LabCoP Cookbook

of best practices

RECIPE #9:
ELECTRONIC RETURN AND NOTIFICATION OF TEST RESULTS

Mobile Apps
Stakeholder Engagement
Data Privacy
Regulations
Infrastructure
Monitoring & Evaluation

Lab CoP

ASLM

1 INTRODUCTION

Timely access to the results from diagnostic testing is critical for the effective management of recipients of care. Healthcare workers need access to results to make decisions such as selecting the appropriate model of care, initiating treatment, and switching treatment regimens, if required. Recipients of care are also empowered through access to their results, as this can allow them to play a more active role in their healthcare. In the management of conditions like HIV, efficient and timely return of results is particularly important, as recipients of care will undergo regular testing of their viral load (VL) to monitor disease status and the effectiveness of treatment.

The turn-around time for results is the delay between the moment when a person provides a sample to when the results are shared with the clinician and/or recipient of care for decision-making. What constitutes an optimal turn-around time (TAT) for test results can vary by population and medical condition. For example, a two-week TAT for HIV VL results, while generally acceptable, may be too long for HIV-positive pregnant women presenting late to antenatal clinics, who need rapid testing and results to prevent mother-to-child infection. Results from testing for early infant diagnosis of HIV are needed almost immediately to start treatment in an effort to reduce mortality. In cases of neonatal sepsis, results are needed even more quickly – within hours – to prevent death.

The testing process can be thought of in terms of three key phases: pre-analytical (test selection, sample collection, transport to laboratory), analytical (analysis of sample), and post-analytical (interpretation and reporting of results back to the clinician and/or recipient of care for decision-making).[1] Although progress has been made in shortening the time taken for the pre-analytical and analytical phases, the post-analytical phase often remains a challenge. Traditionally, results are provided in paper format, largely delivered using the sample transportation route, via courier or dedicated vehicles for sample transportation. In many cases, the timely return of results can be challenging, due to issues such as inefficient or long sample referral routes, overburdened laboratories and inefficient systems to deliver results to recipients of care. The delayed return of test results can represent a dramatic missed opportunity to initiate (potentially lifesaving) treatment, prevent complications or interrupt the chain of transmission of infectious diseases. Overall, long TAT for test results translate into morbidity, mortality and financial cost to the health system, despite the investments made in establishing diagnostic capacity.

In recent years, there has been growing interest in using electronic systems to improve the return of results to recipients of care and healthcare providers, particularly for long-term conditions like HIV where treatment decisions are based on laboratory results. Electronic methods to return results can include sending results by text messaging, using the Short Message Service (SMS) or Unstructured Supplementary Services Data (USSD) protocols, and utilising mobile applications, email, dashboards or via the existing laboratory information management system connected to different referral facilities. Using electronic methods to return results can reduce delays in the post-analytical phase, and improve the TAT and ease of delivering results from the laboratory to the clinician and recipient of care.

Traditionally, recipients of care have to wait to see a clinician to receive their results, which can create a bottleneck if clinician appointments are limited, and some may not follow through with making a physical appointment to see a clinician. For example, TAT for HIV results in some regions may be greater than 30 days,[2] meaning that individuals with unsuppressed VLs will return for their next adherence visit without a result. There are notable gaps and inefficiencies in how VL testing is used to guide clinical management. Concerningly, an estimated 50% of CD4 tests and early infant diagnosis of HIV tests performed in sub-Saharan Africa are not used.[3] Issues and inefficiencies around VL testing represent a missed opportunity to tackle poor adherence to HIV treatment, which results in treatment failure, advanced HIV disease and increased costs. Consequently, issues with VL testing represent a barrier to ending the HIV/AIDS epidemic by 2030. In this context, systems for electronic return of results provide an opportunity to improve the timely dissemination of results and further incentivise the clinician to use VL results appropriately.

Although they hold much promise to improve the return of results by improving the speed and ease of result delivery, effective electronic systems for returning results need to be accompanied by appropriate policies, standards and guidance for their implementation. Electronic systems also need to be interoperable with the other health data systems used in the country's healthcare system, so results can be shared easily between various components of the health system and stakeholders (e.g., the national HIV programme, the surveillance network).

In this recipe, we share key considerations for countries considering the implementation of electronic systems to improve the return of results in their settings and best practices based on experiences where the electronic return of results has been implemented in Africa.

2 RATIONALE FOR USING ELECTRONIC SOLUTIONS FOR RETURN OF RESULTS

Electronic solutions to return results can be of benefit where there is a need to improve the post-analytical phase of TAT, particularly in terms of rapidly disseminating results to healthcare providers and recipients of care (Figure 1). In other situations, traditional paper-based reporting may be acceptable as long as sufficiently short TAT can be achieved.

Electronic return of results is particularly suited where the analytical phase is short, but the existing reporting system creates a backlog in the post-analytical phase, in terms of delivering results to the healthcare provider and recipient of care. In this case, solutions such as SMS delivery of results can help to increase the efficiency and speed of reporting. Electronic return of results is also suited for large-scale testing programmes, as deployed during the coronavirus disease 2019 (COVID-19) pandemic, as a more cost-effective and efficient way to rapidly return results to large numbers of people. In addition, electronic return of results can be helpful for remote monitoring of recipients of care, for example, when people may receive healthcare consultations by telephone or video call. In addition, electronic methods can enable integration of results with existing electronic health records or laboratory information management systems, improving data collection and transmission throughout the health system.

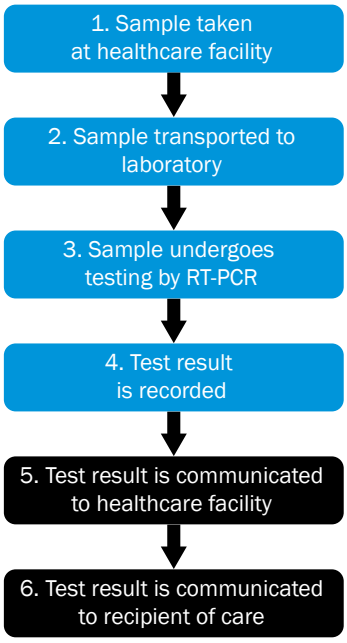


Figure 1. HIV viral load sample testing pathway showing where electronic return of results can be implemented (black boxes). Step 1 to Step 6 represents the TAT from sample collection to the return of results to the recipient of care.

3 STAKEHOLDER ENGAGEMENT

KEY CONSIDERATIONS

When developing a programme for the electronic return of results, it is critical to conduct a stakeholder analysis to identify the key stakeholders. The success of an intervention also hinges on early engagement with stakeholders, to obtain their buy-in and ensure that the intervention is acceptable to healthcare workers and recipients of care. Key stakeholders can include:

- Ministry of health personnel, including healthcare and laboratory workers involved in testing/return of results for the disease programme in question and other disease programmes for which the programme may be expanded to cover in the future
- Ministry of telecommunications
- Ministry of finance
- Ministry of research
- Recipients of care, including key patient groups for the specific intervention (e.g., people living with HIV, pregnant women, etc.)
- Data managers responsible for the design, operation and management of health information platforms and applications
- Donors/development partners
- Telecommunication/private providers
- Civil society organisations

Various stakeholders may have different perspectives on and approaches to the implementation/use of electronic return of results. Those working to implement systems for the electronic return of results should consider that these conflicting perspectives could lead to potential confusion and inconsistency in how systems are applied or how systems can be scaled up. The most effective way to mitigate these issues is through early engagement with stakeholders and facilitating communication and decision-making tween relevant parties.

