MINISTRY OF HEALTH

Utilization of Viral Load Test Results a Quality Improvement Collaborative

Change Package

March 2017 to July 2018

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Disclaimer:

The contents of this change package are the responsibility of ICAP and do not necessarily reflect the views of the United States Government.

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Introduction

ICAP Kenya Quality Improvement Collaborative to Improve Timely Completion of Enhanced Adherence Counseling and Timely Switch to Second-line Antiretroviral Therapy among Eligible Patients.

Project Description

In collaboration with the U.S. Centers for Disease Control and Prevention (CDC) Kenya, the Ministry of Health (MoH) of Kenya and the Kenyan National AIDS & STI Control Program (NASCOP), ICAP launched a routine viral load testing (RVLT) quality improvement collaborative (QIC) at 30 facilities in Siaya County, Kenya in March 2017. Two aim statements were developed, based on a 12-month retrospective baseline analysis conducted in September 2016:

1. Increase the proportion of clients with an unsuppressed viral load (UVL)[1] who complete three enhanced adherence counseling (EAC) sessions within four months of receiving high viral load (VL) test results from a baseline of 18%* to 90% between April 2017 and May 2018; and
2. Increase the proportion of clients with a repeat UVL who are switched to second-line antiretroviral therapy (ART) within two months of receiving repeat high VL test results from a baseline of 36%* to 90% between April 2017 and May 2018.

The following describes successful change ideas (interventions) identified and tested during the 14-month implementation phase of the project that can be scaled and spread to improve timely completion of the nationally recommended EAC sessions and timely switch to second-line ART regimens among eligible clients.

[1] This project defined unsuppressed (high) viral load as greater than 1,000 copies/mL

Summary of Key Recommendations

1.1. Human Resources Modification

- Task shifting certain responsibilities to other cadres for efficiency in service delivery e.g. the nurses can also conduct home visits as well as provide adherence counseling.
- Develop and utilize a working schedule for the facility-based staff entailing a proper hand-off process from staff members who plan to have some time-off and others.
- Every client with UVL is assigned a case manager (member of the MDT) whose main duty is to ensure the clients receive interventions in time.

1.2. Viral load test results management, Data Quality and Documentation

- Appoint rotational VL focal person to utilize NASCOP Early Infant Diagnosis/Viral Load (EID/VL) System at the health facility, download results on a daily basis, and document results in relevant registers.
- Flag unsuppressed results for immediate follow-up
- Filling of clients' file with unsuppressed VL and/ or on second-line regimen in a separate filing area
- Facility based Health Records and Information Officer to conduct weekly reviews for data quality in the High VL Register
- Color code client files using stickers to indicate the last EAC session completed
- Review client contact information at every visit

1.3. Workflow Modification

- Utilize counseling summary tool to concisely convey findings from other EAC tools
- Conduct and document pill count during all clinical consultations
- Develop and utilize an EAC tool to standardize counseling sessions
- Convene MDT1 and MDT2 meetings to review clients with UVL, discuss and address barriers to adherence prior to switching to second-line regimen.
- Implement retrieving files a day before clinic appointment.
- Schedule 30-day follow-up appointment for all clients after VL sample collection.
- Provide convenient appointment and support group scheduling
- The QI team defines a maximum number of clients to be given clinic appointments per day
- Offer peer-led psychosocial support groups tailored for specific patient population.

1.4. Client and Family Education and Engagement

- Contact clients (via SMS or phone call) a day prior to their appointment dates, usually a peer educators' responsibility
- Introduce and enroll clients from the same family into family-centered care, PAMA care.
- From a peer perspective, engage virally suppressed clients to share their stories. This should be voluntary.
- Provide pills boxes and train clients on how to use them, this boosts adherence to medications.

1.5. Healthcare Worker Capacity Building

- Conduct on-the-job training and mentorship especially on tools to optimize and standardize services.

Change Package

Change Idea	How Change Idea was Implemented
Change Concept: Human Resources Modification	
Appoint rotational VL focal person to oversee results tracking and documentation *(Applicable in all facilities)*	● The quality improvement (QI) team develops a pool of volunteer VL focal persons and agrees upon a rotating schedule » VL focal persons must be a health care worker in the facility ● The QI team develops a list of all pending VL test results ● Each day, the VL focal person is responsible for: » Updating the list of pending results (as results are received they are crossed off the list); » Sharing a copy of the list with the facility MDT and sub-county lab focal persons for follow-up; » Monitoring documentation of VL test results received by the facility; and » Flagging UVL results for immediate action
Implement task shifting to reduce clinical workload *(Applicable in all facilities)*	● The QI team, facility leadership and nurse in-charge meet to discuss possible task shifting to reduce workload ● Based on group consensus, tasks are shifted (i.e. reallocated): » Laboratory technicians take responsibility for updating VL Sample Tracking Log (as samples are collected and results are received) from nurses » Clinicians or designated staff takes responsibility for updating the VL Monitoring Log from peer educators » Adherence counselors or a designated health care worker take responsibility for updating the High VL Register from peer educators » Peer educators or a designated health care worker take responsibility for matching VL results with patient files and restoring them per facility standards (previously unassigned duty)
Assign individual facility-based case managers to monitor UVL patients' care *(Applicable in all facilities)*	● Adherence counselor or a designated health care worker lists all clients with UVL ● During weekly multidisciplinary team (MDT) meetings, the nurse in-charge assigns each client with UVL to a member of the MDT to act as case manager » MDT members are facility-based clinic staff ● Case managers are responsible for tracking their individual client(s) to ensure they receive timely interventions (see Appendix 1 for case manager standard operating procedures, or SOPs) ● Progress reports are provided during weekly MDT meetings
Implement home visit task shifting	● Print copies of NASCOP Home Visit Checklist (Appendix 2) to standardize case manager home visits

