An impact evaluation of the OpenELIS laboratory information system and the dependent data dashboard in Côte d'Ivoire

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Abstract

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The open-source electronic laboratory information system (OpenELIS) in Côte d'Ivoire has been in routine implementation at clinical laboratories since 2009. The data dashboard that displays aggregate data on HIV viral load (VL) testing and early infant diagnosis (EID) are becoming tools that support people to use OpenELIS data in HIV service delivery. Although various theories, models, and frameworks exist to evaluate or explain implementation effectiveness of health information systems and public health data dashboards, evidence is limited in routine clinical laboratory settings in low- and middle-income countries (LMICs).

This dissertation consists of three aims that examine the OpenELIS implementation, context of data-driven decision-making, and user perceptions of the VL and EID data dashboard in Côte d'Ivoire. The first aim quantifies the effects of

implementing OpenELIS on data quality at 21 clinical laboratories through an interrupted time series analysis from 2014-2020. The second aim uses a mixed-methods design to assess the sustainment of OpenELIS use at 27 laboratories, identify implementation facilitators and barriers, and explain how high-sustainment laboratories differ from low-sustainment ones. The third aim is a qualitative study of the values, attitudes, and experiences regarding data-driven decision-making and the VL and EID dashboard among existing and potential dashboard users.

The implementation of OpenELIS led to an immediate five-fold increase in data timeliness (OR=5.27; 95% confidence interval [CI]: 4.33, 6.41; $p<0.001$) and a 3.6-fold increase in completeness (OR=3.59; 95% CI: 2.40, 5.37; $p<0.001$), sustained until 72 weeks after adoption. Weekly post-implementation improvements in completeness were significant (OR=1.03; 95% CI: 1.02, 1.05; $p<0.001$). However, validity did not show a significant immediate change (OR=1.34; 95% CI 0.69, 2.60; $p=0.38$). Sustainment of routine OpenELIS use at the laboratories ranged from 9.0% to 99.3% of the implementation period when test results were recorded in OpenELIS. Reported common implementation facilitators included relative advantages and access to knowledge, while common barriers included adaptability issues and power outages. Barriers specific to low-sustainment sites included lower motivation and capability and less reflection and feedback about implementation. Participants valued data-driven decision-making and found the VL and EID data dashboard easy to use and useful for monitoring and decision-making.

This dissertation identifies lessons about implementing a laboratory information system and data dashboards that may be useful for other routine settings in LMICs.

Table of Contents

Acknowledgment 3
Chapter 1. Introduction 7
Chapter 2. Development and national scale implementation of an open-source electronic laboratory information system (OpenELIS) in Côte d'Ivoire: Sustainability lessons from the first 13 years 13
2.1 Abstract 13
2.2 Background 14
2.3 Methods 17
2.4 Results 18
2.5 Discussion 27
2.6 Conclusion 30
2.7 Tables and Figures 32
Chapter 3. Laboratory data timeliness and completeness improves following implementation of an electronic laboratory information system in Côte d'Ivoire: An interrupted time series analysis on 21 clinical laboratories from 2014-2020 35
3.1 Abstract 35
3.2 Background 36
3.3 Methods 39
3.4 Results 43
3.5 Discussion 45
3.6 Conclusion 49
3.7 Tables and Figures 50
Chapter 4. Determinants of implementation for electronic laboratory information systems in routine settings in Côte d'Ivoire: A mixed-methods study applying the Consolidated Framework for Implementation Research (CFIR) 63
4.1 Abstract 63
4.2 Background 64
4.3 Methods 68
4.4 Results 73
4.5 Discussion 85
4.6 Conclusion 92
4.7 Tables and Figures 93
Chapter 5. Perceptions and experiences of data-driven decision-making and data dashboard for HIV viral load testing and early infant diagnosis in Côte d'Ivoire 102

5.1 Abstract 102
5.2 Background 103
5.3 Methods 107
5.4 Results 111
5.5 Discussion 123
5.6 Conclusion 127
5.7 Tables and Figures 129
Chapter 6. Conclusion 135
Bibliography 137

