OPEN

Improving Utilization of HIV Viral Load Test Results Using a Quality Improvement Collaborative in Western Kenya

Miriam Rabkin, MD, MPH* • Dunstan Achwoka, MD, MSc • Steve Akoth, BS • Rodrigo Boccanera, MPH • Maureen Kimani, MD, MPH • Isaac Leting, BS • Caitlin Madevu-Matson, MSc • Redempta Mutei, BSc, MPH • Lilly Nyaga, MD, MSc • Christian Onyango, BS • Christopher Ouma, MD • Ilka Rondinelli, RN • Peter Rumunyu, MD • Fatima Tsiouris, MSc • Anne Wakoli, BScN, MPH • Lauren Walker, MPH • Gillian Dougherty, BSN, MPH

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Kenya has the world's fourth largest burden of HIV, with an estimated adult HIV prevalence of 4.8% and 1.6 million people living with HIV (Joint United Nations Programme on HIV/AIDS, 2019). In response, the Government of Kenya, with the support of its development partners, has scaled up HIV services and achieved 75% treatment coverage; 1.1 million people were accessing antiretroviral therapy (ART) by year end 2018 (Joint United Nations Programme on HIV/AIDS, 2019). The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that there has been a 55% drop in AIDS-related deaths and a 30% drop in new HIV infections in Kenya since 2010 (Joint United Nations Programme on HIV/AIDS, 2019). As Kenya strives to attain HIV epidemic control and to achieve the UNAIDS 90:90:90 goals, scaling up routine HIV viral load testing (VLT) is a priority for the Ministry of Health (MoH) and its National AIDS and Sexually Transmitted Infections Control Program (NASCOP), which have successfully expanded VLT coverage throughout the country (National AIDS and Sexually Transmitted Infections Control Program, 2016, 2019). As VLT coverage expands, MoH has also emphasized the importance of swift and accurate VLT result utilization. National guidelines recommend that people on ART with unsuppressed viral load (UVL) receive three enhanced adherence counseling (EAC) sessions at monthly intervals for 3 months followed by repeat VLT, with a switch to second-line ART if persistent UVL is found (Figure 1). However, despite rollout of national policies, guidelines, and training, programmatic data suggest such VLT utilization has been suboptimal (National AIDS and Sexually Transmitted Infections Control Program, 2019).

The gap between what health care workers (HCWs) know should be performed and what health systems actually do to improve health outcomes has been called the "know-do gap" and is seen in both resource-rich and resource-limited settings (Haines, Kuruvilla, & Borchert, 2004). Modern quality improvement (QI) methods address this challenge by empowering HCW teams to systematically identify root causes of suboptimal services,

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Miriam Rabkin, MD, MPH, is an Associate Professor of Medicine and Epidemiology, Columbia University, Mailman School of Public Health, New York, New York, USA. Dunstan Achwoka, MD, MSc, is a Doctoral Student, University of Nairobi Institute of Tropical and Infectious Diseases (UNITID), Nairobi, Kenya. Steve Akoth, BS, is a Data Officer at ICAP at Columbia University, Nairobi, Kenya. Rodrigo Boccanera, MPH, is an International Public Health Analyst, Health Resources and Services Administration (HRSA), US Department of Health and Human Services, Rockville, Maryland, USA. Maureen Kimani, MD, MPH, is a Program Manager, National AIDS and STI Control Programme (NASCOP), Kenya Ministry of Health, Nairobi, Kenya. Isaac Leting, BS, is a Monitoring and Evaluation Officer, ICAP at Columbia University, Nairobi, Kenya. Caitlin Madevu-Matson, MSc, is an Informatics and Data Use Manager, ICAP at Columbia University, New York, New York, USA. Redempta Mutei, BSc, MPH, is a Quality Improvement Coordinator, ICAP at Columbia University, Nairobi, Kenya. Lilly Nyaga, MD, MSc, is Surveillance Lead, Strategic Information Unit, National AIDS and STI Control Programme (NASCOP), Kenya Ministry of Health, Nairobi, Kenya. Christian Onyango, BS, is a Data Officer, ICAP at Columbia University, Nairobi, Kenya. Christopher Ouma, MD, is Regional Director for Western Kenya, ICAP at Columbia University, Nairobi, Kenya. Ilka Rondinelli, RN, is a Quality Improvement Technical Advisor, ICAP at Columbia University, New York, New York, USA. Peter Rumunyu, MD, is Director of Programs, Centre for Health Solutions, Nairobi, Kenya. Fatima Tsiouris, MSc, is Deputy Director of the Clinical and Training Unit, ICAP at Columbia University, New York, New York, USA. Anne Wakoli, BScN, MPH, is a Quality Improvement Coordinator, ICAP at Columbia University, Nairobi, Kenya. Lauren Walker, MPH, is a Senior Program Officer, ICAP at Columbia University, New York, New York, USA. Gillian Dougherty, BSN, MPH, is a Senior Quality Improvement Technical Advisor, ICAP at Columbia University, New York, New York, USA.