(Applicable in all facilities)	● During weekly MDT meeting, assign each case manager one to five clients with UVL ● Case managers are responsible for conducting at least one home visit between each client's first and second EAC or ensures the clients home visit has been done to eligible clients » Case manager home visits typically occur within two weeks of the first EAC session ● Home visit checklist reports and oral updates are provided during weekly MDT meetings ● All home visit activities are done with client consent and documented in relevant registers and patient files
Develop and utilize a working schedule for facility-based staff *(Applicable in all facilities)*	● During weekly MDT meetings, each member reports upcoming time off to a member of the QI team and colleagues volunteer to fill-in » Upcoming leave and designated replacements are documented on a monthly calendar template ● Prior to time off, staff conduct a written and a verbal hand-off for all clients with UVL to ensure continuity of care ● Designated replacements take over responsibility for those who are on off duty and feedback are also shared during weekly MDT meetings
Change Concept: Viral Load Test Results Management, Data Quality and Documentation	
Develop and implement VL results management SOPs *(Applicable in all facilities)*	• The QI team convenes to brainstorm and develop a process map of ideal VL test results management processes, starting from the time results are received at the facility •SOPs are crafted based on the process map (Attachment 3)
Engage facility-based VL focal person to communicate electronic VL test results before hard copies are available *(Applicable in dispensaries and health centres)*	● The facility-based VL focal person is mentored on proper use of Mobile Laboratory and SMS platforms which transfer electronic VL test results to facilities before hard copies arrive ● The VL focal person is responsible for downloading results on a daily basis, and documenting them in relevant registers » Result type (i.e. electronic v. hard copy) is also documented ● All UVL results received are flagged, and the VL focal person is responsible for immediate follow-up with a nurse or clinician
Utilize online NASCOP Early Infant Diagnosis/Viral Load (EID/VL) System at the health facility to access and communicate VL test	● A facility-based EID/VL System focal person is identified ● The laboratory technical lead provides training to the EID/VL System focal person and additional facility staff on accessing the EID/VL Results System » This online system, maintained by NASCOP, acts as a warehouse for early infant diagnosis (EID) and VL test results » Users sign-on with password-protected, individual user names to access and print results before hard copies are available

results before hard copies are available *(Applicable in county and subcounty facilities)*	» Implementing partner provides facilities with internet airtime to access the system ● The EID/VL System focal person is responsible for accessing, downloading and printing all VL test results on a daily basis, and documenting them in laboratory register ● After results are documented, the printed test results are carried to the Comprehensive Care Center (CCC) for immediate follow-up ● Designated staff such as a peer educator files the VL results at the clients` files
Store files for clients with UVL and/or on second-line ART regimens separately from other client files for easy access and follow-up *(Applicable in all facilities)*	● The facility QI team and CCC in-charge identify a separate filing area for clients with UVL and/or on second-line ART regimens » The QI team convenes an all-staff meeting to introduce the new filing area ● Filing cabinets are moved to the separate space, and labelled "HIGH VL CLIENTS" and "2nd LINE CLIENTS and 3RD LINE CLIENTS" ● A clinician/Nurse lists all clients with UVL and/or on second-line ART regimens at the facility ● A designated staff locates all client files and stores them in the new filing area ● As clients become virally suppressed, their files are moved back to the original filing area (with other HIV+ clients not on second-line ART or with UVL)
Conduct weekly reviews for data quality in the High VL Register *(Applicable in all facilities)*	● Facility-based Health Records and Information Officers are responsible for reviewing the High VL Register weekly » Patient files (i.e. source data) are used to gauge data quality ● The register is updated to include any missing information found in patient files
Conduct monthly reviews for data quality in relevant registers *(Applicable in all facilities)*	● The QI team and nurse in-charge meet monthly to review relevant registers and gauge data quality » 10 entries per register (Pediatrics, Adolescents and adults are randomly selected and compared with patient files for completeness and accuracy, focusing on availability of information in national registers ● Following monthly meetings, the facility QI team meets with individual peer educators to review findings and provide necessary support to one another ● Registers are updated to include any missing information found in the patient file
Cross-reference client information across multiple sources and	*Information on VL testing is documented in the Laboratory Tracking Log, Viral Load Monitoring Log, Clinician Viral Load Monitoring Log and High Viral Load Register* ● A peer educator is assigned to cross-reference the three data sources