BEST PRACTICES

- **Stakeholder alignment and coordination**

In practice, each country should undertake a stakeholder analysis as a first step to implementing a system for the electronic return of results. Engaging the relevant stakeholders ensures comprehensive evaluation and facilitates collaborative improvement efforts. Close collaboration should be established between the HIV programme, patient associations, phone service providers, the statistical unit at the Ministry of Health and information technology personnel. For example, when a system for the electronic return of VL results was implemented in Kenya, a diverse group of stakeholders were involved. This included the National HIV and STI Control Program, the national HIV reference laboratory, representatives from regional reference laboratories and the regional government, the National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK); United States Centers for Disease Control and Prevention, Kenya Branch; the University of Nairobi and message application developers.

The most effective way of ensuring the acceptability and feasibility of the approach by recipients of care is by ensuring that they are involved in designing the messages and approaches to be used. For instance in Kenya, representatives from NEPHAK were involved in the development and structuring of the VL result messages and notifications to be provided to recipients of care.[4]

Buy-in from the Ministry of Health is also important to ensure that the intervention is sustained beyond the initial pilot, particularly if implemented by an external partner. The value of the intervention, collected through monitoring and evaluation (see Section 6 below) should be made clear to partners to encourage continuation. The sustainability of the intervention can be improved by developing a system for the electronic return of results that can deliver results from a diverse array of diseases and their associated diagnostic tests, so the system has broader utility. Consideration should also be given to the parties responsible for funding the intervention, e.g., the Ministry of Health, donor organisations, implementing partners or recipients of care, as ensuring continuity of funding is necessary for the sustainability of the intervention.

Ethics

The electronic return of results poses a number of ethical considerations, related to informed consent, data privacy and potential harms to the recipient of care from unintended disclosure of sensitive medical information via electronic channels. Stakeholders may have different opinions on these issues, which need to be resolved.

KEY CONSIDERATIONS

- **Potential benefits and harm to recipients of care.** Potential risks and benefits for recipients of care related to the electronic return of results should be evaluated prior to implementation. For example, benefits of the approach include that electronic return of results can facilitate timely access to test results and allow recipients of care to receive information in a more convenient manner than having to return to a medical facility each time. However, care should be taken to ensure that the means by which results are communicated to the recipients of care are culturally and socially acceptable. Efforts should also be made to ensure that information shared with users is clear, understandable and not overwhelming to reduce the risk of miscommunication or psychological harm from receiving potentially distressing results outside of a medical environment. An example would be how to effectively communicate an infant's positive HIV PCR result to the caregiver. One approach would be to consider sending a notification for the caregiver to return to the health facility to collect the child's result in person, to ensure they receive the psychological support required. In this case the message should not disclose the status of the mother nor child. Box 1 provides an example message for results from early infant diagnosis of HIV, as used in Kenya.

- The message does not disclose the status of the mother nor child
- This message is sent to ALL mothers regardless of result (positive or negative)

English

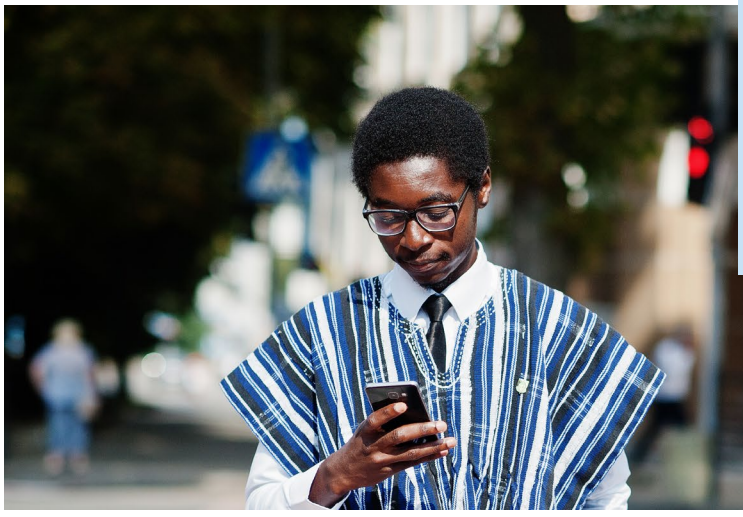
Jambo, baby's results are ready, please come to the clinic when you can, thank you.

Kiswahili

Jambo, Matokeo ya mtoto tayari, kuja kliniki utakapoweza, asante.

Box 1: Example result delivery messages for early infant diagnosis of HIV

In addition, health data security and confidentiality are fundamental to any electronic medical record system to ensure that the privacy of patient data is maintained. As such, efforts should be made to identify and minimise potential violations of data privacy during the electronic return of results. This includes ensuring the security of the platforms used for data collection/ management and the method by which the recipient of care will receive the result (e.g., email or SMS). Implementers should consider using a method to authenticate recipients of care, for example, by requesting that they enter a passcode when receiving results through a portal. Stakeholders such as recipients of care, healthcare providers and regulators may have different perspectives on managing personal data, and these should be considered ahead of implementing an electronic system to avoid potential conflicts.



BEST PRACTICES

- **Informed consent**

  Recipients of care must provide informed consent to have their results shared electronically and understand how their information will be used and communicated (e.g., via SMS). This is important to avoid the unintended disclosure of results (e.g., an individual shares a mobile phone with other members of the family). The informed consent form used in Kenya for electronic return of results is provided in Annex 1 as an example.

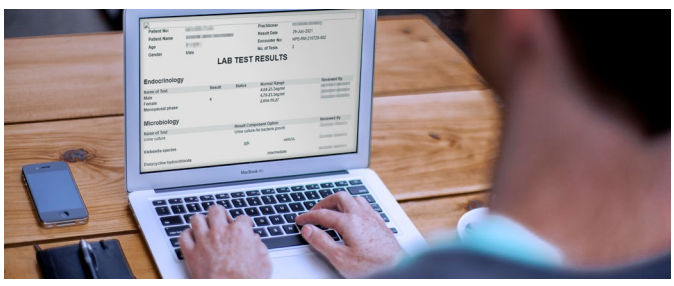
- **Data privacy and confidentiality**

  For secure data handling, implement robust access controls, detailed audit trails, standard login practices, data protection measures and technical security functions, including encryption. In Kenya, the authentication process for accessing health records typically involves several steps to ensure the privacy and security of recipient of care information, as summarised below.

  In Kenya, electronic medical record systems are required to:

  - Have access-control functions that limit access to health data to selected individuals, based on defined and documented user roles.
  - Maintain detailed audit trails of all events within the system. Every access attempt and action performed on the health records is logged in an audit trail. This includes details such as the user's identification number, timestamp, accessed records and the purpose of access. The audit trail serves as a record for monitoring and accountability purposes.
  - Follow defined standard practices for logins and passwords. This can include a username, employee identification number or any other identifier specific to the healthcare organisation.
  - Ensure data protection by meeting requirements regarding data backup, recovery and documentation of systems.
  - Incorporate technical security functions in line with requirements regarding encryption and data transmission.

  It is important to note that the specific authentication process may vary depending on the healthcare organisation, system and technological infrastructure in place. The example provided outlines a general framework for health records authentication in Kenya.



