	Yes O No O
7	Kaposi's sarcoma	Yes O No O
8	Central nervous system (CNS) toxoplasmosis	Yes O No O
9	HIV encephalopathy	Yes O No O
10	Extrapulmonary cryptococcosis including meningitis	Yes O No O
11	Disseminated non-tuberculous mycobacteria infection	Yes O No O
12	Progressive multifocal leukoencephalopathy (PML)	Yes O No O
13	Candida of trachea, bronchi or lungs	Yes O No O
14	Cryptosporidiosis	Yes O No O
15	Isosporiasis	Yes O No O
16	Visceral herpes simplex infection	Yes O No O
17	Cytomegalovirus (CMV) infection (retinitis or of an organ other than liver, spleen or lymph nodes)	Yes O No O
18	Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis, penicilliosis)	Yes O No O
19	Recurrent non-typhoidal salmonella septicaemia	Yes O No O
20	Lymphoma (cerebral or B cell non-Hodgkin)	Yes O No O
21	Invasive cervical carcinoma	Yes O No O
22	Visceral leishmaniasis	Yes O No O

A-3 (iv) Cause of death *as documented in patient's chart (abstracted from chart)*

.....
.....
.....

A-4: Panelist's Cause of Death Determination:

Disease or condition directly leading to death

IMMEDIATE CAUSE: Disease or condition directly leading to death (a) .....
.....
.....
.....

Approximate interval between onset and death: [_____] Time units:

O Hours O Days O Weeks O Months

Due to:

ANTECEDENT CAUSE: Morbid conditions, if any, which gave rise to immediate cause (b): .....
.....
.....
.....

Approximate interval between onset and death: [_____] Time units:

O Hours O Days O Weeks O Months O Years

ANTECEDENT CAUSE: Due to, stating the underlying cause last (c): .....
.....
.....
.....

Approximate interval between onset and death: [_____] Time units:

O Hours O Days O Weeks O Months O Years

UNDERLYING CAUSE: Due to, stating the underlying cause last (d): .....
.....
.....
.....

Approximate interval between onset and death: [_____] Time units:

O Hours O Days O Weeks O Months O Years

OTHER SIGNIFICANT CONDITIONS: Contributing to death but not related to (a):

.....
.....
.....

Approximate interval between onset and death: [_____] Time units:

O Hours O Days O Weeks O Months O Years

OTHER SIGNIFICANT CONDITIONS: Contributing to death but not related to (a):

.....
.....
.....

***Approximate interval between onset and death*:** [_____] Time units:

O Hours O Days O Weeks O Months O Years

OTHER SIGNIFICANT CONDITIONS: Contributing to death but not related to (a):

……
……
……

***Approximate interval between onset and death*:** [_____] Time units:

O Hours O Days O Weeks O Months O Years

A-5: Conclusion:

Was cause of death (COD)determined? O Yes O No)

If COD was not determined, why was panellist unable to determine it?

A-6 (*Complete this section only for patient charts discussed by a panel (2 or more panellist MOs)*

If Panel discussion: Panelist consensus results (for underlying cause)

O Unanimous Consensus (100%) O Non-unanimous Consensus (51-99%)

O Non-consensus (50% or less)

List contributing factors/reasons why consensus was not reached for underlying COD (e.g. not enough data, different interpretation of results……

……

……

Panelist Medical Officer initials………

OR

If case concluded by panel discussion:

Panelist 1_____

Panelist 2 _____

Panelist 3 _____

Panelist 4_____

Date form completed: ……..(dd/mm/yy)

Appendix 10: Hospital Records Link Sheet

H1

MORTALITY SURVEILLANCE

Hospital Records Link Sheet

v 16.08.18

IDENTIFICATION

Mortuary: ☐ Study ID: ☐ IPN No. ☐

1- JOOTRH 2 - Kisumu County Referral Hospital 3 - Other, specify: _____

DEMOGRAPHICS

Deceased name initials: *First.Middle.Last* ☐☐☐

Date of birth (DD/MM/YYY) ☐☐/☐☐/☐☐☐☐

Age
Specify: Years [Y], Months [M], weeks [W], or Days [D] ☐☐ ☐

Deceased Sex:
☐ 1 - Male
☐ 2 - Female
☐ 3 - Unknown

Date of death (DD/MM/YYY) ☐☐/☐☐/☐☐☐☐

Time of death(HH:MM) ☐☐:☐☐
AM [ ] PM [ ]
Unknown [ ]