fill in any gaps to ensure proper follow-up action for all clients with UVL *(Applicable in all facilities)*	» Gaps (i.e. missing client information) are filled immediately ● Any discrepancies are immediately brought to the attention of the attending nurse in-charge (e.g. missed opportunities for follow-up)
Color code client files using stickers to indicate the last EAC session completed *(Applicable in Health centres and Dispensaries)*	● The QI team purchases stickers in different colors, each indicating completion of a specific EAC session at the client's last appointment: » Color 1: Zero EACs Completed » Color 2: First EAC Completed » Color 3: Second EAC Completed » Color 4: Third EAC Completed ● A designated staff such as a peer educator retrieves all files for clients with UVL and separates them by the last EAC session completed (i.e. the categories listed above) ● A colored sticker is placed in the top left corner of each client's file to indicate the last EAC session completed ● Client files are stored following facility policy, and stickers are added as EAC sessions are completed
Review client contact information before every consultation, and revise as needed *(Applicable in all facilities)*	● Prior to every consultation, peer educators are responsible for reviewing contact information with clients » Contact information includes home address, telephone number and treatment supporter telephone number (where appropriate), nearest landmark ● Clients are asked to confirm whether existing information is correct; required changes are made immediately
Change Concept: Workflow Process Modification	
Develop and utilize a counseling summary tool to concisely convey findings from other EAC tools (Ap*plicable in all facilities)*	● The QI team convenes to develop a formal adherence counselling summary tool to consolidate findings from nationally recommended EAC screenings (Appendix 4) ● A member of the QI team volunteers to train all adherence counselors in the use of the new tool ● Adherence counselors summarize key activities for each client using the tool
Conduct and document pill count during all clinical consultations *(Applicable in all facilities)*	● All clients are advised to bring remaining ART with them to clinical consultations ● At the end of each clinical consultation, a Clinician /Nurse or pharmacy technologist or an adherence counselor conducts a pill count » Findings are documented using the Pill Count-Based Assessment Tool (Appendix 5); a copy is stored in the patient file

Develop and utilize an EAC tool to standardize counseling sessions (*Applicable in all facilities)*	• The QI team convenes a meeting with all adherence counselors to review and list key messages and actions that should be delivered at each EAC session • A member of the QI team volunteers to develop a tool based on the list developed during the meeting (Appendix 10) • The same member of the QI team volunteers to train all adherence counselors in the use of the new tool • The tool is piloted and standardized for use in all the facilities
Convene MDT1 meetings to review clients with UVL, discuss and address barriers to adherence *(Applicable in all facilities)*	• An adherence counselor gathers all patient files of clients with UVL results received in the past week • The MDT reviews each client's history and individual barriers to adherence/ retention (meetings are convened weekly) • Meeting minutes are taken, shared with MDT members and stored where available to all • Recommendations and possible solutions are documented on a separate paper stored within the patient's file to guide future EAC sessions
Implement retrieving files a day before clinic appointment (*Applicable in all facilities*)	• Each day, an adherence counselor is assigned to collect all patient files for clients with UVL due for an appointment the prior to the visit » Files are stored in a separate filing cabinet, organized by date of next appointment (weekly) and alphabetically by client last name • Files are segregated according to services due such as repeat VL, EAC session or for switching to eligible regimen • Clients are reminded of their scheduled appointment by a phone call or an SMS • Files of clients who missed their scheduled appointment are shared with peer educators to perform follow-up actively in the community
Convene MDT meetings to review clients with repeat UVL prior to switching to second-line treatment (Applicable *in all facilities*)	• A QI team member convenes a weekly MDT meeting specifically to review clients with repeat UVL • An adherence counselor or a designated health care provider gathers all patient files of clients with repeat UVL results received in the past week • The MDT reviews each client's history and individual barriers to adherence/ retention » Peer educators, social worker and adherence counselors provide qualitative feedback on the client's progress with EAC sessions and other, related activities (e.g. home visits, other clinic visits, etc.) • Following discussion, the MDT makes a recommendation for each patient: » Flag file for switch to second-line ART; clients due for a switch are contacted to schedule a clinic appointment » All clients who complete at least three satisfactory EAC sessions and have repeat UVL are scheduled to switch

	• Recommendations and findings are documented and submitted using the client-specific NASCOP Case Summary Form (Appendix 11) » A copy of the submitted form is also stored in the patient file • Meeting minutes are taken, shared with MDT members and stored where available to all
Schedule 30-day follow-up appointment for all clients following VL sample collection *before* providing ART (*Applicable in all facilities*)	• Following VL sample collection (regardless of whether it is first or repeat test) and consultation with an adherence counselor, a peer educator schedules a 30-day follow-up appointment for all clients » Appointments are documented in an appointment diary » Clients receive a paper reminder, with the appointment date/time as well as contact information for the facility • Clients receive ART from the on-site pharmacy technologist; in order to receive refills, they must show their paper appointment reminder
Provide convenient appointment and support group scheduling (*Applicable in all facilities)*	• Facility staff attempt to accommodate all client appointment and support group schedule requests, including: » Adolescent support groups and appointments on weekends and when school is not in session; » Women's groups and appointments on non-market days; and » Appointments outside routine work hours (i.e. early morning and late evening) for working staff and men
Reduce the maximum number of pre-scheduled appointments per day (*Applicable in all facilities)*	• The QI team convenes a meeting with the CCC in-charge and facility leadership to discuss the importance of reducing pre-scheduled appointments (to ensure sufficient time for scheduled consultations as well as walk-ins) • With leadership approval, the QI team defines a maximum number of appointments per day (typically between 25-40) • Once member of the QI team is responsible for communicating changes to the peer educators responsible for making and tracking appointments in an appointment diary » When the maximum number of appointments has been reached for a specific day, peer educators stop taking appointments for that day and liaise with the clinician/nurse on the next appointment date
Offer peer-led psychosocial support groups tailored for specific patient populations (*Applicable in all facilities)*	• The QI team meets to identify volunteer High VL Champions responsible for coordinating support groups » Peer-led support groups are offered separately for young adolescents (10-14); adolescents (15-19); caregivers of clients with UVL; women; adults; and clients on second- or third-line ART • Suppressed VL Champions meet with their support group to agree on a day and time that best suits the group's needs

