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REVIEW



# Racing for results: lessons learnt in improving the efficiency of HIV viral load and early infant diagnosis result delivery from laboratory to clinic

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## ABSTRACT

**Introduction:** In pursuit of the 90–90–90 goals, emphasis has been placed on accelerating centralized-laboratory HIV viral load testing of a population that is largely rural and decentralized. Successful outcome requires effective specimen transport, laboratory testing, and results delivery. This paper focuses on the methods currently employed for results delivery. New innovations in this area are yielding mixed results; we analyze different approaches and estimate the impact of each on achieving the third ‘90.’

**Areas covered:** Strategies employing electronic or mobile health platforms, such as online portals, SMS, and SMS printers are showing potential to deliver results in significantly improved turnaround times but are not without challenges. Also, merely delivering a result to the clinic is not sufficient; results need to be actioned to ensure improved patient linkage and retention. Innovative solutions that not only support real-time reporting but monitor receipt of results and address infrastructure constraints faced by limited-resource settings are discussed.

**Expert commentary:** There is tremendous opportunity to inform better patient care and directly contribute to ‘90–90–90’ progress by developing digital systems for result delivery. Besides infrastructure and technical challenges, systems should address the entire cascade of care from initial diagnosis to monitoring treatment response.

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## KEYWORDS

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## 1 Introduction

Significant progress is being made towards achieving the global UNAIDS Human Immunodeficiency Virus (HIV) ‘90–90–90’ targets through expansion and scale up of diagnostic and anti-retroviral treatment programs [1]. In sub-Saharan Africa, which accounts for almost 70% of the global HIV burden [2], as many as 60% of the population live in rural areas [3] and therefore rely on remote health facilities for their HIV disease management. To meet these clinical needs, an estimated 95% of HIV service delivery has now been decentralized to the primary health care level [4]. The standard method used to monitor response to treatment in an HIV-positive individual is to test their HIV viral load level. Treatment failure is defined by two consecutive HIV viral load results exceeding 1000cp/ml, reported within a two to three-month interval, depending on the country [4]. However, besides viral load, numerous other chemistry and hematology assays are also required to ensure prompt clinical decision-making and appropriate management.

For both HIV viral load testing and diagnosis of HIV in infants (early infant diagnosis), a centralized testing approach is still preferred due to prohibitive cost, complexity, infrastructure, and personnel requirements [5,6]. In this centralized-testing model, patient samples are collected at often remote health facilities and are transported tens or hundreds of kilometers for testing; a hard-copy of the printed result is then returned to the

facility. One of the most important factors for a clinician is the availability of a test result within a clinically relevant timeframe. There are various points along the HIV care cascade where an increase in turnaround time can compromise patient attrition rates and ultimately patient outcomes. Many studies have therefore focused on sources of delays and errors in the pre-analytical, analytical and post-analytical phases of the care continuum [7–10]. Pre-analytical delays are those that result from inappropriate test request or order entry or delayed specimen collection and transportation, while analytical delays occur during the testing process due to delays in specimen processing, equipment malfunction or quality control failures [11]. Although all phases can contribute to delays in the total testing process, the post-analytical phase, whereby laboratory results are delivered into the patient record and to the referring clinician, is one of the main drivers of extended turnaround time. Delays in this phase are mainly as a result of excessive turnaround time in delivery of paper-based reports but can also occur due to failure in reporting, failure to address the result report or delays in reporting critical values [11]. Any delay in receipt of a laboratory result can have a significant clinical effect. For HIV viral load, delayed result receipt could postpone initiation of adherence counseling and switch to second- or third-line treatment regimens [12]. When one considers that only 44% of those currently receiving antiretrovirals are

achieving viral load suppression [1], timely reporting of laboratory results becomes especially pertinent toward achieving global targets. Similarly, in infants born with HIV, mortality rates significantly peak at age two to three-months [13] and thus it is imperative to enable rapid diagnosis and treatment initiation within this limited timeframe.