HOSPITAL RECORDS

1	Ward number ☐☐	Hospital file available: Yes O / No O	If yes go to 2 If no collect blood
2	HIV results available from hospital records?	Yes O / No O	If yes go to 3 If no collect blood
3	HIV STATUS Known positive at hospitalization	Yes O No O	If yes, record status If No, go to 3a
3a	If no, were they tested for HIV at this hospitalization?	Yes O No O	If Yes, go to 3b
3b	If tested, HIV test result	Positive O	Do not collect blood
		Negative O	Check the date
		>3 months O	Collect blood
		≤ 3 months O	Do not collect blood
	Notes		

Appendix 11: Laboratory Reporting Form

KEMRI/CGHR HIV-R LABORATORY

RAPID HIV TESTING REPORTING FORM

STUDY/PROTOCOL_____

PARTICIPANT ID _____ **Visit code:** _____ **Collection Date:** ___/___/___ **collection Time:** ____ **Testing Date:** ___/___/___

ALERE DETERMINE KIT Lot: _____ **Exp date:** _____

Assay Type	Start Time	Stop Time	Results • Positive • Negative • invalid	Results Interpreted By(Initials)	Interpretation Time	Results Confirmed By(Initials) Initials	Confirmed Time
Determine HIV 1/2							

FIRST RESPONSE KIT Lot: _____ **Exp date:** _____

Assay Type	Start Time	Stop Time	Results • Positive • Negative • invalid	Results Interpreted By Initials	Interpretation Time	Results Confirmed By Initials	Confirmed Time
First Response HIV 1/2							

FINAL RESULTS: Non-Reactive (Negative) ❑ Reactive (Positive) ❑ Invalid ❑ Indeterminate ❑