	• Clinical appointments are offered to all support group members on the day their support group meets • Support groups provide emotional support and targeted health information specific to the patient population
Change Concept: Client and Family Education and Engagement	
Introduce telephone-based appointment reminder system (*Applicable in all facilities)*	• Each day, an adherence counselor is assigned to list all clients with UVL due for an appointment the following day » Contact information, gathered from patient files, is included • The adherence counselor or designed health care worker provides this list to peer educators who are responsible for contacting all clients the day before scheduled appointments • Peer educators contact each client by phone no later than 05:00 pm previous day » Peer educators document activities in the appointment dairy and phone log » If a client in un available for their appointment, the peer educator offers to reschedule by phone » Multiple attempts are made to call the client and the treatment supporter » If a client is not available by phone or the phone number is no longer in service, or has missed the scheduled appointment the peer educator or a community health volunteer performs active follow-up in the community
Introduce and enroll eligible clients in family centered Care (*Applicable in all facilities)*	• A peer educator is assigned to list all ART clients and group them by household • In households with one or more client with UVL, an adherence counselor designates pairs so that one household member who is virally suppressed is paired with one household member with UVL if disclosure has been done and consent given • An adherence counselor introduces family centered Care to newly enrolled clients, reviews roles and explains that pairs are provided the same clinic appointment schedule to minimize travel » The virally suppressed household member is to mentor the household member with UVL » Household pairs are provided with a family centered Care package to help them improve adherence » Clinic appointments are scheduled based on the need of the client with UVL

Introduce treatment supporters to increase retention in care (*Applicable in all facilities*)	• All clients with UVL are introduced to the idea of a treatment supporter, and asked if they would like to participate • Consenting clients nominate a trusted family member or close friend that lives nearby to act as a main source of support and back-up contact and provide contact information » Treatment supporters are contacted in the event of a missed appointment or return of test results, if the client cannot be reached directly • Treatment supporters provide psychosocial support, and help remind patients to take medications and keep upcoming appointments • Document details of the treatment supporter in the file in the locator forms and green card MoH 257
Recruit and engage virally suppressed clients to provide health education from the peer perspective (*Applicable in all facilities)*	• The QI team enlists MDT to help identify virally suppressed clients who have completed three EAC sessions and are currently on second- or third-line ART willing to act as mentors to their peers • Peer mentors are requested to share their personal story with peers • A member of the QI team connects peer mentors with facility-based suppressed VL Champions responsible for coordinating support groups » High VL Champions follow-up with peer mentors to schedule time for them to participate in upcoming psychosocial support groups • Peer mentors are provided an entire support group session to share, followed by Q&A; a facility nurse/clinician accompanies the peer mentor to provide key health information to the audience
Provide pill boxes and training on their use to help clients manage medications (*Applicable in all facilities)*	• The MDT identifies clients who can benefit from pill boxes to support adherence and orders from the supporting partner through the program officer/ • Adherence counselors distribute one pill box to each eligible client with UVL during EAC sessions, and demonstrate how they are used » The client's treatment supporter is invited to attend this consultation, where applicable • Provision of pill boxes is documented in the patient file and Pill Box Log • Adherence counselor's follow-up with clients at least twice a month for three months after providing pill boxes • Progress is documented in the patient file and reported during weekly MDT meetings
Change Concept: Healthcare Worker Capacity Building	
Provide on-the-job mentorship on optimizing and standardizing EAC	• The HIV mentorship team develops an on-the-job mentorship schedule to ensure all adherence counselors receive equal support • Members of the HIV/AIDS Technical team observe EAC sessions, and provide real-time feedback to adherence counselors

services with tools to all adherence counselors (*Applicable in all facilities)*	• The Client Education and Adherence Counseling Tools are reviewed, as necessary, to ensure EAC messaging is both optimized and standardized across all counselors, ensuring standardized tools are available, Sensitization on the tools, ensuring proper utilization of the tools, Monitoring and review the utilization of the tools
Train Clinician/nurses on proper coding of VL samples (*Applicable in all facilities)*	*Facility-based clinician is responsible for coding all VL samples accordingly to indicate first v. repeat test before they are sent to the central lab for processing. This informs follow-up action taken upon receipt of results (e.g. EAC counseling, switch to second-line ART).* • A clinician and laboratory technologist assigned provides a half-day refresher training for all nurses on the standards and importance of correct coding of VL samples

List of Acronyms

ART	Antiretroviral Therapy
CAGE-AID	Screening Tool for Alcohol and Drug Use Disorders among Adults
CCC	Comprehensive Care Center
CDC	U.S. Centers for Disease Control and Prevention
CME	Continuous Medical Education
CRAFFT	Screening Tool for Alcohol and Drug Use Disorders among Adolescents
DSD	Differentiated Service Delivery
EAC	Enhanced Adherence Counseling
EID	Early Infant Diagnosis
EID/VL	Early Infant Diagnosis/Viral Load
FGD	Focus Group Discussion
HRIO	Health Records & Information Officer
MDT	Multidisciplinary Team
MDT	Multidisciplinary Team
MLAB	Mobile Laboratory Application
MMAS-8	Morisky Medication Adherence Scale
MoH	Ministry of Health
NASCOP	National AIDS & STIs Control Program
PHQ-9	Patient Health Questionnaire-9 for Depression Screening
PSSG	Psychosocial Support Group
QI	Quality Improvement
QIC	Quality Improvement Collaborative
RVLT	Routine Viral Load Testing
SMS	Short Message Service
SOP	Standard Operating Procedure
TWG	Technical Working Group
UVL	Unsuppressed Viral Load
VL	Viral Load

Appendices

Appendix 1. Standard Operating Procedures for Case Managers (NASCOP 2016)

Case management refers to planning, obtaining, coordinating and monitoring of services due to the patient, on behalf of the patient by a person assigned. The assigned person is the case manager

Who is a case manager?