It is this need for faster turnaround time that is driving much of the point-of-care testing market today. While many hail point-of-care as the 'holy grail' to address issues around timely testing and receipt of results and indeed, point-of-care testing has many advantages, such as improved testing efficiency, it is not a panacea and still suffers from costing, operational, and quality issues. There are also currently no true point-of-care devices for HIV viral load testing at scale in the market. Innovative strategies for delivering results in a centralized testing model are therefore needed. To be successful, such strategies must work with existing infrastructure and operational constraints to strengthen program efficiencies and ensure success of any national HIV program.

This review discusses the primary existing efforts and new initiatives to improve the delivery of laboratory results to the primary healthcare level and describes some of the challenges and lessons learnt in this process.

## 2 The status quo for laboratory result reporting

### 2.1 Paper-based result reporting systems

As antiretroviral treatment programs continue to scale, paper-based systems are adding enormous strain on already overburdened facilities, leading to delays in result receipt and frequent loss of results. Traditional result delivery systems often 'piggy-back' on existing specimen transport networks and courier services. However, challenges, such as poor road infrastructure and weather conditions, vast distances between laboratories and facilities, and lack of human resources, have contributed to long waiting times experienced in receipt of laboratory results in many countries [14].

In sub-Saharan Africa, the turnaround time from collection of a specimen at the referring facility to return of a HIV viral load result back to the facility is highly variable, ranging from three days in South Africa and 31 days in Kenya [15], to up to 90 days for some health facilities in Malawi [16]. The same is true for early infant diagnosis, where major delays, up to 60 days, have been reported in result return to facilities in Kenya, Tanzania, and Zambia [17–19].

The loss of hard-copy results is also frequently reported for both HIV viral load and early infant diagnosis leading to unnecessary repeat testing. In South Africa, an assessment of healthcare services found that in some rural clinics, loss of results was due to paper reports being piled up in corners instead of being placed in patient files [14]. Similarly, in a recent review, Clinton Health Access Initiative (CHAI) estimated that only 50% of HIV viral load laboratory results were ever returned to referring facilities in Mozambique, Malawi, and South Africa [20]. A six-country study in Africa, found that only 77% of caregivers received their infant's diagnostic HIV test results and the median turnaround time from blood collection to result receipt was 53 days (but this could range from 2 to 438 days) [21].

The availability of results at the referring facility should also coincide with the scheduling of clinic appointments [17] and this inconsistency in time to result receipt can make it extremely difficult to schedule patient return appointments. Both delays and lack of result availability often leads to clinician reliance on empirical treatment, patient loss to follow up, delayed treatment initiation or treatment switch and higher risk of transmission [14]. It is also thought that delays in switching patients to second line can lead to an accumulation of resistant mutations [22]. Further time is wasted, and reliability of results are questioned due to healthcare providers having to manually transcribe results into facility registers.

Several countries are attempting to overcome many of these challenges by implementing strategies to strengthen their national specimen and result transport networks. Uganda is one such example, where hubs have been established throughout the country to each service a 40 km catchment area and provide a more integrated specimen transport network [23]. The hub model has not only improved access to early infant diagnostic services and reduced transportation costs by 62%, but has also led to an impressive 47% reduction in sample to result delivery time from a previous turnaround time of 49 days (22) now down to 26 days.

Similarly, Riders for Health, an initiative working in seven African countries, utilize vehicles and motorcycles to collect specimens and return results back to remote facilities. In Malawi, the Riders initiative collects specimens from 711 anti-retroviral treatment sites and transports them to 12 central reference laboratories for viral load and early infant diagnostic testing and then returns the result reports back to facilities [16]. This program is demonstrating enormous potential in improving the efficiency of specimen transport. However, as efforts to scale up viral load testing across the country continue and testing volumes more than doubled between 2015 and 2016, there has also been a corresponding increase in turnaround time for result delivery. In 2015, the average time from sample collection to result printing was between 20 and 30 days. By mid-2016, this estimate had risen to anywhere between 40 and 90 days for the majority of specimens [16].