Policies and Regulations

KEY CONSIDERATIONS

- **Enabling policies and regulations**
  Policies and regulations around health information exchange and digital health systems can differ between African countries. A systematic review published in 2022 identified several eHealth-related strategic documents and policies around the development, improvement, adoption and implementation of health information exchange architecture, interoperability and standards in Africa.[5] While most African countries do not yet have comprehensive policies or regulations for health information exchange, a few countries have existing policies.[5]

BEST PRACTICES

- **Evaluation of existing policies and regulations around electronic return of results**

  Consequently, as a first step to implementing any electronic return of results, countries will need to evaluate which policies and regulations exist in their country around data protection, exchange of health information and use of digital tools in returning results. Any approaches to return results electronically should comply with these policies and regulations. Given that electronic return of results is a relatively new concept for recipients of care and healthcare providers, countries are likely not to have policies governing its implementation. However, some countries have been developing concept documents to guide the implementation of the electronic return of results. For example, during the COVID-19 pandemic, South Africa introduced systems to return results electronically and issued guidance on the capturing and reporting of COVID-19 testing information that can be consulted.[6] In addition, South Africa has a National Health Normative Standards Framework for interoperability, which provides a foundation for interoperability standards in the country[7] The British Medical Association has also released guidance that explains doctor's clinical responsibility around acting upon electronic test results, including around the communication of critical results, and receiving results from other clinicians, hospital teams and patient-generated data.[8] In the United States, a toolkit is available from the College of American Pathologists to provide guidance for healthcare practices planning to release test results directly to patients.[9]

BEST PRACTICES (Cont.)

- **Following international regulations**

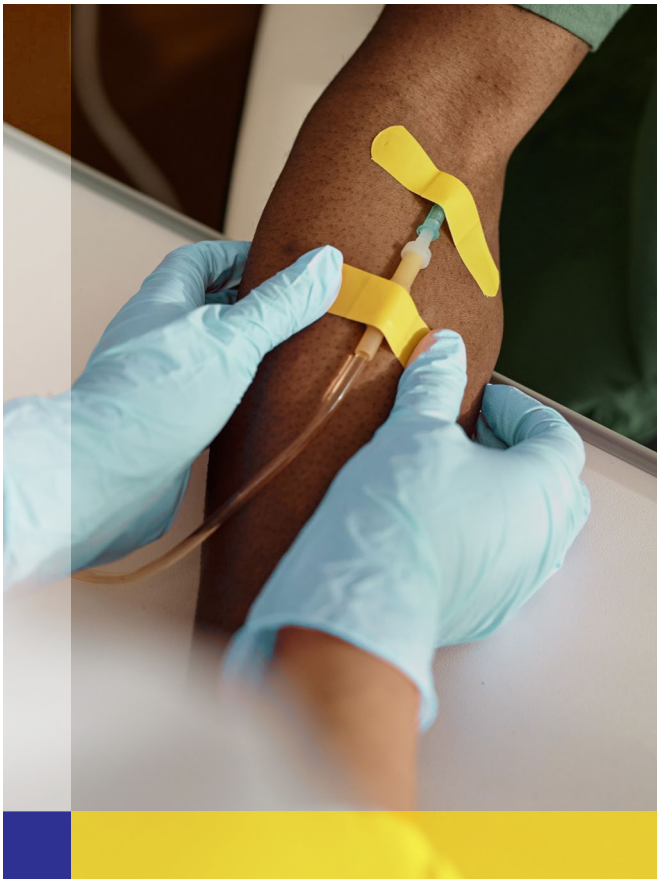
  Where no local policies exist, international regulations apply. Primary among these are the *African Union's Health Information Exchange Guidelines and Standards*, which suggests guidelines and standards for African Union Member States to help develop and implement health information exchange for digital health systems in Africa.[5]

- **Development of national policies**

  One way to mitigate the lack of policy is through South-to-South sharing of documents between countries in Africa, which can be quickly adapted to the local context through *ASLM's Laboratory Systems Strengthening Community of Practice* (LabCoP) initiative. The LabCoP initiative fosters South-to-South knowledge exchange and joint learning by linking country teams from across Africa with global experts, and sharing knowledge and best practices of laboratory systems strengthening amongst ministries of health.[10]

  Additionally, it is important to hold discussions among policymakers and healthcare providers regarding the need for strong cybersecurity measures and data protection regulations to safeguard sensitive personal information. Guidelines from the African Union on cybersecurity measures should be referred to if national policies do not exist.[7] As an example from Kenya, the stakeholders involved in the development of Kenya's National Cybersecurity Strategy were:

  - Government ministries and agencies, including the Ministry of Information, Communications and the Digital Economy, the National Intelligence Service and the Communications Authority of Kenya
  - Kenya National Computer Incident Response Team
  - Private companies, particularly those in the telecommunications, banking and critical infrastructure sectors, who can provide input on industry-specific cybersecurity needs and challenges
  - Academic and research institutions, who provide input into the development of cybersecurity expertise, research and training programmes
  - Civil society organisations, non-governmental organisations and advocacy groups, who can participate in discussions and advocate for cybersecurity awareness and best practices



Prior to Implementation

KEY CONSIDERATIONS

- **Assessment of infrastructure**

  Introducing electronic return of results requires a robust technological infrastructure to ensure the safe and secure transmission of personal data. Stakeholders such as healthcare providers and recipients of care may have limited access to such technology, which can hinder the adoption of electronic return of results. As such, it is essential to conduct a feasibility assessment before rolling out new technology to assess whether it can be implemented within existing infrastructure. This should include assessment of infrastructure (e.g., laboratory information systems) at the health facility level. It is also important to assess the capacity of communications companies to provide such services (e.g., in terms of whether companies have wide enough coverage and strong enough signal across target areas) and whether the application works on Android or other software (e.g., iPhone). Another key consideration is the level of mobile phone usage among target population groups.

KEY CONSIDERATIONS (Cont.)

- **Platform choice considerations**

As a first step to selecting a delivery method, it is important to assess the digital literacy of the target population and what proportion has access to a mobile phone/smartphone.

This will help inform the choice of delivery method. Options include:

- Simple SMS messages, which do not require a data package/smartphone
- Messaging platforms like WhatsApp, which requires a smartphone and data
- Mobile applications that are downloaded and used on mobile devices by both healthcare workers and recipients of care
- Web-based tools developed for use on computers or tablets by healthcare workers
- Innovative tools, such as SMS printers, which may be useful where traditional electronic clinic-laboratory systems are not available. SMS printers can facilitate the rapid delivery of laboratory results from the laboratory information system to the health facility via mobile communication at a low cost.[11]

When considering the choice of platform to manage and return results, considerations should include which platforms are available in country and, if they are publicly available, do they have sufficient reach and the required functionality. In general, simpler technology is usually a better choice, as more people are likely to have access, without requiring technical knowledge. If digital tools are not already available in the country, priority should be given to open access platforms. For example, if mobile phone usage in the target population is low, web-based platforms may be more appropriate.

It is also important to assess whether platforms are interoperable with existing health management systems, so data can be transmitted seamlessly across the healthcare system and to the national database for surveillance purposes. Interoperability of health data systems ensures efficiencies in the provision of healthcare. For example, data sharing between various health systems can eliminate duplicative tasks by recipients of care or healthcare workers when it comes to the documentation of clinical records in multiple forms. If platforms are not interoperable, the availability of interoperability solutions should be sought.