Analyst_____ **Date:** _____

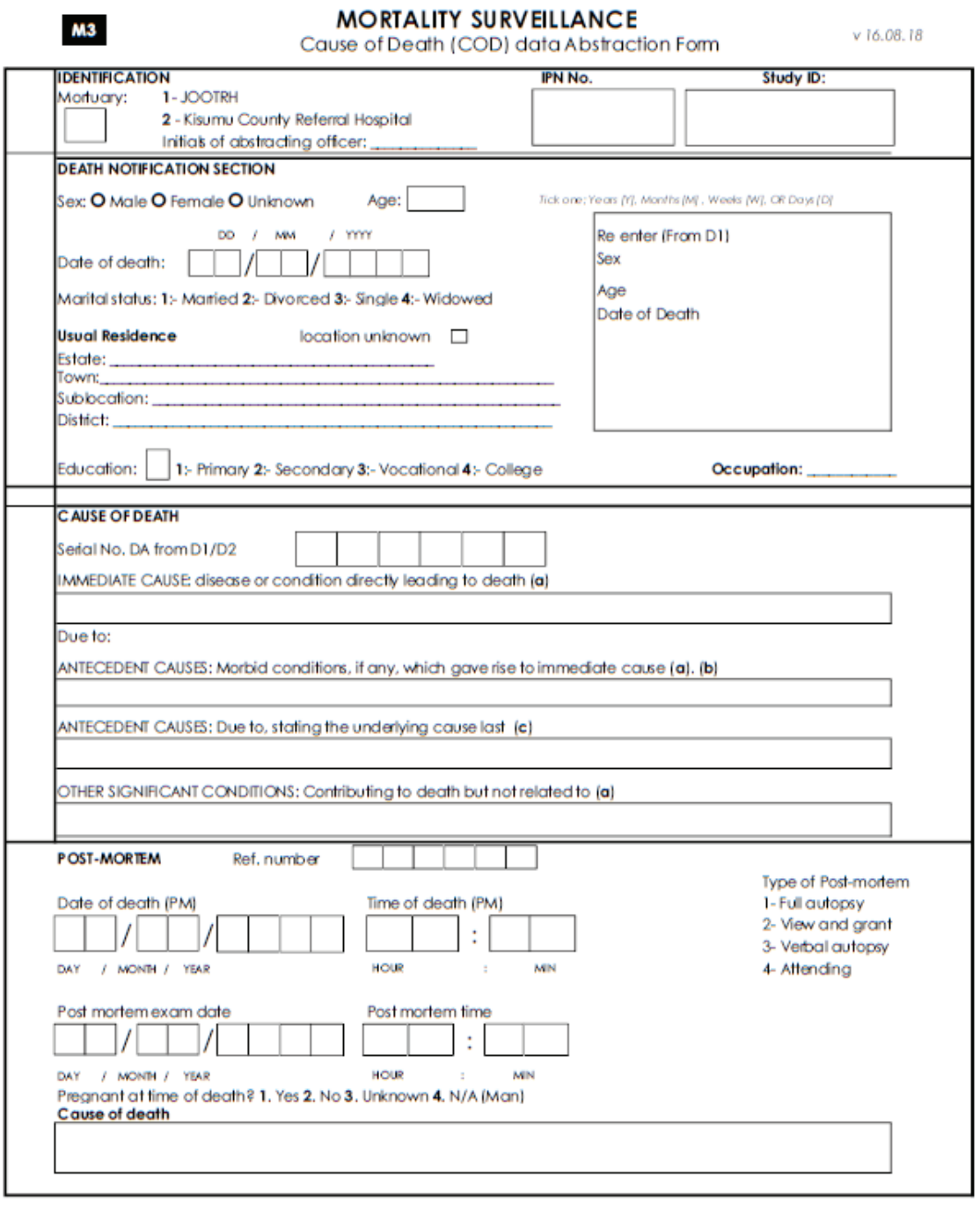
Reviewed by:_____ **Date:**_____

Page 1 of 1

Version: Original

Ref Doc: 165&167

Appendix 12: Cause of Death Data Abstraction Form (M3)



M3

MORTALITY SURVEILLANCE
Cause of Death (COD) data Abstraction Form

v 16.08.18

IDENTIFICATION
Mortuary: **1**- JOOTRH
2 - Kisumu County Referral Hospital
Initials of abstracting officer: _____

IPN No.

Study ID:

DEATH NOTIFICATION SECTION

Sex: O Male O Female O Unknown Age:

Tick one: Years (Y), Months (M) , Weeks (W), OR Days (D)

DD / MM / YYYY
Date of death: / /

Marital status: **1**:- Married **2**:- Divorced **3**:- Single **4**:- Widowed

Usual Residence location unknown
Estate: _____
Town: _____
Sublocation: _____
District: _____

Re enter (From D1)
Sex
Age
Date of Death

Education: **1**:- Primary **2**:- Secondary **3**:- Vocational **4**:- College

Occupation: _____

CAUSE OF DEATH

Serial No. DA from D1/D2

IMMEDIATE CAUSE: disease or condition directly leading to death **(a)**

Due to:

ANTECEDENT CAUSES: Morbid conditions, if any, which gave rise to immediate cause **(a)**, **(b)**

ANTECEDENT CAUSES: Due to, stating the underlying cause last **(c)**

OTHER SIGNIFICANT CONDITIONS: Contributing to death but not related to **(a)**

POST-MORTEM Ref. number

Date of death (PM) / / DAY / MONTH / YEAR

Time of death (PM) : HOUR : MIN

Type of Post-mortem
1- Full autopsy
2- View and grant
3- Verbal autopsy
4- Attending