## 3 The next generation of laboratory result reporting systems

### 3.1 eHealth and mhealth result delivery systems

To overcome many geographical, organizational, and temporal challenges associated with traditional result delivery systems, innovative technologies, such as digital or electronic health (eHealth) platforms are being introduced (Table 1). eHealth is defined by the World Health Organization (WHO) as *the use of information communication technologies to support health and health-related interventions* [24]. Incorporation of an eHealth strategy in supporting health care delivery systems has now become the norm for many countries and most report having an eHealth information system policy in place [24].

#### 3.1.1 Laboratory information system software integrations

Linking of laboratory information systems with electronic medical records via web-based portals allows healthcare

**Table 1.** Summary of key features of result delivery systems.

Intervention	Average turnaround time	Estimated loss of results (%)	Operational considerations
Paper-based systems	Highly variable: 3–90 days	30–50%	Extended delivery time, inconsistency in delivery time and lost/misplaced results leads to delayed patient management.
SMS alerts	Seconds	0%	Reliable and timely automated delivery but cannot remotely monitor whether result is being actioned. Challenged by high staff turnover (changing phone numbers) and patient confidentiality concerns.
SMS printers	1 – 3 days	Estimated the same as paper-based systems	Still paper-based, lost/misplaced results, cannot remotely monitor whether result is used, requires continuous supply chain, maintenance, power, support staff, quality of paper result degrades over time.
Laboratory Information Systems	<1 day	0%	Insufficient infrastructure existing in clinics to scale this intervention. Training 'heavy' (computer skills required).
Aspect Reporter	< 0.5 days	0%	Automated, near-real time result delivery, result management and tracking clinical acknowledgement of result, self-contained power, Internet and connection.

providers direct access to view or print laboratory results. Kenya's HITSsystem is a web-based eHealth intervention which, among other things, provides users with access to laboratory results online as soon as they are available in the central laboratory [19]. Similarly, the DisaLab laboratory information system (in use in Mozambique, Malawi, South Africa and several other countries) is a basic laboratory module for test requisitions, workflow and workload management, result entry and review [25], that has an add-on module called DisaLink. DisaLink allows facilities the ability to pre-register specimens and test requests, create barcodes and track specimens to the laboratory thus addressing pre-analytical errors and delays. Similar to the HITSsystem, once results are available, healthcare providers can log in to the system to view or print results.

However, to succeed as an approach to delivering diagnostic results from laboratory to peripheral clinic, these systems assume multiple computers, a stable internet connection suitable for web page browsing, stable electrical power and sufficient staff computer skills at the clinical site. Many low- and middle-income countries have limited infrastructure, a wide variation in mobile data network coverage and staff lacking computer skills, each a major hindrance to adoption of these systems [26,27]. In addition, Africa has low mobile bandwidth (e.g. 2g, 3g) and the cost of internet services are prohibitive for many clinical facilities [27], especially in the lower healthcare tiers.

### 3.1.2 Mobile health

Mobile Health ('mHealth') strategies are a subset of digital health, which hold great potential for transformative impact on healthcare due to the rise in mobile phone users in low- and middle-income countries [28] and are essentially a consumer-funded deployment of the necessary infrastructure (computer, Internet, power, and user training). There are an estimated five billion mobile phone subscriptions worldwide; 70% of these subscriptions belong to users residing in low- and middle-income countries [27]. Current strategies utilizing short message services (SMS) or Interactive Voice Recognition services have focused largely on providing supportive interventions for healthcare providers and patients [29–31]. However, the delivery of laboratory results directly to the healthcare provider at the point of patient care, via SMS or mobile application, are being integrated in many countries to improve timely and accurate communication.

Diagnostic connectivity solutions, such as GxAlert (SystemOne, LLC), provide not only remote program management and comprehensive dashboards for facility, district and national levels, but can also push automated result notifications to the healthcare provider via email or SMS and thus do not rely on users actively having to log onto any system. Across the 40 countries where GxAlert is currently being utilized, approximately 20% of users actively log into the GxAlert dashboard (mostly program managers), while the remaining users, mostly healthcare providers, rely on this automated and passive result receipt system. While some studies have shown limited impact of SMS result delivery platforms in terms of improving turnaround time versus paper-based result receipt [32,33], others, such as Project MWANA in Zambia, demonstrated a 50% overall reduction in time for early infant diagnosis result delivery at the referring facility using a SMS service (from 66 to 33 days) [34].