If using a mobile application, it is important to consider whether the application will be supported by the mobile devices used by people in the target population. For example, a trial of an Android mobile application to improve HIV linkage to care in South Africa found that the features required by an initial iteration of the application were not supported by a third of the participants' mobile phones.[12]

BEST PRACTICES

- **Choice of digital health application**

A number of digital health applications are in use across Africa, including electronic surveillance and digital health applications and telemedicine applications.[5] The most widely used digital tools are DHIS2 (District Health Information System 2), an open-source, web-based platform for data collection, management and analysis, and OpenMRS (Open Medical Record System), an open-source, customisable electronic medical record system.[5,13,14] SMS-based programmes, mobile health (mHealth) applications and mHealth tools have also been deployed for various healthcare services across Africa.[5] Several mHealth applications, such as *Vula*, *MomConnect*, *WelTel* and *Omomi*, have been used for healthcare delivery and surveillance in Africa.[5]

As discussed, selected platforms should be interoperable with other health systems in use in the country. In addition, to ensure that sensitive health data are shared appropriately and securely, interoperability solutions should be compliant with the *United States' Health Insurance Portability and Accountability Act of 1996*, which is a globally accepted regulatory standard for patient data security and privacy.[15]

When determining which approach may be most appropriate for the target population, implementers should seek to assess mobile usage and literacy among the target population. Survey reports from the government and other stakeholders can be consulted for insights (e.g., the annual reports on the mobile economy in sub-Saharan Africa from the GSMA [*Global System for Mobile Communications Association*]).[16]

If appropriate, multiple platforms can be deployed in tandem. For example, in Uganda, a system utilising both a web-based platform and USSD messages was implemented to improve access to and utilisation of laboratory results by healthcare workers and recipients of care. The Laboratory Results Dispatch System comprises both a web-based system, which can be accessed on a computer with an active internet connection, and USSD-based system, which can be accessed from any mobile phone with a keypad, with no charge or service fee. The system provides easy access to results for tests such as early infant diagnosis of HIV, HIV VL and COVID-19. Healthcare workers and recipients of care are provided with the option to access results via the web-based system or via mobile phone, depending on which is most convenient and/or accessible. Offering both a web-based and mobile phone-based way to access results may be useful in settings where mobile phone penetration may be low or very variable.

In addition, an electronic application for the return of VL results via SMS and USSD was developed for use in Malawi. This combined approach enables usability for both smartphone and feature phone users, as smartphone use is limited in the country. The application was found to improve the TAT of VL results, with clients receiving results 44% to 55% faster than paper-based reporting of results.

- **Available technologies**

Several countries in Africa have used different approaches to disseminate results electronically, in addition to those previously highlighted. In Zimbabwe, an electronic system to return results was introduced to improve the TAT of VL test results during the COVID-19 pandemic, which was previously slow (at around 28 days). A system to return results by SMS was subsequently introduced at a high-volume site to improve timely utilisation of results from VL testing. The system works by sending SMS notifications to both the health facility and recipient of care once results are available. Recipients of care receive an SMS notification that results are available, or an SMS asking them to return to the facility for additional testing, if the sample was rejected by the laboratory. Health facilities receive an SMS with details of the individual's result and notification of whether the results require critical intervention. In cases where samples are rejected by the laboratory, the facility is notified that the sample has been rejected.

BEST PRACTICES / Available Technologies (Cont.)

An mHealth solution known as *eLABS* has also been deployed to strengthen the clinic-laboratory interface across several African countries. eLABS is a digital health application that allows tracking and tracing of specimens across the pathology value chain workflow, including the electronic return of results (Figure 2). The application is used by healthcare workers and courier drivers. The eLABS application is accessed through mobile and desktop digital platforms, has offline capability and is supported with back-end business intelligence dashboards. The application delivers all available results, i.e., both normal results and results for action (abnormal, invalid, rejected and amended). Notifications for results requiring action are delivered with an alert notification as soon as results are released by the laboratory. eLABS is recognised as a tool to assist with reaching the VL suppression part of the *UNAIDS 95-95-95* treatment goals and is used by approximately 3500 facilities to strengthen the interface of the clinic, laboratory and patient.

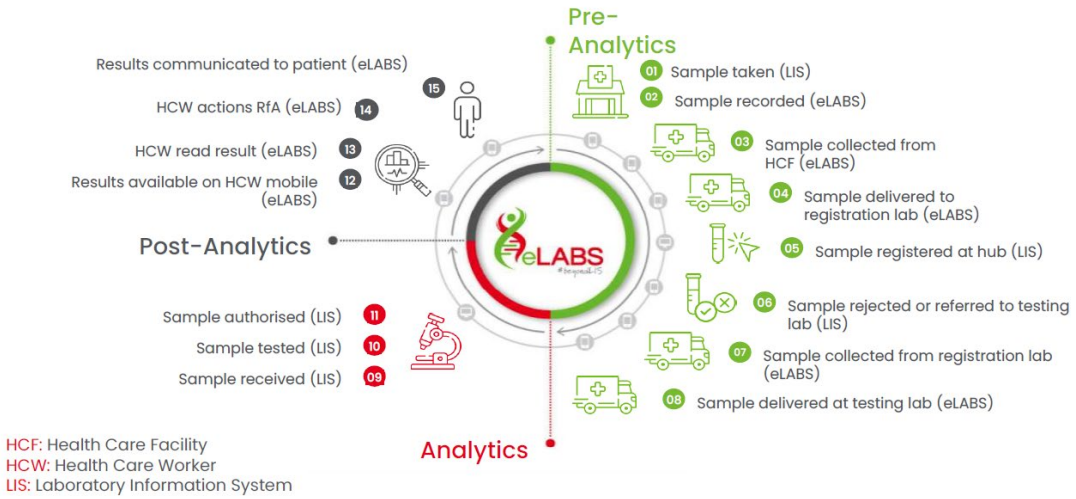


Figure 2. eLABS workflow: pathology value chain.

An eLABS patient support system has also been developed to support recipients of care and improve utilisation of HIV VL results (Figure 3). As part of the patient support system, VL result outcomes are sent directly to recipients of care via their mobile phone, along with appointment reminders and educational health messages.

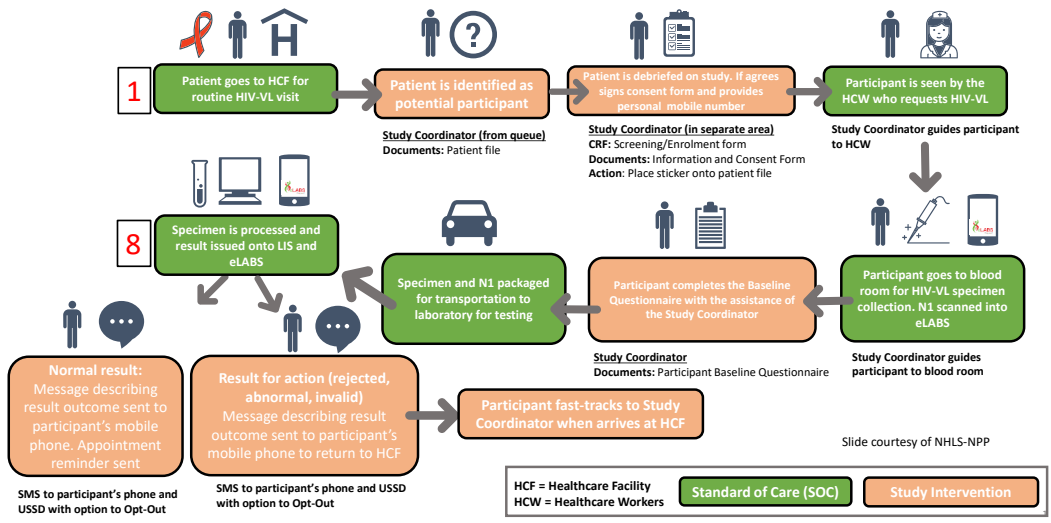


Figure 3. eLABS patient support system.