**Corresponding author: Miriam Rabkin, e-mail: mr84@columbia.edu*

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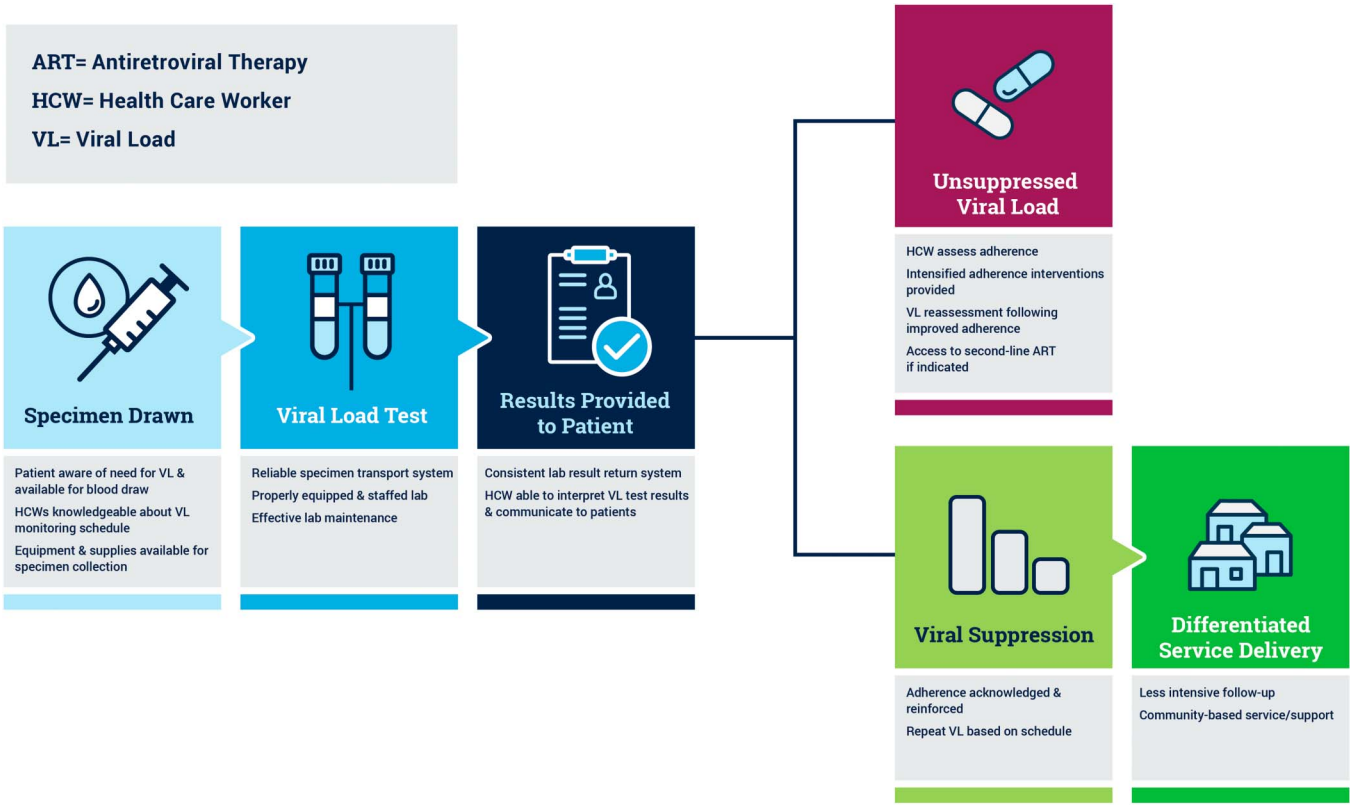

Figure 1. The HIV viral load utilization cascade.

design locally appropriate interventions, and conduct rapid, iterative tests of change that lead to sustained system improvements (Heiby, 2014).