The case manager can be a Doctor/clinician, nurse or any other health care provider and acts as the link between patient and MDT

Who allocates case manager?

Ideally it is the MDT however depending on the urgency of the matter and if the MDT has not met yet, the clinical service provider (nurse, clinical officer, medical officer, consultant) can assign then this is ratified by the MDT

Who manages the case manager? (Super case manager)

There must be someone who tracks to see all case managers are up to date on their assignment

The task can be given to the CCC coordinator or in charge who supports the case manager where expected tasks assigned are not happening as assigned

Tools required

Generally, in day to day follow up of cases tools that have been outlined in the MOH 2016 guidelines are utilized. Other tools agreed upon by the program will also be utilized.

The case manager will ensure that all tools are updated and available to support patient management.

Facilities will need a tool to track who has been allocated which case and the progress thereof

Roles of a case manager

- Coordinating multidisciplinary management for patients under case management
- Follow-up on appointment keeping for the patients
- Coordinating home visits to their patients
- Identifying patients to be discussed
- Planning MDT meetings
- Organizing patient's reminder (SMS, calling the day before)
- Ensuring appropriate defaulter tracing

Who requires case management?

- Orphaned and vulnerable children
- Patients with alcohol and substance abuse
- Patients with suspected or confirmed treatment failure including high VL patients
- All children and adolescents not achieving (not achieving optimum treatment outcome
- Patients with mental illness and deaf clients
- Any patient whom the health care team feels has poor adherence or high risk of defaulting from care (high risk clients)
- Pregnant women

NB. Sites can identify high risk clients e.g. Persons experiencing GBV, persons with financial challenges recent job losses, recent family disruption, patients with no social support, patients with self-stigma or experiencing stigma from their community, immigrant workers

Reporting

Case manager will provide a specific client reports during MDT. Actions e.g. home visit, laboratory, MDT, case discussion and links to psychosocial group At the facility level it should be clear how many clients required a case manager in the month the outcome (either successful- patient now stable, patient still assigned to a case manager, LTF or dead
Case managers for different populations **Adolescents**: In addition to working with caregivers, include adolescent mentors to work with primary case manager. This may include peer to peer pairing with those who are virally suppressed. CCC coordinator should ensure additional support required is available e.g. Psychologist support or other appropriate linkages **Children:** Children should be prioritized. From high viral load audit, the caregiver and child should be reviewed as one and assigned a case manager. CCC coordinator should ensure additional support required is available e.g. Psychologist support or other appropriate Linkages **Key population/priority population:** Case manager may be may be a clinician/nurse/social worker or HIV positive peer counsellor who is trained in psychosocial support **Adults**: Men and women face different challenges; some men may prefer a male case manager hence need to ensure gender balance in the peer educators we have hired **Pregnant women:** The case manager should be a mentor mother or a PMTCT nurse or a clinician

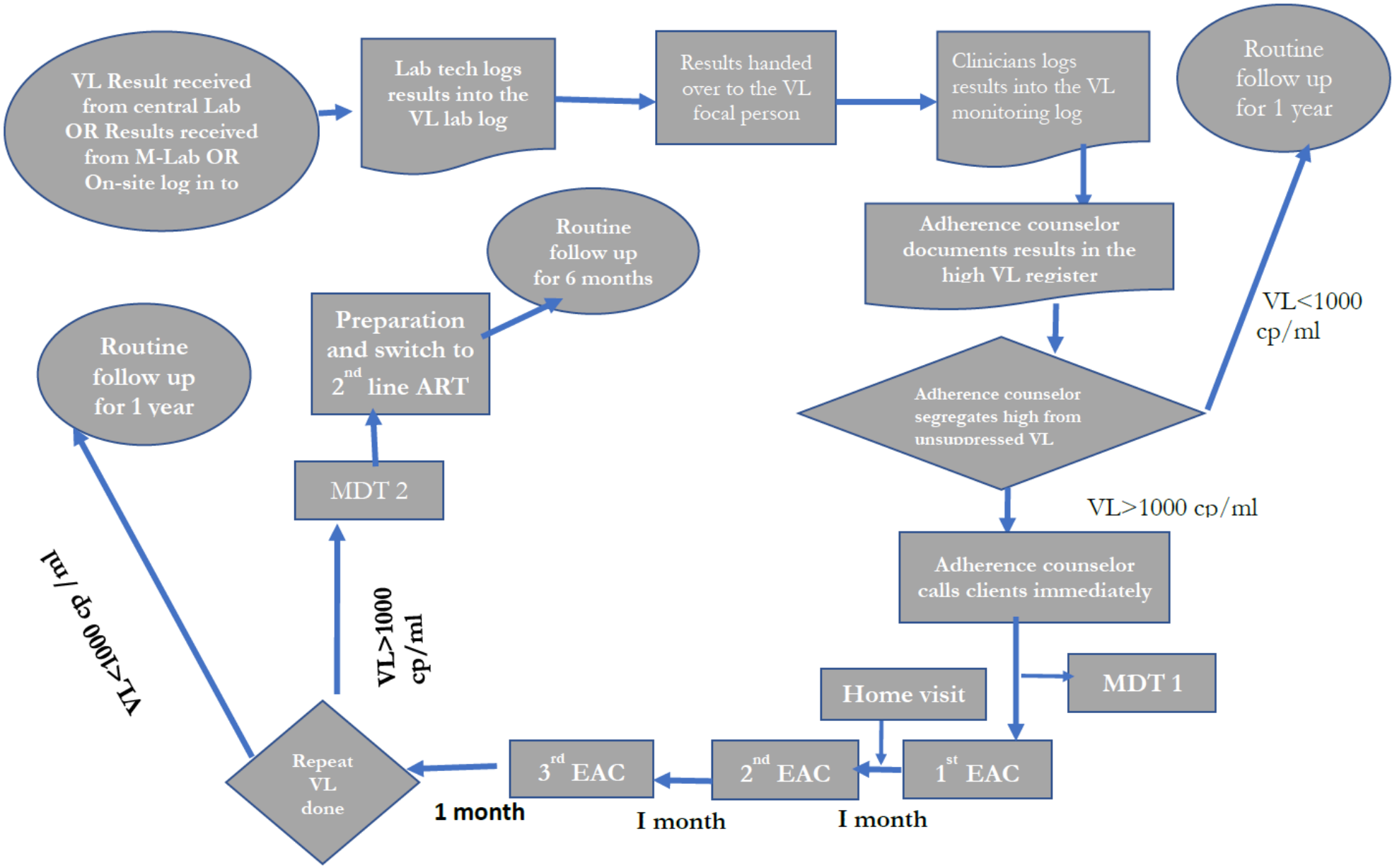
Appendix 2. NASCOP Home Visit Checklist (2016)