HCF, healthcare facility; HCW, healthcare worker; LIS, laboratory information system; N1, laboratory request form; NHLS-NPP, National Health Laboratory Service National Priority Programmes; SMS, Short Message Service; USSD, Unstructured Supplementary Service Data; VL, viral load.

BEST PRACTICES / Available Technologies (Cont.)

In order to strengthen the clinic-laboratory-patient interface for HIV and tuberculosis testing in South Africa, the feasibility and usability of the eLABS mobile application was investigated for sending appointment reminders to recipients of care as to when their next laboratory test is due (e.g., an HIV VL test), as well as the outcome of the test result, sent via secure information and communication technology platforms to their mobile phones. Messages were sent to the recipient of care to return to the facility for a follow-up appointment in the case of an abnormal test result, an invalid test result or a rejected specimen.

eLABS was piloted and implemented in Zambia, South Africa, Mozambique and Nigeria and with a planned pilot in Liberia. To date, eLABS has been implemented in over 3500 facilities and returned approximately 18 million results to facilities. eLABS is helping to improve result TAT, reduce specimen rejection rates and increase the percentage of VL results acknowledged in the countries where it is being used.

- **Development of messaging approach**

Messages used to share results can be understood differently depending on factors such as the literacy, language and age of the target population. The specific messaging approach should therefore depend on the target population and their demographics, and should consider the social/cultural context, languages in use, digital literacy levels and type of information to be shared in the message.

  - **Language.** If the target population includes people who speak different languages, messages may need to be developed in more than one language to ensure the messages will be understood by the recipients of care.

  - **Content of message.** Messages can be used to provide varying levels of information and a decision needs to be made around what information is appropriate depending on the target population. For example, messages can include:

    - **Result notification.** Messages can simply notify recipients of care that results are available and provide information about they can access those results (e.g., by returning to the clinic), without providing any specific details of the test findings (see Box 1, page 5).

    - **Actual test result.** If deemed appropriate, messages can also include details of the specific test result. For example, for people with HIV, this could include the actual VL level. Alternatively, messages can be adapted for different cohorts (e.g., individuals with suppressed vs non-supressed VLs). In this case, the message can indicate if the VL test result is 'good' or, if the result requires clinical management, request that the individual returns to the clinic/healthcare provider (Box 2).

SMS content for VL <1000

English 1: *Congratulations, Your VL result is good. Continue taking your drugs and remember to come on your appointment date.*
Swahili 1: *Pongezi! Majibu yako ya VL iko kiwango kizuri! Endelea kuzingatia maagizo ya daktari na kumbuka tarehe yako ya kuja cliniki!*

SMS content for VL >1000

English 2: *Your VL results are ready. Please come to the facility as soon as you can.*
Swahili 2: *Majibu yako ya VL yako tayari. Tafadhali tembelea kituo cha afya umuone daktari!*

Box 2: Example of result delivery messages from implementation of electronic return of HIV VL results in Kenya.

- **Educational health messages.** Educational messages can also be shared to highlight the importance of testing and adhering to medication. The previously mentioned eLABS mobile application also includes educational health messages, as well as appointment reminders and result messages (Figure 4).

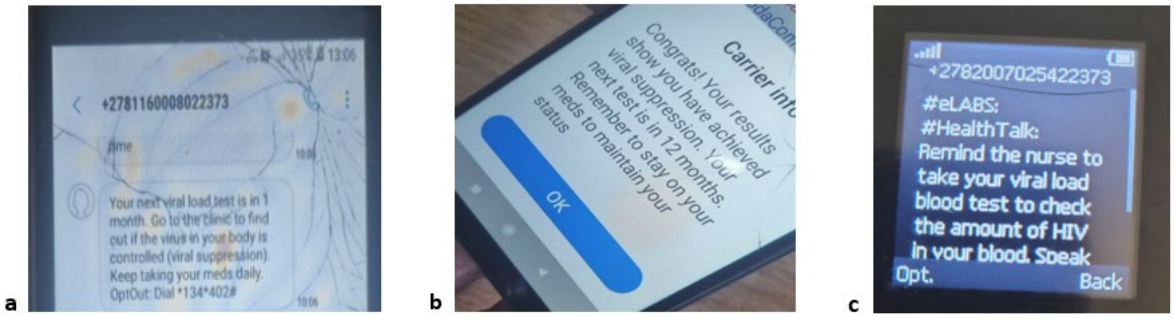


Figure 4. Examples of patient messages sent through eLABS. a) Appointment reminders; b) result outcomes; c) educational health messages.

- **Appointment management.** If result messages request that recipients of care return to the clinic, consideration should be given to ensure that there is a process to manage existing appointments, so that existing appointment slots are not wasted.

- **Estimate of costs for the electronic return of results**

Costs for the electronic return of results should be estimated prior to implementation to ascertain affordability by the programme. Assessment of costs should consider both the initial setup costs and the ongoing operational expenses. The costs to take into account include:

- Cost of sending bulk SMS messages
- Costs for customisation of the tool/local information systems
- Cost of orienting recipients of care on the new tool/app
- Costs for training of healthcare workers on the new tool/app
- Costs for support staff required for implementation of the new system

The stakeholder(s) responsible for bearing the cost of implementation should be advised of the costs in advance and agree to the cover those costs ahead of the approach being rolled out.

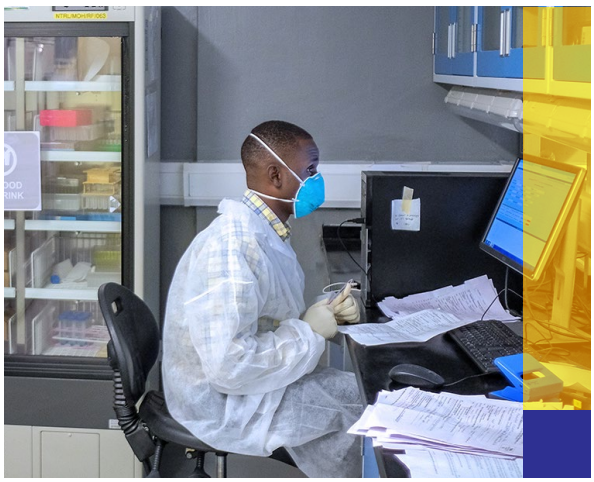
For SMS-based systems, the startup costs can vary depending on the platform used. Integrating SMS systems with existing databases or software may incur additional costs. Operational costs include the costs for sending individual SMS messages, which can vary depending on the mobile network provider, the volume of messages, and the specific SMS plan or bundle to which the user has subscribed. As an example, in Kenya, the cost of sending an SMS in typically ranges from 1 Kenyan Shilling (KES) to KES 3 (equivalent to about $0.01 to $0.02 United States dollars) per SMS. In Uganda on average, the cost of sending an SMS from 50 Uganda shillings (UGX) to UGX 220 (equivalent to about $ 0.01 to $0.06 USD) per SMS, while in South Africa, the average cost of sending an SMS is approximately 0.50 Rand (R) to R1.50 (equivalent to about $0.03 to $0.08 USD per message). Cost negotiations and the bulk procurement of SMS packages in advance can be used to lower overall costs.