The need for improvement in VLT utilization in Kenya despite the availability of policies, standards, training, staff, and supplies suggested a know-do gap amenable to an QI approach. In response, ICAP at Columbia University (ICAP) partnered with MoH/NASCOP, the Siaya County Health Management Team (CHMT), the US Centers for Disease Control and Prevention, the US Health Resources and Services Administration, and the Centre for Health Solutions (CHS) to design and implement an QI collaborative (QIC), using well-established QI methods to empower frontline HCW to explore and address the root causes of suboptimal VLT utilization.

Methods

Setting

The project was implemented in Siaya County, an area of high HIV prevalence in Western Kenya, with 135 health care facilities (HFs) providing ART at the time of project launch. In 2016, 31% of VLT performed in Siaya County were unsuppressed, and a retrospective review of data from October 2015 to September 2016 showed that only 22% of patients with UVL received three documented EAC sessions and only 35% received a repeat VLT (unpublished program data).

Quality Improvement Collaborative Design

The QIC is an evidence-based approach in which QI teams from multiple HFs work together to address a shared quality challenge with the support of external trainers and/or coaches (Catsambas et al., 2008; Wells et al., 2018). The methodology is based on the theory that the process of collaboration accelerates diffusion of innovation and the uptake of successful interventions, typically called "change ideas" in the QIC setting (Shaw, Chase, Howard, Nutting, & Crabtree, 2012). Often implemented over a 12- to 18-month period, QICs include identification of a shared quality challenge and development of shared targets ("aim statements") and indicators. After training and baseline data collection, multidisciplinary teams at each HF are supported to identify contextually appropriate change ideas and perform rapid, iterative tests of change using the model for improvement and plan-do-study-act cycle methodology. Quarterly in-person learning sessions provide a venue for participants to share successful change ideas and innovations while comparing their progress to the shared

targets; friendly competition often provides additional incentives for teams to perform. Between learning sessions, QI teams are supported with monthly mentoring and data supervision visits. At the end of each QIC, a "change package" of tested interventions, tools, and related innovations is developed to disseminate and scale-up improvement to additional facilities and regions.

ICAP worked with MoH/NASCOP, the Siaya CHMT, CHS, and other local stakeholders to design and implement the viral load (VL) utilization QIC. Preparatory stakeholder engagement began in March 2017, with site selection and collaborative development of QIC aim statements and indicators. A purposive sample of 30 public sector HFs in Siaya County was selected, with eligibility criteria that included HF support from the US President's Emergency Plan for AIDS Relief, patient volume of at least 500 people on ART, previous training on VL utilization, and an existing QI team. Participating HFs included 1 community hospital, 1 referral hospital, 6 subcounty hospitals, 17 health centers, and 5 dispensaries.

Health care facilities worked to achieve the QIC aims of (a) increasing the proportion of patients with UVL completing three EAC sessions within 4 months to 90% and (b) increasing the proportion of patients with UVL appropriately switching to second-line ART within 2 months of receiving a repeat unsuppressed VLT to 90%. The QIC also tracked the occurrence of second-line ART stockout, as a balancing indicator.

Quality Improvement Collaborative Implementation

Quality improvement collaborative teams from the 30 participating HFs attended the first learning session in March 2017. The 5-day workshop provided participants with a practical refresher training on modern QI science tools, including the model for improvement and plan-do-study-act cycle methodology. Participants also consolidated their knowledge of how to perform root cause analyses using fishbone diagramming and process mapping and generated change ideas based on the system weaknesses, bottlenecks, and gaps they identified. The HF QI teams then prioritized potential change ideas using a prioritization matrix and practiced tracking progress with run charts. Each team left the first learning session with a well-constructed QI plan with which to implement and test their first change ideas.

After the first learning session, monthly supportive supervision visits were made to each facility by ICAP staff in collaboration with MoH/NASCOP, CHS, and CHMT. During supportive supervision visits, ICAP staff met with facility-based QI teams to review implemented change ideas and their effect on progress toward achieving the shared aims. As a group, they used data to make decisions about which change ideas to adopt into routine practice, which to adapt for further testing, and which to abandon.