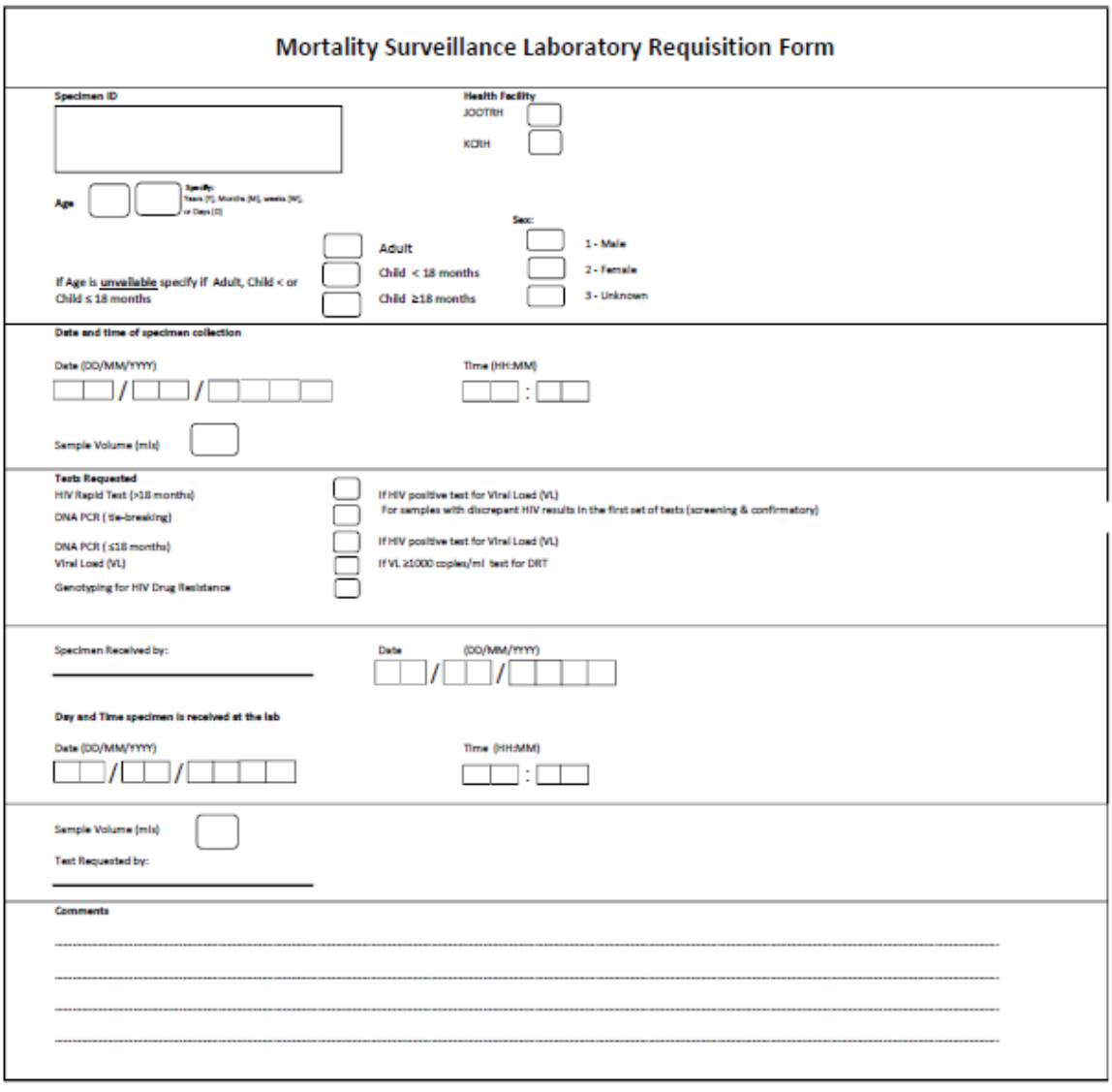
Post mortem exam date / / DAY / MONTH / YEAR

Post mortem time : HOUR : MIN

Pregnant at time of death? **1**. Yes **2**. No **3**. Unknown **4**. N/A (Man)

Cause of death

Appendix 13: Laboratory Request Form



Mortality Surveillance Laboratory Requisition Form

Specimen ID

Health Facility
JOOTRH ☐
KCRH ☐

Age ☐☐ Specify: Years [Y], Months [M], weeks [W], or Days [D]

Sex:
1 - Male ☐
2 - Female ☐
3 - Unknown ☐

If Age is unreliable specify if Adult, Child < or Child ≤ 18 months
Adult ☐
Child < 18 months ☐
Child ≥18 months ☐

Date and time of specimen collection

Date (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐ Time (HH:MM) ☐☐:☐☐

Sample Volume (mls) ☐

Tests Requested

HIV Rapid Test (>18 months) ☐
DNA PCR (tie-breaking) ☐
If HIV positive test for Viral Load (VL)
For samples with discrepant HIV results in the first set of tests (screening & confirmatory)