For web-based applications, costs will vary depending on whether an existing platform will be licenced for use in the country or whether a platform needs to be developed or adapted. The cost for developing and maintaining a web-based application can be substantial, particularly if the platform requires customised features or integrating with existing healthcare databases. Web-based applications will also entail infrastructure costs, such as web hosting services, domain registration and the maintenance of servers and security. Nevertheless, web-based systems may be more cost-effective than alternative electronic methods (e.g., SMS-based systems) in the long-run.

Trialling Programmes

KEY CONSIDERATIONS

Trialling programmes through pilots can help demonstrate the value of the programme to stakeholders before progressive scale up. An initial pilot of the new tool/application to facilitate electronic return of results should be conducted to assess feasibility and acceptance, prior to the tool being rolled out more broadly. During the pilot, the country needs to monitor the TAT for results, cost of implementation and how easily the system can be used by recipients of care to inform scalability.



BEST PRACTICES

Designing a pilot for the electronic return of results involves several key steps, including outlining the workflow, mobilising resources, selecting facilities and measuring the success of the pilot. Several countries have used pilots to trial the electronic return of results before rolling out the programmes more broadly. In Zimbabwe, the first pilot using the SMS system was introduced in 2020 and following introduction, TAT improved from 28 days to 14 days. The introduction of SMS result return for VL testing also improved the clinical management of recipients of care. The programme has since been rolled out to other facilities and now around 1000 sites in Zimbabwe are using SMS notifications to return results to health facilities and recipients of care.

In South Africa, a feasibility study was conducted to evaluate the use of a mobile application known as *iThemba*, to support test result utilisation and engagement in HIV care. The iThemba phone app delivers HIV VL results, education and clinical support directly to users' smartphones, empowering people living with HIV to remain engaged in care (Figure 5).

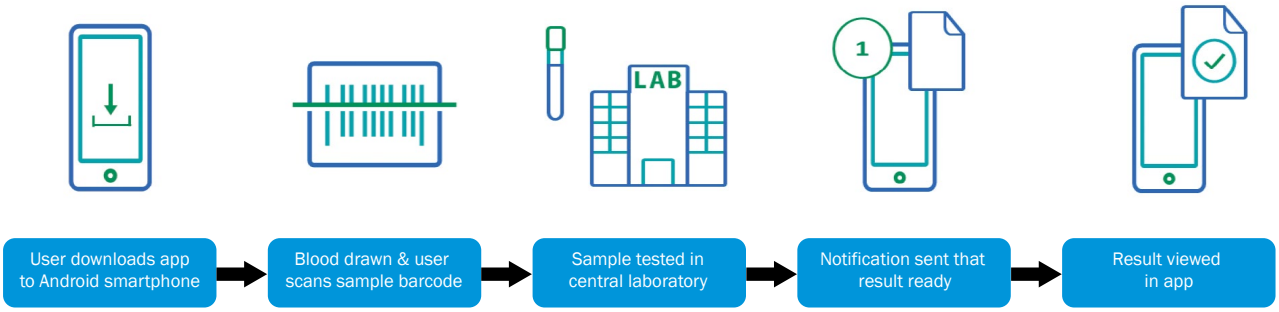


Figure 5. iThemba workflow.

The feasibility and acceptability of the iThemba app was evaluated part of a study enrolling 500 HIV-positive adults who provided informed consent for the electronic return of results.[17] iThemba was found to be feasible and well received by users, with HIV VL results returned faster than standard of care. Results were released to 92.2% (461/500) of participants' phones, with 78.1% of results viewed in iThemba. TAT from phlebotomy to the result being received was significantly reduced from 56 days before the app to 6 days with the app – around 10 times quicker. Users were found to be eager to receive their HIV VL results with the app. The feasibility study allowed for the identification of operational and technical challenges around the implementation, which included technical proficiencies of users, mobile phone capabilities, network connectivity issues and stakeholder buy-in, among other factors.

Scaling up electronic return of results and programme sustainability

KEY CONSIDERATIONS

Once feasibility has been demonstrated through pilots, the programme can be scaled up across the country and potentially tailored for use in other disease programmes. Lessons learnt from the pilot can then be used to improve the implementation of the return of results.

Aspects to consider while scaling up electronic return of results include:

- **Infrastructure.** With additional enrolment of participants comes additional infrastructure requirements. This includes additional data storage considerations, upgrading software and hardware and data security protocols.
- **Participant engagement.** As the programme is scaled up, it remains important to engage new participants and provide education and awareness-raising around the electronic return of results. This may involve developing educational materials or engaging additional personnel to conduct training sessions.
- **Personnel.** Additional personnel may be necessary to support training, participant enrolment and answering queries during the implementation period.
- **Quality assurance.** It remains vital to ensure that quality is maintained as the numbers of results being transmitted increases. As such, routine quality assurance measures need to be implemented to allow ongoing evaluation of the programme.
- **Sustainability.** Consideration should also be given to how to ensure the sustainability of the intervention beyond the initial project, e.g., in terms of continuity of funding and ongoing management.

BEST PRACTICES

- **Education and literacy around electronic return of results**

  Prior to implementation, recipients of care should be provided with information about the proposed electronic return of results and efforts should be made to ensure that the target population understands the intervention and risks. For example, recipients of care should be oriented on the use of SMS/USSD to retrieve results, if the country chooses that as the mode of return of results. Additionally, users should be made aware of the potential for unintended disclosure of information (e.g., if they share a mobile phone with family members).

  For example, in Zimbabwe, client education (i.e., healthcare workers and recipients of care) was found to be important to ensure that clients were able to use the SMS system used to electronically deliver COVID-19 test results. To facilitate this, a job aid was developed to standardise the handling of electronic results. On-the-job training support was also offered to the various facilities implementing the approach. In addition, to improve the process to obtain client consent, a consent request was incorporated in the VL request form.

- **Sustainability**

  For programmes using the electronic return of results to be impactful, they must be sustained beyond the initial pilot. This requires early engagement with key stakeholders and funders to establish continued funding and resources for the project. For example, when implementing the eLABS digital health intervention to strengthen the clinic-laboratory interface in several countries in Africa, it was found that engagement of stakeholders across all levels of the countries' ministries of health, the national laboratory service and the support partners was vital to ensure sustainability of the project beyond implementation.

  Evidence generated from implementing systems to electronically deliver results is also valuable to demonstrate the impact and feasibility of the intervention. As such, it is important to establish systems to monitor and evaluate the intervention (see next section) and processes to disseminate the evidence and lessons learned. The total cost of the intervention also needs to be assessed to evaluate the cost-effectiveness of implementing the electronic return of results and determine the funding required to sustain or expand the project. Establishing normative guidance for the electronic return of results, particularly for priority conditions like HIV, can also help encourage uptake and continued implementation of the electronic system.

Monitoring and Evaluation

KEY CONSIDERATIONS

It is essential to monitor and evaluate the electronic return of results, to ensure that the approach is feasible and provides a benefit for recipients of care, healthcare workers and the health system. It is equally crucial to assess its effectiveness, identify areas for improvement and ensure quality outcomes. For HIV programmes, monitoring and evaluation would be geared towards improving HIV programming, recipient of care satisfaction in the use of the system and the cost effectiveness of the intervention (i.e., return of results).