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Chapter 1. Introduction

Laboratory medicine services are an essential part of health service delivery and are crucial for controlling and managing communicable and non-communicable diseases to achieve the Sustainable Development Goals.[1–3] Laboratory medicine plays a particularly central role in reducing disease burden and premature mortality related to HIV, since diagnosis, prognosis, and guidance for treatment depend on them.[4,5] However, the availability of and access to timely and quality laboratory medicine services is still under-resourced in low- and middle-income countries (LMICs).[6] Shortages of a skilled workforce, aging and inadequate laboratory infrastructure, absence or unenforced regulation, and inconsistent quality assurance oversight remain major barriers to quality laboratory service delivery in LMICs. The absence of functional laboratory information systems (LIS) is one of the main issues of inadequate infrastructure.[7]

LIS is important for laboratory operation and information management. The World Health Organization (WHO) established the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist to guide clinical laboratories in Africa through continuous quality improvement and towards accreditation to international standards.[8] The SLIPTA checklist characterizes computerized LIS as integral to ensuring laboratory operation and fulfilling the criteria of laboratory information management on ensuring data quality, data storage and back-up, and patient confidentiality.[8]

LIS can also improve the quality of care, patient safety, and disease surveillance.[7,9–12] Compared to paper-based information systems, electronic LIS provide

more timely and more accurate monitoring and reporting of turnaround time, test failure rates, and other indicators, which improve the quality of the laboratory data that informs clinical care.[7] A study in Kenya demonstrated that reduced turnaround time and timely communication of laboratory test results are some of the key factors for improving HIV treatment retention.[10] In terms of patient safety, LIS reduced the probability of errors in patient identification and subsequent inappropriate treatment by reducing manual clerical work through automation and user-friendly widgets.[7] A survey of clinicians in Malawi revealed that laboratories' poor documentation of test results was one of the reasons for having little trust in laboratory capability and not frequently using laboratory test results in patient management.[11] Last but not least, LIS can also improve disease surveillance by making it easier to record accurate demographic data that informs disease classification, assessment of population-specific rates, and contact tracing for infectious diseases,[9] as well as to report laboratory-confirmed diagnoses to surveillance systems that allow more accurate estimation of disease burdens.[12]

Systematic LIS implementation across the health system is rare in LMICs. A rapid literature review of peer-reviewed articles identified eight different LIS that six countries implement at a national or sub-national scale, namely South Africa, Vietnam, Namibia, Ethiopia, Peru, and Malawi.[13–21] The LIS in South Africa is the only one that has the capacity of recording data on all laboratory testing services at all public laboratories as well as the connection to the national patient registration system to support the national health insurance program.[13] Usage of laboratory data in research has also increased since the nationwide scale-up of the LIS, since almost 20% of the rapid literature review

search results from LMICs were epidemiological studies from South Africa using data from the LIS.[22–30]

There is also a dearth of evidence on how LIS interventions enhance data quality, data use, and health system management in LMICs.[31] The e-Chasqui LIS for tuberculosis testing data at 14 laboratories in Peru is the only one that has been implemented and evaluated through a cluster randomized controlled trial.[18] The trial shows that the LIS decreased turnaround time and improves quality of care, but the study team did not offer explanations on how the LIS has achieved such impact.[18]

Despite the proliferation of data dashboards in public health, studies that assessed data needs and user experience of dashboard users were limited. After reviewing 1,191 papers, the authors of a systematic review on public health dashboards only identified 18 user studies, while most of the remaining papers reviewed were only about the design and technical development process of a specific dashboard.[32] Only five of the 18 user studies considered data demands and self-efficacy in dashboard user experiences,[32] highlighting a persistent, notable gap in research that other reviews already identified previously.[33,34]

The International Training and Education for Health (I-TECH) has been collaborating with the Ministry of Health and Public Hygiene (MOH) in Côte d'Ivoire since 2009 with funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR) to build a functional, accredited diagnostic and laboratory network for effective HIV care and treatment. Two of the key program interventions are 1) supporting the use of OpenELIS (an open-source enterprise-level laboratory information system interfacing with analyzers) since 2009 and 2) building and maintaining an

interactive dashboard of laboratory-level data on HIV VL testing and EID since January 2019. Following a two phased approach to development and implementation (phase 1: 2009-2015, phase 2: 2016-2021), OpenELIS is currently installed at 108 laboratories in Côte d'Ivoire, including 68 sites that use it for HIV data, one for food and drug safety data, 27 for tuberculosis data only, and 12 sites that use a discontinued, reduced version for routine laboratory testing data. The dashboard displays monthly aggregate data on VL and EID to assist MOH, PEPFAR implementing partners (IPs), and HIV service providers in programmatic monitoring and decision-making.