SMS printers are small devices located at the facility level that connect via cellular or WIFI network. A compatible laboratory information system can transmit results from the central laboratory to the facility via SMS messaging; the result is printed for use. SMS printers are in use or are in pilot phases in several countries, including Kenya, Mozambique, Namibia, Rwanda, South Africa, Zambia, and Zimbabwe, to improve turnaround times for result delivery [4]. In South Africa, over 200,000 CD4, early infant diagnosis, viral load, and tuberculosis results are sent via SMS printers every month to facilities [35]. In Namibia, 232 printers have been deployed since 2015 and over 55,000 pathology results were sent in 2016 alone [36]. One of the most promising use cases for SMS printers has been demonstrated for early infant diagnostic result delivery. A recent systemic review of 11 East and Southern African studies demonstrated an average reduction of 17 days from early infant diagnosis sample collection to result receipt (from 68 days for paper-based result delivery to 51 days via SMS printer) [37]. Uganda similarly demonstrated a 46.2% decrease in total time for early infant diagnostic reporting, from 26 days using their hub model, to just 14 days through implementation of SMS printers [23]. The cost of delivery of a SMS result via a printer was also found to be lower compared with existing paper-based delivery methods; \$1.98 versus \$2.73 per result. Both these studies assessed the overall turnaround time from sample collection to result delivery but did not detail how much of this time was dedicated solely to delivery of the result to the facility after completion of testing. This

post-analytical phase of the cascade was assessed in Mozambique, during an evaluation of their Expedited Result System, a SMS printer system for early infant diagnosis result delivery. The study focused on the reduction in time from result readiness at the laboratory to delivery at the health facility and evidenced an improvement in result delivery from an average of 17–22 days, down to 1–3 days [38].

Although promising, these mHealth solutions require a stable platform and adequate cellular phone network coverage, which is not always possible in resource limited settings [39]. SMS printers require a continuous supply of printer paper and associated supply chain management [37], as well as capacity and readiness by the healthcare system to utilize the technology effectively [39]. They also require that the facilities within which they are located have a continuous electric power source to power the units or a rechargeable battery. Technical staff to support maintenance and remote troubleshooting of the system are imperative. Training of technical in-country field staff who can mobilize quickly, may provide a more efficient option to deal with issues in the field.

#### 4 Emerging solutions to address result delivery turnaround time

With many countries still experiencing gaps in meeting the '90–90–90' targets, innovative systems are needed to support the entire cascade of care from initial diagnosis of HIV to monitoring treatment response. Initiatives, such as the Aspect Reporter™ platform (SystemOne, LLC, Boston, U.S.A.) (Table 1), is a self-contained, solar-powered, digital reporting terminal that receives test results directly from the central laboratory over available 2g/3g cellular networks and displays results to healthcare providers on an inexpensive Android-based tablet. The healthcare worker at the peripheral clinic is able to review and acknowledge test results as they arrive and are also alerted immediately if retesting is required due to lost or rejected specimens. This solution was designed to address the shortcomings of previous systems and the underlying infrastructure challenges by supplying an 'all-in-one' kit of solar power and network connection powered by global SIM cards, and a simple, task-oriented user interface. In a pilot of the system in Malawi, Aspect Reporter has managed to improve the time to delivery of HIV viral load and early infant diagnosis results by 95% versus paper reporting (from 22 days to less than 1 day) [40].

Emerging integrated solutions like Aspect Reporter provide the potential for additional software to rapidly deploy and scale nationwide using the same infrastructure (hardware, software, network, power). This could introduce tremendous new capabilities at these remote clinical sites, for example:

- Order entry or barcoding of specimens to facilitate tracking and improve laboratory efficiencies.
- Specimen transport tracking or integration with transport companies, e.g. Riders for Health.
- Ability to deliver other diagnostic test results at the clinic, such as Tuberculosis, Hepatitis C virus, or other. Laboratory information systems and GxAlert are already

collecting this information and could feed it directly into Aspect Reporter.