Common data sources that healthcare providers may use to monitor the implementation can include:

- **Electronic health records.** Electronic health record systems are built to contain comprehensive clinical records; thus, healthcare providers can access and review these records to identify relevant results for return to the recipient of care.
- **Laboratory information systems.** Laboratory information system databases store and manage laboratory test data; thus, providers can retrieve and interpret the results for sharing with recipients of care. These data can also be merged with electronic health record data to provide a more comprehensive perspective to the attending clinician and inform clinical decision-making.
- **Smart devices.** Recipients of care may use wearable devices, smartphone apps, or other health monitoring tools to track various health metrics. Recipients of care may use data from such devices to monitor their health metrics.
- **Facility registers.** Facilities/countries documenting clinical records in physical registers can obtain records from the registers to monitor the return of results.

BEST PRACTICES

Best practices for monitoring and evaluating the implementation of electronic return of results include:

- **Establish clear objectives and indicators.** Identify measurable indicators that align with these objectives, such as reduced TAT of result delivery, recipient of care satisfaction, improved clinical outcomes, etc. These indicators will serve as benchmarks for evaluation.
- **Establish data management.** Collect and analyse data to inform the implementation.
- **Establish continual quality improvement.** Establish a culture of continual quality improvement by utilising the findings from the monitoring and evaluation process to identify areas for enhancement, implement changes, and monitor the impact of these changes. Continually refine the implementation process based on feedback and data-driven insights. In Zimbabwe, data were collected to monitor and improve the SMS result delivery programme. This included data on the number of SMS messages sent to recipients of care each day, the average number of SMS messages sent each month to facilities and the proportion of facilities receiving SMS notifications. Collection of client feedback also allowed for improvements of the SMS system after implementation.
- **Conduct quality audits.** Routinise quality audits to assess compliance with privacy regulations, data security measures and other legal requirements. Address any identified issues or vulnerabilities promptly to maintain compliance and trust by recipients of care.
- **Collect feedback from recipients of care.** Use recipient of care satisfaction surveys, focus groups or individual feedback sessions to gather the perspectives of recipients of care. Incorporate inputs from recipients of care into the evaluation process and adjust the implementation accordingly.

BEST PRACTICES (Cont.)

It is also important to establish key indicators for monitoring and evaluation prior to any assessments taking place. These can include:

- Increased percentage of results delivered to recipients of care
- Reduction in TATs for return of results, i.e., reduction in time from when an individual provides a sample to when the individual receives their result
- Greater utilisation of results, e.g., greater number of recipients of care receive medication
- Better adherence to treatment
- Improved clinical outcomes, e.g., increased viral suppression for recipients of care receiving HIV VL results via messages

For the VL results return application in Malawi, a simple dashboard was developed to show key indicators, such as number of samples collected, clients notified by SMS and USSD and result TAT (Figure 6).

For the eLABS digital health application, a monitoring strategy was developed based on the *Rapid Testing Continuous Quality Improvement* model to monitor and evaluate the performance of eLABS.[18] The monitoring strategy includes measurable indicators, which are displayed on dashboards to enable daily monitoring of key metrics (Figure 7). Countries can develop their own monitoring strategy using the framework provided by the Rapid Testing Continuous Quality Improvement model.

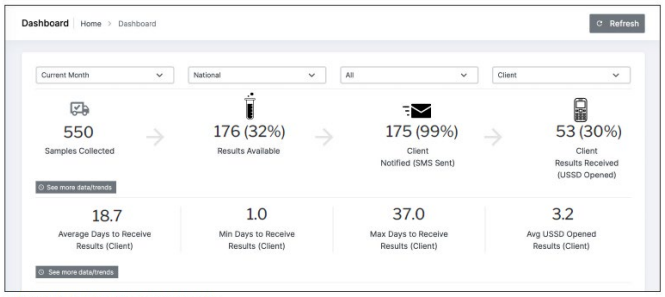
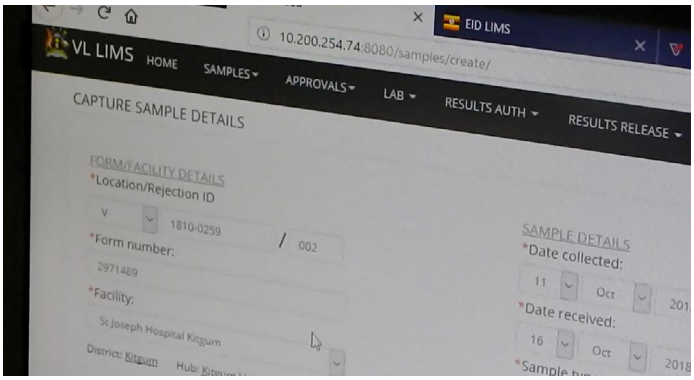


Figure 6. Monitoring and evaluation dashboard for the VL results return application in Malawi.



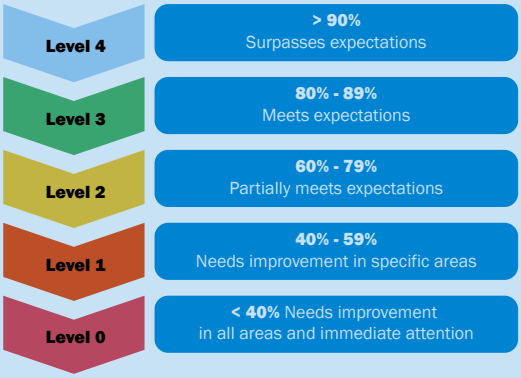


Figure 7. eLABS continuous quality improvement model. Quality Improvement model to monitor and evaluate the performance of eLABS.

Indicator	Surpasses expectations Score=4	Meets expectations Score=3	Partially meets expectations Score=2	Needs improvement in specific areas Score=1	Needs improvement in all areas and immediate remediation Score=0	Score
Adoption (use of eLABS devices)	✓					4
Specimens scanned by Facility		✓				3
Specimens delivered by Courier		✓				3
Specimen rejections			✓			2
Turnaround time			✓			2
Results for Action read			✓			2
Total Performance Grading						16/24 = 67%

7 CONCLUSIONS

Electronic solutions to return results can improve the efficiency and speed of disseminating results to healthcare providers and recipients of care. The approach is particularly useful in situations where tests are completed quickly, but there is a delay delivering results to the healthcare provider and recipient of care. Here, digital approaches, such as using SMS messages, mobile applications or web-based platforms can increase the speed at which results can be delivered and used for clinical decision-making. In the case of HIV VL testing, this is particularly important, as recipients of care require regular tests to inform treatment decisions.

Several countries in Africa have already implemented electronic solutions to return results for HIV VL and COVID-19 testing. Moving forward, it is likely that digital and electronic means of returning results will be used more broadly to share test results and health information. By following the considerations and best practices provided in this recipe, countries can design practical and feasible approaches using electronic solutions to improve the return of results in their settings for HIV VL testing and other tests.