Between March 2017 and May 2018, ICAP convened five follow-up learning sessions and provided ongoing monthly supportive supervision. The 2-day learning sessions provided a platform for HF QI teams to present progress toward achieving shared aims, exchange best practices and lessons learned, review aggregate data, discuss implementation challenges, and collaboratively develop solutions.

On completion of the QIC in May 2018, results were shared at stakeholders' meetings convened with MoH/NASCOP, CHMT, regional and county leaders, civil society organizations, implementing partners, and US President's Emergency Plan for AIDS Relief agency representatives. Both the national- and county-level meetings were used to review aggregate QIC data and successful strategies to improve timely completion of EAC sessions and switch to second-line ART for eligible patients. A "change package" of the most successful interventions and tools was developed, and time was provided for stakeholders to develop a draft plan for dissemination outside the original QIC.

Data Collection, Management, and Analysis

Facility QI teams used a paper-based tool to collect monthly performance data, which was plotted on run charts to track monthly progress and link progress to change ideas. ICAP staff then entered the aggregate anonymized data from each HF into a secure, online District Health Information Software 2 database for storage, analysis, and generation of aggregate and site-level descriptive statistics and visualizations to demonstrate progress toward achieving the shared aims. Data quality assurance verifications were built into the District Health Information Software 2 database and systematically reviewed; errors identified were immediately addressed and resolved with support from facility QI teams.

Facility-level and aggregate data on shared indicators were monitored monthly and analyzed quarterly. The aggregate mean, median, and range for all indicators were calculated at the conclusion of the project. Summary statistics were used to demonstrate the magnitude, speed, and sustainability of improvements made during the QIC. Chi-squared tests of significance were used to compare baseline and endline performance. SqUIRE (Standards for

QUality Improvement Reporting Excellence) guidelines were used to optimize project reporting (Ogrinc et al., 2016).

Ethical Review

The project received nonresearch determination from the Columbia University Institutional Review Board (protocol: AAAR2573-M00Y01), the US Health Resources and Services Administration, and the Centers for Disease Control and Prevention's Center for Global Health, Office of the Associate Director for Science and was approved by the Maseno University (Kenya) Ethics Review Committee. As a nonresearch project, no individual consent was obtained.

Results and Discussion

All 30 HFs participated in the QIC. Learning sessions were well attended, with an average of 56 participants per session. The QI methods refresher at the first learning session boosted participant knowledge, as demonstrated by an increase of 30% in test scores from an average pre-test score of 50% to an average post-test score of 80%. The QI teams tested interventions over 14 months, including test result management, improved staff and client education, staffing modifications, workflow process modifications, commodity management, documentation, and data QIs. Successful interventions ("change ideas") tested by the QI teams are described in Table 1.

All HFs met the performance target for aim 1, increasing the proportion of patients with UVL completing three EAC sessions within 4 months to at least 90%. During the 14-month implementation period, 3,314/4,133 (80%) of clients with UVL at the 30 HFs received three EAC sessions within 4 months of their test results, and, in aggregate, HF performance for this aim improved from an average of 40% in the 3 months before QIC launch to an average of 93% in the final 3 months of QIC implementation ($p < .001$; Figure 2).

On average, it took facilities 2.6 months (median 2, range 0–10) to achieve 90% EAC completion, and this performance was sustained for 8 of 14 months. There were no substantive differences by region; hospitals achieved the aim somewhat faster than health centers. Although not a formal QIC aim, HFs did track the percentage of clients who had VL suppression on repeat VLT, which improved from 27% to 64% ($p < .001$) over the course of the QIC.

All HFs also showed improvement for aim 2, appropriate switching to second-line ART within 2 months for patients with persistent UVL. In aggregate, HF performance for this aim improved from 58% at baseline to 84% at endline ($p < .001$; Figure 3). As with aim 1, there were no substantive differences by region, and hospitals achieved the aim somewhat faster than health centers. On average, it took QI teams 0.3 month (median 0; range 0–3) to reach 90% of switching to second-line ART for clients with persistent UVL, and this performance was sustained for 10 of 14 months. None of the HFs reported stockouts of second-line ART during the QIC. The harvest package detailed successful interventions and tools developed for the project, including a high VL register, standard operating procedures (SOPs) for case managers, SOPs for VL results management, and an enhanced EAC tool.