- Clinical decision support applications to integrate these diagnostic results and provide real-time guidance on treatment algorithms and conditions.
- Integration with drug stock applications to assist in treatment enrollment, e.g. mClinica, mSupply, or others.
- Integration with patient record systems.

#### 5 Conclusion

Timely and consistent receipt of pathology results at the site of patient care have a significant role to play in viral load and early infant diagnosis scale-up efforts and if not addressed, negate the impact of these programs. There is tremendous opportunity to inform better patient care and directly contribute to the '90-90-90' progress. However, simply solving the problem of result delivery will not result in earlier patient management without systems adapting to existing structural and behavioral barriers and without an interplay with appropriate and complementary health system strengthening.

#### 6 Expert commentary

Simply placing a computer in a rural clinic is rarely enough to provide a lasting solution, especially since there is a direct correlation between robustness and cost; inexpensive computer hardware is seldom capable of performance in environments with extremes of temperature and humidity. For example, fans designed to cool an overheating system also draw in dust, requiring vigilance in cleaning and replacing filters.

Without a dedicated support staff to maintain it, any technology will ultimately suffer from software issues, viruses, networking problems, etc. A digital intervention will require ongoing support, so agreements and budget, must address this ongoing support cost, and include provisions for replacement of failing hardware, software fixes and upgrades, and network management. Programs should demand a 5- to 10-year lifetime for deployed solutions; with anything less, the investment required to develop, deploy, train, and incorporate an intervention into the system is too high.

There can also be challenges above and beyond the limitations of infrastructure and technical support. The structure of the global health economy makes it difficult to create scalable solutions, since most of the efforts to improve care delivery are based on, and paid for, in a 'project' model. Many interventions similar to those discussed are built on a small scale, paid for out of a particular budget that may only cover enough development for a small pilot project. This funding often ends before the project can be fully evaluated and scaled, with the result that there are many similar, but often incompatible, solutions in development at any given time. In order to build systems to support patients and providers going into the future, investments need to be made strategically focused on critical pathways and ensure that thorough reviews of the quality of systems are completed prior to full scale-up. This should include long-term issues, such as service contracts, plans for ongoing

training for healthcare workers and well-thought-out plans for upgrades to ensure investments are not lost due to poor planning or technical improvements in hardware and software. In addition, implementing partners need to be held accountable for poor performance which should include ongoing critical reviews and changes in working practices and giving contracts to other technical partners based on performance.

Furthermore, because different funding sources may manage separate segments of a healthcare system, ‘turf-wars,’ and politics can play a major role in the evaluation and rollout of any solution, as several agencies champion their own solution to a single problem. This is further exacerbated by funding models that support only a single disease; if a solution is pioneered by the team supporting one disease, they may not be interested in enabling the delivery of results for another disease, even though a single laboratory may provide testing for both diseases. This happens not out of a lack of caring, but out of a lack of resources; which group should pay for the support of a results-delivery solution? There are few models that support sharing the cost. These costs include not only ‘hard’ costs like installation and capital equipment, but ongoing support, data transmission costs (which are not trivial in areas with limited connectivity) and required consumables. Given the constraints of the global health economy, the most promising ‘solution’ is to bundle the job of results reporting alongside the job of running the test, i.e. marry the costs of results reporting method (whichever one selected by the country) with the per test cost of the assay.

Finally, it must be noted that getting a result to a clinic is necessary but not sufficient. Delays along the cascade of care are also experienced in the communication of results to patients or caregivers [17]. This is particularly pertinent when considering SMS printers where results are still delivered as paper-based reports that need to make their way into the patient record. In Botswana, implementation of SMS printers for HIV-infected pregnant women improved turnaround time for results delivery but did not improve initiation rates onto treatment [41]. This study served to highlight the need for parallel implementation of clinical workflow, educational, and behavioral changes to be put in place in order to ensure the success of these systems. With results reporting done correctly, you have the opportunity to build the other interventions required for successful patient outcomes (e.g. counseling, patient follow up, adherence, etc.). Effective results reporting is therefore a necessary condition for improved healthcare, but it is not a sufficient condition.