DNA PCR (≤18 months) ☐
Viral Load (VL) ☐
If VL ≥1000 copies/ml test for DRT

Genotyping for HIV Drug Resistance ☐

Specimen Received by: _____ Date (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

Day and Time specimen is received at the lab

Date (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐ Time (HH:MM) ☐☐:☐☐

Sample Volume (mls) ☐

Test Requested by: _____

Comments

Appendix 14: Sample Manifest

Mortality Surveillance Study

Sample Manifest for Blood Specimen

Facility name: _____ **Date**:_____

S.No	Blood Specimen ID	Date Collected (DD/MM/YY)	Time Received at CRC lab (HH/MM)	Samples Labelled Well (Yes/No)	Samples Correctly packaged Yes/No	Quality Code (s)	CRC lab staff receiving or Rejecting samples (initials)	Comments

Quality Codes:

1) Acceptable – No Rejection
2) Broken/cracked/open container
3) Haemolysis
4) Leaking container
5) Insufficient blood
6) Clotting
7) Incorrectly labelled/unlabelled
8) Specimen lost
9) Specimen mix-up
10) Others (specify)

Appendix 15: Summary of Successful Blood Draw Attempts

Number of Blood Draw Attempts	Counts N=659
1	480 (72.8%)
2	116 (17.6%)
3	38 (5.8%)
4	18 (2.7%)
5	7 (1.1%)

Appendix 16: Kisumu County Department of Health Letter of Support

COUNTY GOVERNMENT OF KISUMU

Telegrams: "PRO.(MED)"
Tel: 254-057-2020105
Fax: 254-057-2023176
E-mail: kisumucdh@gmail.com

When replying please quote:

County Director of Health,
Kisumu.
P. O. Box 721-40100,
KISUMU.

DEPARTMENT OF HEALTH

RE: GN 133 VOL. IX (326)

Date: November 14, 2018

To:
Associate Director for Science,
Division of Global HIV and TB,
Centers for Disease Control and Prevention

Re: Letter of Support for HIV Mortuary Surveillance

Kisumu County Department of Health in partnership with the National AIDS and STI Control Programme (NASCOP) intends to implement routine surveillance of HIV testing of all cadavers admitted to hospital mortuaries with unknown HIV status. The goal of this surveillance activity is to provide information on HIV-associated mortality and deaths among HIV-infected persons in Kisumu County.

The county directs that all deaths, except those of known HIV-positive status or that were tested for HIV during the hospitalization leading to death, will be tested for HIV when resources allow, unless otherwise inappropriate due to legal or religious reasons. All the samples will be collected and handled as per an approved protocol and guided by the Anatomy Act CHAP 249 on handling of samples from the dead[1]. HIV testing will be done according to the Ministry of Health guidelines on HIV testing in Kenya[2] and supports the Kenya HIV Prevention and Control Act[3]. The results of the HIV test will be maintained confidentially as per national guidelines for disclosure and used for public health action or to support the determination of cause of death upon request by the pathologist examining the case.

[1] The Anatomy Act, Chapter 249
[2] National AIDS and STI Control Programme Ministry of Health. Guidelines for HIV Testing Services 2015.
[3] The Kenya HIV & AIDS Prevention and Control Act

This activity will complement the existing data sources for HIV program planning and HIV surveillance in Kenya. We look forward to cooperating with you this important surveillance activity.

Dr. Onyango D.

County Director of health

Kisumu County.

CC

Dr. Kigen Bartilol,

Head, National AIDS and STI Control Program,

Ministry of Health

National AIDS and STI Control Programme (NASCOP)
Ministry of Health, Kenya
P.O Box: 19361, Code: 00202 Nairobi, Kenya
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E: headnascop.moh@gmail.com

HARAMBEE

NASCOP

COUNTY GOVERNMENT OF KISUMU
HARBOUR OF PROSPERITY

USA Marafiki

KENYANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS
PEPFAR

UCSF Institute for Global Health Sciences
Global Strategic Information

KENYA MEDICAL RESEARCH INSTITUTE
KEMRI

JOOTRH
QUALITY HEALTH CARE