These results are consistent with other published reports of QI projects and QICs, which have shown success in enabling facility-level QI teams to design, test, and scale contextually appropriate interventions that improve the quality of health services (Hargreaves et al., 2019; Schouten, Hulscher, van Everdingen, Huijsman, & Grol, 2008). As is typical for an QI project, there was no control group, so results at these 30 HFs cannot be compared with sites not participating in the QIC or generalized to other HF.

Among the key lessons from the QIC were that the intervention empowered HCWs at each of the 30 HFs to conduct root cause analyses specific to their immediate context, develop and prioritize change ideas to address these challenges, and conduct rapid, iterative tests of change to identify which interventions were associated with improvement. The learning sessions spurred friendly competition, and enabled QI teams to share what worked, swiftly diffusing innovations from one site to the next. Although the harvest package can be used to "jump start" QI projects at additional HF and has been used as a resource for a new QIC focusing on VL utilization for HIV-positive adolescents in a different region of Kenya, it is the QIC process itself, not any specific change idea, that is the critical intervention.

Conclusions

Routine VL testing is endorsed by the World Health Organization and Ministries of Health as an essential tool for individual patient management and a means of assessing the impact of HIV treatment scale-up (World Health Organization, 2017). Across sub-Saharan Africa, countries and their development partners have made substantial investments in the laboratory infrastructure and staffing required to markedly expand

Table 1. Successful Change Ideas Tested by Health Facility Quality Improvement Teams

Human resources systems and processes
Appoint rotating VL focal person to oversee results tracking and documentation
Implement task shifting to reduce clinical workload
Assign individual facility-based case managers to monitor UVL patients' care
Implement task shifting for home visits
Develop and use a working schedule for facility-based staff
VL test result management, data quality, and documentation
Use the national high VL register to generate a "line list" of clients with UVL to assist in longitudinal follow-up and assessment of timeliness of interventions
Develop and implement VL results management standard operating procedures (SOPs)
Utilize online NASCOP EID/VL system at the health facility to access and communicate VL test results before hard copies are available
Engage a facility-based VL focal person to communicate the online/electronic VL test results before hard copies are available
Store files for clients with UVL and/or on second-line ART regimens separately from other client files for easy access and follow-up
Conduct weekly reviews for data quality in the high VL register
Conduct monthly reviews for data quality in other relevant registers
Cross-reference client information across multiple sources and fill in any gaps to ensure proper follow-up action for all clients with UVL
Color-code client files using stickers to indicate the last EAC session completed
Review client contact information before every consultation and revise as needed
Workflow process modification
Develop and use a counseling summary tool to concisely convey findings from other EAC tools
Conduct and document pill count during all clinical consultations
Develop and use an EAC tool to standardize counseling sessions
Convene MDT meetings to review UVL clients and address barriers to adherence
Systematically retrieve client files a day before clinic appointment
Convene MDT meetings to review clients with repeat UVL before switching to second-line treatment
Schedule 30-day follow-up appointment for all clients after VL sample collection before providing ART
Provide convenient appointment and support group scheduling
Reduce the maximum number of prescheduled appointments per day
Offer peer-led psychosocial support groups tailored for specific patient populations
Client and family education and engagement
Introduce telephone-based appointment reminder system
Introduce and enroll eligible clients in family-centered care
Introduce treatment supporters to increase retention in care

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Table 1. (*continued*)
Recruit and engage virally suppressed clients to provide health education from the peer perspective
Provide pill boxes and training on their use to help clients manage medications
HCW capacity building
Provide on-the-job mentorship on optimizing and standardizing EAC services for all adherence counselors
Train clinicians/nurses on proper coding/labeling of VL samples

Note. ART = antiretroviral therapy; EAC = enhanced adherence counseling; EID = early infant diagnosis; HCW = health care worker; MDT = multidisciplinary team; NASCOP = National AIDS and Sexually Transmitted Infections Control Program; UVL = unsuppressed viral load; VL = viral load.

access to VLT for people on ART. It is important to recognize, however, that the challenge of VL scale-up extends beyond the laboratory, and that attention to the issue of results utilization is also critically important (El-Sadr, Rabkin, Nkengasong, & Birx, 2017).