Patient Name:	Tel No:	*Sex: M F*
Family Member:	Tel No:	
Physical landmark:		*File no.*

	Areas to Assess and Discuss	Comments
1.	Is the patient independent in the activities of daily living (e.g. feeding, grooming, toileting)?	
2.	Are the patient's basic needs being met (e.g. clothing, shelter, food etc.)?	
3.	Has the patient disclosed their HIV status to other household members?	
4.	How are the patients ARVs stored and taken?	
5.	Does the patient receive social support from household members?	
6.	Is the patient linked to non-clinical services (e.g. spiritual, legal or nutritional)?	
7.	Does the patient receive social support in the community?	
8.	Does the patient have mental health issues that need to be addressed (use PHQ9 to screen for depression), or use drugs or alcohol?	
9.	Is the patient suffering from a stressful situation or significant loss/grief?	
10.	Is the patient having any side-effects from the medications?	

Other comments/Observations:

Appendix 3. Standard Operating Procedures for Viral Load Results Management



Appendix 4. Adherence Counseling Summary Form (NASCOP 2016)

Instructions: This tool will be used to document ongoing adherence counselling for patients with adherence challenges: those with poor viral load suppression or failing second line ART and on third line ART. It should capture dates, issues discussed and action plan/next steps, including a date for the next session if indicated.

1. Ensure each session by reviewing the adherence barriers and counselling goal/action plan from previous session;
2. Assess and document the adherence level (%) at each visit;
3. Assess the major barriers to adherence which may include cognitive, emotional, behavioral, clinical and/or socio-economic challenges; and
4. Document the counselling goal and action plan at each visit, and the date of next appointment

**NB: If any score not applicable to clients put "N/A"

Name	**Age**	**Sex**	**Unique ID Number**

Date	**Pill Count-Based Adherence Score**	**MMAS-8 Score**	**CRAFFT or CAGE-AID Score**	**PHQ-9 Score**	**Adherence Barriers and Solutions Discussed**	**Action Plan (Counseling Goal)**	**Next Appointment Date**	**Provider Name & Signature**

Appendix 5. Pill Count-Based Adherence Assessment Tool (NASCOP 2016)

Missed Doses per Month		Percent Medication Taken	Adherence Rating	Required Action(s)
Daily Regimen	Bi-Daily Regimen			
1 dose	1-3 doses	>95%	Good	Continue with routine monitoring, counseling and support
2-4 doses	4-8 doses	85-94%	Inadequate	• Review client file at next MDT meeting • Assign client-specific case manager • Assess for barriers to adherence, and develop solutions to address each • Engage treatment support staff in adherence counseling sessions • Follow-up in two to four weeks
>5 doses	> 9 doses	<85%	Poor	• Review client file at next MDT meeting • Assign client-specific case manager • Assess for barriers to adherence, and develop solutions to address each • Engage treatment support staff in adherence counseling sessions • Implement directly observed treatment (DOT) • Follow-up in one to two weeks

Appendix 6. Morisky Medication Adherence Scale (NASCOP 2016)

MMAS-8: *Ask the patient each question below. Circle the corresponding score for each response. After completion of all questions, add up all the points you have circled for the total score.*

Question	Yes	No
1. Do you ever forget to take your medicine?	1	0
2. Are you careless at times about taking your medicine?	1	0
3. Sometimes if you feel worse when you take the medicine, do you stop taking it?	1	0
4. When you feel better, do you sometimes stop taking your medicine?	1	0
5. Did you take you medicine yesterday?	0	1
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	1	0
7. Taking medication every day is a real inconvenience for some people. Do you ever feel under pressure about sticking to your treatment plan?	1	0
8. How often do you have difficulty remembering to take all of your medications? (Please circle the correct answer below) A. Never/rarely B. Once in a while C. Sometimes D. Usually E. All of the time	 A. 0 B. ¼ C. ½ D. ¾ E. 1	
Total Score (sum of all items)		

Interpretation of MMAS-8 Score

MMAS-8 Score	Adherence Rating	Action Required
0	Good	Continue with routine monitoring, counseling and support
1-2	Inadequate	• Discuss at MDT • Assign client-specific case manager • Assess for barriers to adherence • Engage treatment support staff in adherence counseling sessions • Follow-up in two to four weeks
3-8	Poor	• Review client file at next MDT meeting • Assign client-specific case manager • Assess for barriers to adherence, and develop solutions to address each • Engage treatment support staff in adherence counseling sessions • Implement DOT • Follow-up in one to two weeks