REFERENCES

1. Hawkins R. Managing the pre- and post-analytical phases of the total testing process. Ann Lab Med 2012; 32: 5-16. 2012/01/20. DOI: 10.3343/alm.2012.32.1.5.
2. Moirana EL, Muro EP, Kiwelu IE, et al. Evaluation of HIV viral load turnaround time in Moshi, Tanzania. J Infect Dev Ctries 2022; 16: 1500-1505. 2022/10/13. DOI: 10.3855/jidc.14145.
3. Peter T, Zeh C, Katz Z, et al. Scaling up HIV viral load - lessons from the large-scale implementation of HIV early infant diagnosis and CD4 testing. J Int AIDS Soc 2017; 20 Suppl 7 2017/11/14. DOI: 10.1002/jia2.25008.
4. NEPHAK. About, https://nephak.or.ke/about/#:~:text=NEPHAK%20is%20a%20national%20Network,non%2Dgovernmental%20organizations%20and%20networks. (accessed 4 March 2024).
5. Mamuye AL, Yilma TM, Abdulwahab A, et al. Health information exchange policy and standards for digital health systems in africa: A systematic review. PLOS Digital Health 2022; 1: e0000118. DOI: 10.1371/journal.pdig.0000118.
6. Department of Health RoSA. Guide to antigen testing for SARS-CoV-2 in South Africa, https://www.health.gov.za/wp-content/uploads/2021/08/GUIDE-TO-ANTIGEN-TESTING-FOR-SARS-COV-2-IN-SOUTH-AFRICA_V4_06.07.2021.pdf (2021, accessed 4 March 2024).
7. African Union. African Union Health Information Exchange Guidelines and Standards, https://africacdc.org/download/african-union-health-information-exchange-guidelines-and-standards/#:~:text=African%20Union%20Health%20Information%20Exchange%20Guidelines%20and%20Standards,-Preface&text=The%20application%20of%20digital%20health,to%20remote%20and%20underserved%20communities. (2023, accessed 22 January 2024).
8. British Medical Association. Acting upon electronic test results, https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/primary-and-secondary-care/acting-upon-electronic-test-results (2024, accessed 4 March 2024).
9. College of American Pathologists. Releasing Test Results Directly to Patients, https://documents.cap.org/documents/2014-releasing-test-results.pdf (2014, accessed 4 March 2024).
10. ASLM. Laboratory Systems Strengthening Community of Practice (LabCoP).
11. Cassim N, Olsen F, Stewart-Isherwood L, et al. Assessing the cost and utilization of SMS printers by primary health care facilities: lessons learned from South Africa. J Public Health Afr 2023; 14: 2253. 2023/06/22. DOI: 10.4081/jphia.2023.2253.
12. Venter W, Coleman J, Chan VL, et al. Improving Linkage to HIV Care Through Mobile Phone Apps: Randomized Controlled Trial. JMIR Mhealth Uhealth 2018; 6: e155. 2018/07/20. DOI: 10.2196/mhealth.8376.
13. OpenMRS. https://openmrs.org/ (accessed 5 January 2023).
14. Akanbi MO, Ocheke AN, Agaba PA, et al. Use of Electronic Health Records in sub-Saharan Africa: Progress and challenges. J Med Trop 2012; 14: 1-6. 2012/01/01.
15. U.S. Centers for Disease Control and Prevention. Health Insurance Portability and Accountability Act of 1996 (HIPAA), https://www.cdc.gov/phlp/publications/topic/hipaa.html (accessed 9 May 2023).
16. GSMA. The Mobile Economy Sub-Saharan Africa 2023, https://www.gsma.com/solutions-and-impact/connectivity-for-good/mobile-economy/sub-saharan-africa/ (2024, accessed 4 March 2024).
17. Lalla-Edward ST, Mashabane N, Stewart-Isherwood L, et al. Implementation of an mHealth App to Promote Engagement During HIV Care and Viral Load Suppression in Johannesburg, South Africa (iThemba Life): Pilot Technical Feasibility and Acceptability Study. JMIR Form Res 2022; 6: e26033. 2022/02/03. DOI: 10.2196/26033.
18. Siemens Medical Solutions USA. PEPFAR Rapid HIV Testing Continuous Quality Improvement (RT-CQI), https://pep.siemens-info.com/en-us/pepfar-hiv-rtcqi (accessed 22 January 2024).

ANNEX 1

Informed Consent – Appointment Reminder Form Used in Kenya

INFORMED CONSENT FORM

Consent Ref. No. _____

PART I: Information Sheet

Purpose of the Intervention: USHAURI is an electronic SMS reminder system developed to enhance drug adherence, client retention in care and broadcast health messages.

Type of Intervention: This intervention will involve the broadcast of health-related Short Message Services (SMS) to the phone of your choice on a periodic basis and as agreed upon with your facility service provider. The short text messages will consist of appointment reminders, wellness checks, health education and motivational messages.

Participant selection: All clients who visit the Patient Support Centre.

Procedure: Your registration information, subsequent visits and clinical appointments will be captured into the Ministry of Health Electronic USHAURI system which will automatically send SMS upon registration, two days before, and on the day of your visit. Your service provider may also send wellness and motivational messages.

Confidentiality: We will treat your personal information with the highest level of security and confidentiality.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

Tick below as appropriate:

- ☐ I consent voluntarily to participate in this intervention.
- ☐ I refuse / do not consent voluntarily to participate in this intervention.

Print Name of Participant _____ Reference No. of Participant _____

Contact Telephone Number of Participant _____

Signature of Participant _____

Date _____
day/month/year

If illiterate or a minor, A literate witness must sign. Participants who are illiterate should include their thumb-print as well. Minors will have their guardians give consent.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

Signature of witness _____ AND

Thumb print of participant

Date _____
day/month/year

Statement by the interviewer/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the intervention.
I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Print name of person taking the consent _____

Signature of person taking the consent _____

Date _____
day/month/year

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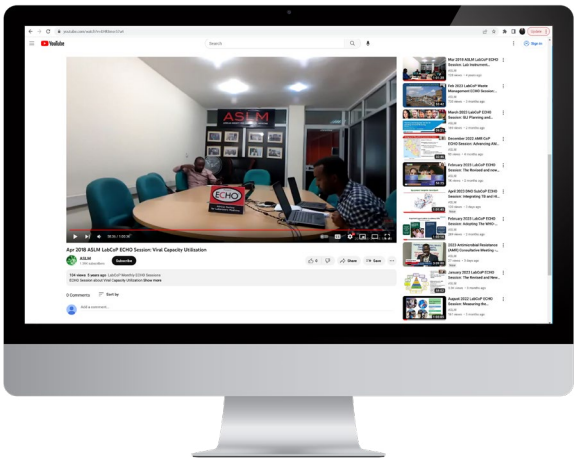

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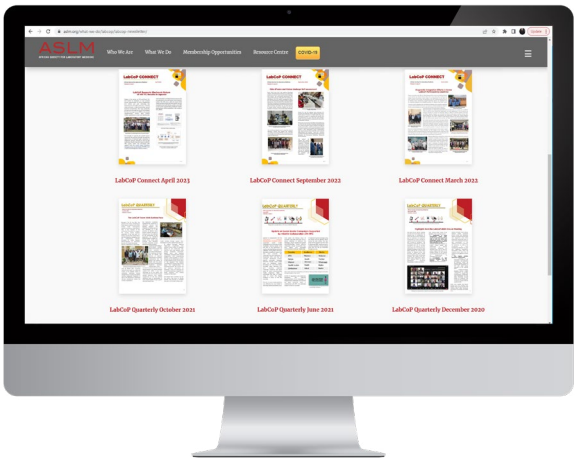

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