Utilization of VL results in Kenya is a good example of the type of "know-do" gap amenable to QI methods. Access to VL testing is widespread, results are swiftly available through an online database accessible to HCWs, and there are existing policies and SOPs that clearly spell out the expected steps after receipt of a test showing UVL. Nonetheless, site- and community-level systems issues act as formidable barriers to performance.

Training HF staff to use QI methods and linking them to peers at other HF through the QIC approach empowered them to address the systems and process issues specific to their context and to design and test contextually appropriate interventions. In this project,

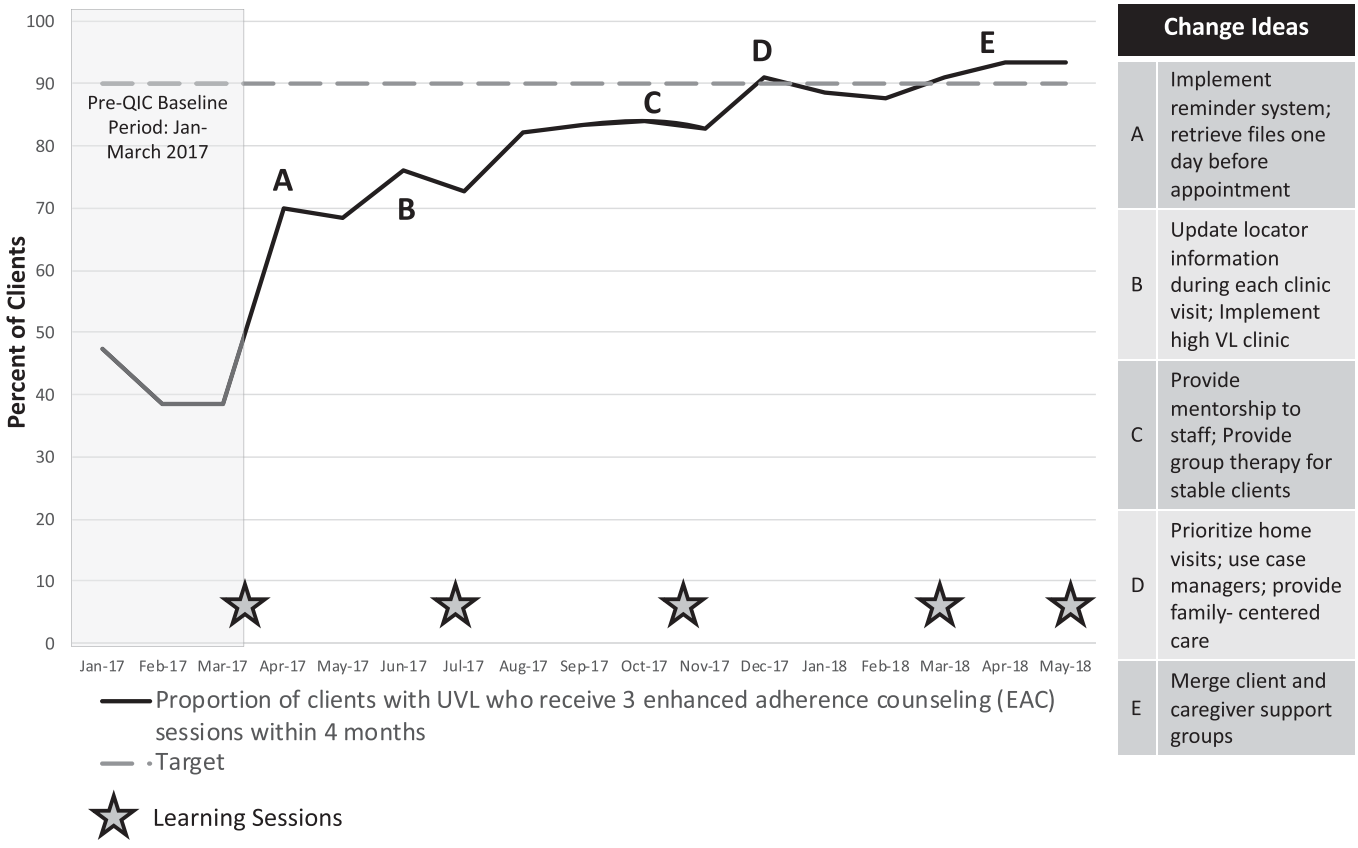

Figure 2. Proportion of clients with UVL completing three enhanced adherence counseling sessions within 4 months. EAC = enhanced adherence counseling; QIC = quality improvement collaborative; UVL = unsuppressed viral load; VL = viral load.