The developers of any solution must study the workflow within and between the clinic and laboratory. Issues to be addressed include patient identification, privacy, security, the process of validating results at the laboratory, and the process required to service an incoming result at the clinic. Healthcare providers cannot interrupt their routine to handle a result coming in, so results must be retrievable when it is convenient for the clinician to do so. The loop should be closed, if possible, so that the clinic knows that a sample arrived at the laboratory, and the lab knows that a result was properly received.

## 7 Five-year view

Over the next 5 years, the general infrastructure both within centralized laboratories and extending to the rural healthcare

centers they serve, will improve. Reliable electricity, improved computer skills, and greater access to technology tools will make it easier to connect the nodes (labs, clinics) of a diagnostic network. In centralized labs, this will result in more widespread use of laboratory information systems, a rich set of diagnostic and patient data. While some countries like Kenya are already investing heavily in hard IT infrastructure in order to enable a ‘connected’ diagnostic network, countries will be in varying stages of sophistication in 2023. The Aspect Reporter™ is a good example of an early IT-in-a-box solution that is more affordable than a robust infrastructure, though necessarily less robust as an intervention than a fully-fledged ‘connected’ clinic.

However, fast the formal infrastructure improves (power, mobile data, PC/computers in clinics), the information infrastructure for patients, nurses, and doctors (smartphones, applications, mobile data access) will improve much, much faster. As the infrastructure improves in rural areas, and as doctors, nurses and patients experience dramatic improvements to information access on their mobile phones and personal data plans, their demand for quality healthcare data will skyrocket. It will no longer be acceptable to lose 50% of paper test results in transit when the most rural patient can instantly access what the President tweeted 3 minutes ago; the current inefficiencies will become inexcusable to individuals within healthcare and that will inspire widespread innovation of applications, hardware, and solutions. The demand for connected systems will quickly outpace the availability of funds to deploy nationwide, holistic, and ‘traditional’ IT systems and networks and thus will drive funding toward more ‘affordable,’ if interim (over the next 10–15-year horizon) solutions. Over the next 5 years, emerging products like the Aspect Reporter™, signal cost effective and available interventions to bridge that gap and serve the needs of the patients and clinicians.

## Key issues

Several lessons can be learnt from the development of improved result delivery systems:

- It is critical to deliver the result as quickly after the test is completed as possible. Compared to paper-based systems, digital solutions can shorten this process from weeks to mere seconds.
- There must be a reliable destination on the clinical end that can receive that result. Reliability means:
  - The result must be easily retrievable and has to integrate with the healthcare workers workflow. Linear reporting systems (e.g. single thread of SMS’s received on a single phone, or a long ream of thermal SMS printer paper) can be problematic if it is difficult to go through a list of results that came in over time.
  - The quality of the result should not degrade over time. Thermal paper fades and tears, so is not reliable by itself and requires a workflow to copy the result to a more permanent medium.
  - The results must be delivered every time. If results are delivered only 20% of the time by a new system,

clinicians will simply default back to waiting for the paper laboratory result. When SMS printers run out of stock of thermal paper, clinical support for the intervention fades immediately.

- A power infrastructure must be present, or provided as part of the intervention, to power a phone, SMS printer, computer, or tablet receiving the results.
- The user interface for receiving results must be paired with an effective and affordable training methodology. While the implementation of full-fledged electronic medical records may promise a comprehensive solution, they also require large amounts of infrastructure and training. Because of their broad scope, electronic medical records are necessarily complex and require continuous training and reinforcement. Simpler, more focused interventions reduce the training needs.
- The solution must provide a feedback loop to confirm that the result has been received, acknowledged, and acted upon. Sending 20,000 SMS messages per month around the country does not equate to patient outcomes. Short of requiring a fully-fledged nationwide electronic medical record, any solution should provide a means to confirm that the clinician saw and acted on the result. This active acknowledgement is a critical component not just of monitoring and evaluation, but of ensuring behavioral change at the clinical level.

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## Declaration of interest

N Gous, J Takle and A Oppenheimer are employees of SystemOne LLC, a connected diagnostics company currently operating in the industry and a developer of a digital reporting solution. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

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