Appendix 7. Patient Health Questionnaire-9 for Depression Screening (NASCOP 2016)

PHQ-9 Depression Screening: *Ask the patient the questions below for each of the 9 symptoms and circle the response for each question. After asking all questions, add the points for each column at the bottom. The total score is the sum of the column totals. Interpretation and management recommendations are provided at the bottom of the table.*

Question: *"Over the last two weeks, how often have you been bothered by any of the following problems?"*	**Not at All**	**Several Days**	**More than Half the Days**	**Nearly Every Day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or helpless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired of having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself, or that you are a failure, or that you have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things (linked with patient's usual activities, such as reading the newspaper or listening to a radio program)	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Total:			(add the points from each column)	

Interpretation of PHQ-9 Score and Recommended Management

Total Score	**Provisional Diagnosis**	**Recommended Management**
0-4	Depression unlikely	Repeat screening in future if new concerns that depression has developed
5-9	Mild depression	• Provide counseling support and continue to monitor; refer to mental health team if available • If patient is on EFV, substitute with a different ART after ruling out treatment failure
10-14	Moderate depression*	• Provide supportive counseling (refer to a psychologist if available) • If patient is on EFV, substitute with a different ARV after ruling out treatment failure *-and-* • Begin antidepressant medication (of, if familiar with use of antidepressants then refer to an experienced clinician) *-and-* • Refer to a medical officer, psychiatrist or mental health team if available
15-19	Moderate-severe depression*	
20-27	Severe depression*	

* Symptoms should ideally be present for at least 2 weeks for a diagnosis of depression and before considering treatment with antidepressant medication. Severe depression may require patients to start on antidepressants immediately.

Appendix 8. CAGE-AID Screening Tool (NASCOP 2016)

CAGE-AID Screening Tool: *Ask the patient the four questions below. Each question requires a yes/no response. Answering 'yes' to two or more questions indicates an alcohol or drug use disorder requiring further assessment and management.*

Begin: "I am going to ask you a few questions that I ask all of my patients. Please be honest, I will keep your answers confidential."

Question	Response	
	No	**Yes**
1. Have you ever felt that you ought to cut down on your drinking or drug use?		
2. Have people annoyed you by criticizing your drinking or drug use?		
3. Have you ever felt bad or guilty about your drinking or drug use?		
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?		

Appendix 9. CRAFFT Screening Tool (NASCOP 2016)

CRAFFT Screening Tool: *Ask the patient the first three questions. If the patient answers 'yes' to any of the first three questions, ask all six CRAFFT questions below; if the patient does not answer 'yes' to any of the first three questions, ask the first CRAFFT question only. Answering 'yes' to two or more of the CRAFFT questions indicates an alcohol or drug use disorder requiring further assessment and management.*

Begin: "I am going to ask you a few questions that I ask all of my patients. Please be honest, I will keep your answers confidential."

Screening Question	Response	
	No	Yes
1. During the last 12 months, did you drink any alcohol (more than a few sips)? (Do not count sips of alcohol taken during family or religious events.)		
2. During the last 12 months, did you smoke any marijuana or hashish?		
3. During the last 12 months, did you use anything else to get high? ("Anything else" includes illegal drugs, over the counter and prescription drugs, and things that you sniff or 'huff'.)		
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?		
CRAFFT Question	**Response**	
	No	**Yes**
1. Have you ever ridden in a car driven by someone (including yourself) who was high or had been using alcohol or drugs?		
2. Do you ever use alcohol or drugs to relax, feel better about yourself or fit in?		
3. Do you ever use alcohol or drugs while you are by yourself or alone?		
4. Do you ever forget things you did while using alcohol or drugs?		
5. Do your family or friends ever tell you that you should cut down on your drinking or drug use?		
6. Have you ever gotten into trouble while you were using alcohol or drugs?		

Appendix 10. Enhanced Adherence Counselling Tool (QIC Adopted from NASCOP 2016)

1st Enhanced Adherence Counseling after first viral load >1,000c/mL

Facility:_____ **Date:**_____ **CCC No:**_____

What is VL What is high VL/ Detectable VL What is suppressed VL Provide VL results Explain the results Explore on Patients feeling on results	Done Y/N	Outcome	**Behavioral barriers (DO MRK 8 score)** How patient takes medication/timing treatment and its` fitness to daily routine clients schedule (adjust with client if not)	Done Y/N	Outcome	**Social economic barriers**	Done Y/N	Outcome
						Community support / support group and importance of patient joining a support group		
Enhanced adherence process Explain 3EACs process to prepare the patient for intensified visits			Missed dose should be taken immediately Reminder systems /what do they do in case they travel/visit to nearby clinic incase run out of drugs while away from usual clinic **Do Adherence scoring %**			Barriers or challenges to getting to the clinic frequently / help patient address them		
						Stigma and discrimination/patients feeling about others knowing his HIV status		
Explore with the patient on previous causes of poor adherence (Outcome of MDT1)			Check for alcohol and drug use in a way not accusing to the patient/does it affects their adherence to treatment **(Do CRAFT/CAGE SCORE to all above 15 yrs.)**			Religious believes / Herbal / traditional medication, PNS, family partner testing, Safe sex,		
Assess for barriers **Cognitive barriers-** what is HIV, CD4 and immune system ART and how does it work Importance of adherence and how can it be achieved			**Social economic barriers** Disclosure status					
Emotional barriers Review patient's motivation Feeling on taking drugs daily What to do in case of side effects Ambitions in life/3 most important things they would want to achieve			Family support Support from treatment buddy/ role of treatment buddy			**Ascertain need for Home visit and Plan to do it**		
Mental health screening – DO IT TO ALL patients (PHQ9) Assess for the five stages of grief Denial and isolation, Anger, bargaining and depression, acceptance			**Referral and networking:** referral to other special clinics, social support / support group / nutrition services / lab services / medical clinic / substance abuse clinic etc.					