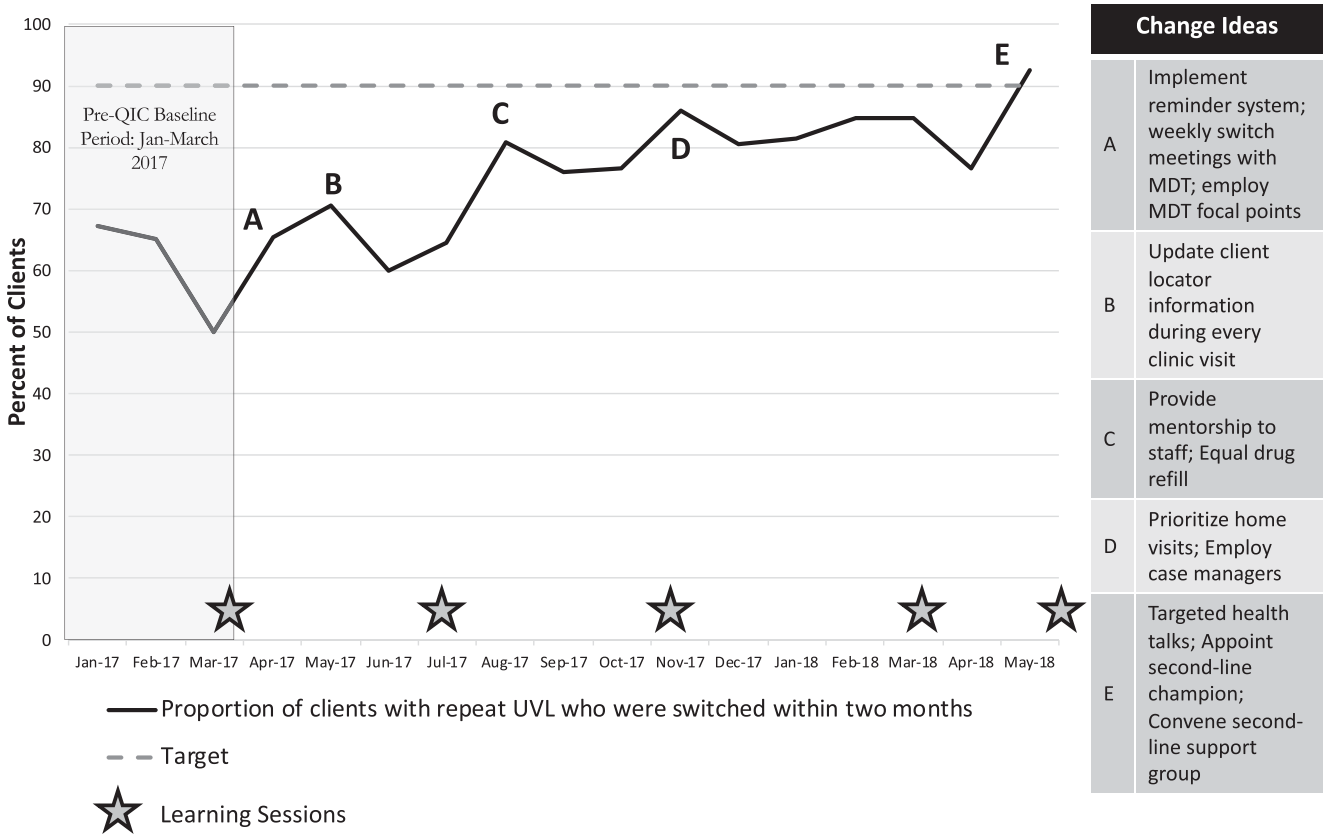

Figure 3. Proportion of clients with a repeat UVL result who were switched to second-line ART within 2 months. ART = antiretroviral therapy; MDT = multidisciplinary team; QIC = quality improvement collaborative; UVL = unsuppressed viral load.

the 30 HFs participating in the QIC demonstrated rapid and sustained improvement in the appropriate and timely utilization of test results for patients with UVL. Lessons learned were captured in the harvest package, which NASCOP is rolling out nationwide in Kenya.

Disclosures

The authors report no real or perceived vested interests related to this article that could be construed as a conflict of interest.