Summary of findings and adherence plan (Copy same to adherence summary tool)		
Counselor's name	Signature	Date

CHECKLIST PLAN after First EAC Session	**Done Y / N**
• Assisted disclosure through counseling and testing, planned home visits in the 1st week of receipt of viral load results or client to get alarm reminders for forgetfulness	
• Client to identify a treatment buddy of their choice	
• Knowledge of the care giver/treatment buddy on HIV and AIDS care, treatment and its complications assessed and gaps addressed	
• Link the client and the treatment buddy with the CHV	
• Do weekly phone calls to client, treatment buddy, CHV to assess progress on adherence	
• Discuss with the client to understand why it's important to reduce the TCA's to one month, involve clinicians	
• Link the client, buddy and CHV to a therapy grouping or support group	
• Assess and sustain adherence to ARVs to 95% and beyond	
Additional counselor's comments	
Counselor's name Signature Date	

2nd Enhanced Adherence Counseling after first viral load >1,000c/mL **Date:**_____ **CCC No:**_____	**Done Y / N**
• Assisted disclosure through counseling and testing. Planned home visits in the 1st week of receipt of viral load results or client to get alarm reminders for forgetfulness	
• Knowledge of the care giver/treatment buddy on HIV and AIDS care, treatment and its complication assessed and gaps addressed	
• Link the client and the treatment buddy with the CHV	
• Do weekly phone calls to client, treatment buddy, CHV to assess progress on adherence	
• Discuss with the client to understand why it's important to reduce the TCA's to one month, involve clinicians	
• Link the client, buddy and CHV to a therapy grouping or support group	
• Assess and sustain adherence to ARVs to 95% and beyond	
• Have the above been achieve? In NO plan as action points for before the third EAC session	
Additional counselor's comments	
Counselor's name Signature Date	

3rd Enhanced Adherence Counseling after first viral load >1,000c/mL **Date:**_____ **CCC No:**_____	**Done Y / N**
In the third month before a second VL is done, may do a second home visit to confirm if all the identified barriers to adherence have been addressed and plan accomplished if there is an indication	
• Do a readiness assessment for the second VL and recommend this to the clinicians to be done	
• If anything is not done, work it out in the next three weeks then recommend a second VL to the clinical team	
Additional counselor's comments	
Counselor's name Signature Date	

Appendix 11. NASCOP Case Summary Form (NASCOP 2016)

Facility Name		**MFL Code**	
Patient CCC no. (*do **not** write name*)		**Date**	
Patient Details	Date of Birth: Enrollment Date: Gender: Current Weight (kg): Height (cm):		
Clinician's Name			
Facility Contacts	Tel:	Email:	
What is the primary reason for this consultation:			
Clinical Evaluation: history, physical, diagnostics, working diagnosis (*excluding the information in the table below)*			

Complete the table below chronologically, including all ART regimen and laboratory results (and any previous history available for transfer-in patients)								
Date	**CD4**	**HB**	**CrCl/ eGFR**	**Viral Load**	**Weight (z-score/BMI for children)**	**ARV Regimen**	**Reason for Switch**	**New OI or other clinical event**

Adherence & Treatment Failure Evaluation	
Parameter	**Findings**
Number of adherence counseling/assessment sessions done in the last 3-6 months, and summary of assessment	
Number of home visits conducted in last 3-6 months, and summary of findings	
Support structures (e.g. treatment buddy, support group attendance, caregivers) in place for this patient	
Evidence of adherence concerns (e.g. missed appointments, pill counts)	
Number of DOTs done in last 3-6 months, and summary of findings	
Likely root cause(s) of poor adherence for this patient (e.g. stigma, disclosure, side effects, alcohol/drug use, mental health issues, caregiver change, religious beliefs, inadequate preparation)	
Evaluation for other cause(s) of treatment failure:	

• Inadequate dosing/dose adjustments (particularly among children) • Drug-drug interaction(s) • Drug-food interaction(s) • Impaired absorption (e.g. chronic, severe diarrhea)	
Action(s) taken to address adherence issues or other cause(s) of treatment failure	
Other Relevant ART History	
Parameter	**Findings**
Comment on treatment interruptions, if any	
Has drug resistance/sensitivity testing been done for this patient? If yes, state date done and attach detailed results here	
Has facility MDT discussed the patient's case? If yes, comment on date, deliberations and recommendations (indicate how treatment failure was established and confirmed, proposed regimen and dosage, current sources of drugs if patient already on 3rd line)	
List MDT members who participated in the case discussion (names and titles)	

***** Completed forms should be sent to ulizanascop@gmail.com *****


HARAMBEE
MINISTRY OF HEALTH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NASCOP


PEPFAR


U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration


CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION


Empowering
Health
for
15
years
ICAP
Columbia University
Mailman School of Public Health


KENYA CONFERENCE OF CATHOLIC BISHOPS
KARP
KENYA AIDS RESPONSE PROGRAM


chs
Centre for Health Solutions - Kenya