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Key Considerations

- The "know-do gap" describes a commonly seen challenge in program implementation—the difference between health worker knowledge and performance. In contexts where policies, guidelines, and trainings have been disseminated but programs are not reaching their goals, QI methods have the potential to bridge this gap.
- Quality improvement collaboratives are organized multihealth facility projects in which QI teams at each site use the same targets and indicators, develop and test contextually appropriate interventions using QI methods and tools, and convene periodically to share results, spurring friendly competition, and rapid diffusion of innovation.
- We used the QIC methodology to improve utilization of VL test results at 30 health facilities in Western Kenya, illustrating the potential of this approach to rapidly improve performance at scale.

References

Catsambas, T. T., Franco, L. M., Gutmann, M., Knebel, E., Hill, P., & Lin, Y.-S. (2008). *Evaluating health care collaboratives: The experience of the Quality Assurance Project*. Retrieved from https://www.usaidassist.org/sites/default/files/evaluating_health_care_collaboratives.pdf. Accessed September 7, 2019

El-Sadr, W. M., Rabkin, M., Nkengasong, J., & Birx, D. L. (2017). Realizing the potential of routine viral load testing in sub-Saharan Africa. *Journal of the International AIDS Society*, *20*(Suppl. 7), e25010. doi: 10.1002/jia2.25010

Haines, A., Kuruvilla, S., & Borchert, M. (2004). Bridging the implementation gap between knowledge and action for health. *Bulletin of the World Health Organization*, *82*(10), 724–731.

Hargreaves, S., Rustage, K., Nellums, L. B., Bardfield, J. E., Agins, B., Barker, P., … Singh, S. (2019). Do quality improvement initiatives improve outcomes for patients in antiretroviral programmes in low- and middle-income countries? A systematic review. *Journal of the Acquired Immune Deficiency Syndrome*, *81*(5), 487–496. doi: 10.1097/QAI.000000000002085

Heiby, J. (2014). The use of modern quality improvement approaches to strengthen African health systems: A 5 year agenda. *International Journal for Quality in Health Care*, *26*(2), 117–123. doi: 10.1093/intqhc/mzt093

Joint United Nations Programme on HIV/AIDS (UNAIDS). (2019). *AIDSinfo data*. Retrieved September 7, 2019, from http://aidsinfo.unaids.org. Accessed September 7, 2019

National AIDS and Sexually Transmitted Infections Control Programme. (2016). *Guidelines on use of antiretroviral drugs for treating and preventing HIV infection in Kenya* (2016 ed.). Retrieved from http://cquin.icap.columbia.edu/wp-content/uploads/2017/04/ICAP_CQUIN_Kenya-ARV-Guidelines-2018-Final_20thAug2018.pdf. Accessed September 7, 2019

National AIDS and Sexually Transmitted Infections Control Programme. (2019). *Online viral load dashboard*. Retrieved September 7, 2019, from https://viralload.nascop.org. Accessed September 7, 2019

Ogrinc, G., Davies, L., Goodman, D., Batalden, P. B., Davidoff, F., & Stevens, D. (2016). SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety*, *25*, 986–992. doi: 10.1136/bmjqs-2015-004411

Schouten, L. M. T., Hulscher, M. E. L. J., van Everdingen, J. J. E., Huijsman, R., & Grol, R. P. T. M. (2008). Evidence for the impact of quality improvement collaboratives: Systematic review. *BMJ*, *336*, 1491–1494. doi: 10.1136/bmj.39570.749884.BE

Shaw, E. K., Chase, S. M., Howard, J., Nutting, P. A., & Crabtree, B. F. (2012). More black box to explore: how quality improvement collaboratives shape practice change. *Journal of the American Board of Family Medicine*, *25*, 149–157. doi: 10.3122/jabfm.2012.02.110090

Wells, S., Tamir, O., Gray, J., Naidoo, D., Bekhit, M., & Goldmann, D. (2018). Are quality improvement collaboratives effective? A systematic review. *BMJ Quality & Safety*, *27*(3), 226–240. doi: 10.1136/bmjqs-2017-006926

World Health Organization. (2017, July). *What's new in treatment monitoring: Viral load and CD4 testing* (WHO Reference No. WHO/HIV/2017.22). Retrieved from https://www.who.int/hiv/pub/arv/treatment-monitoring-info-2017/en/. Accessed September 7, 2019