This dissertation will not only contribute evidence on the effectiveness of OpenELIS on a national scale as well as the dashboard that aim to enhance data use, but also explain the determinants of implementation to provide guidance on potential scale-up in Côte d'Ivoire and similar settings.

This dissertation will apply two established frameworks. The Consolidated Framework for Implementation Research (CFIR) will be used to guide data collection and interpretation related to laboratory-level determinants of OpenELIS implementation, and to explain the perceptions of existing and potential users of the VL and EID dashboard.[35,36] The CFIR is a meta-theoretical framework designed to explain what works where across different contexts and to identify determinants of program implementation.[35,36] The CFIR uses multidisciplinary theories (including those from sociology, psychology, and organizational change) to determine contextual factors for various levels of implementation performance across diverse settings.[37] The findings from this dissertation using the CFIR are robust in the context of Côte d'Ivoire and potentially other similar settings. The CFIR also facilitates comparing and contrasting

across laboratories with different performances in data quality, service capacity, and organizational and geographical characteristics. Such comparisons will highlight best practices and challenges in LIS implementation, which will be informative to future planning.

The conceptual framework for the use of health data in decision-making,[38] building on the Performance of Routine Information System Management (PRISM) framework,[39] highlights key factors that most directly influence data demand and use.[38,40] Specifically, the activities to strengthen demand for and use of data in the conceptual framework will be used to assess the general value, attitude, and experience regarding using data in decision-making and to identify strengths and areas for improvement of the dashboard.

This dissertation has one background paper and three specific research aims:

- **Chapter 2**: Development and national scale implementation of OpenELIS in Côte d'Ivoire: sustainability lessons from the first 13 years
- **Aim 1 (Chapter 3)**: Estimate the intervention effect of OpenELIS on data quality, namely data completeness, timeliness, and validity, using CD4 testing data. Specifically,
    1) Did the use of OpenELIS in Côte d'Ivoire's clinical laboratories lead to statistically significant improvements in the data quality outcomes?
    2) If so, what was the magnitude of the improvements compared to the counterfactual scenario in which the laboratories had not adopted OpenELIS?
    3) Had the improvements persisted after the initial adoption of OpenELIS?

- **Aim 2 (Chapter 4)**: Understand the OpenELIS implementation determinants. Specifically,
    1) What was the extent of sustaining OpenELIS routine use at clinical laboratories in Côte d'Ivoire?
    2) What were the facilitators and barriers to OpenELIS routine implementation at all sites?
    3) What implementation determinants differentiated high- versus low-sustainment sites?
- **Aim 3 (Chapter 5)**: Assess the values, attitudes, and experiences regarding data-driven decision-making and using the VL and EID dashboard among existing and potential users. Specifically,
    1) What were the values, attitudes, and experiences of existing and potential dashboard users on data-driven decision-making in their organizations?
    2) What were the participants' impressions of the VL and EID data dashboard?

Chapter 2. Development and national scale implementation of an open-source electronic laboratory information system (OpenELIS) in Côte d'Ivoire: Sustainability lessons from the first 13 years

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2.1 Abstract

Purpose: Côte d'Ivoire has a tiered public health laboratory system of 9 reference laboratories, 77 laboratories at regional and general hospitals, and 100 laboratories among 1,486 district health centers. Prior to 2009, nearly all of these laboratories used paper registers and reports to collect and report laboratory data to clinicians and national disease monitoring programs.

Project: Since 2009 the Ministry of Health (MOH) in Côte d'Ivoire has sought to implement a comprehensive set of activities aimed at strengthening the laboratory system. One of these activities is the sustainable development, expansion, and technical support of an open-source electronic laboratory information system (OpenELIS), with the long-term goal of Ivorian technical support and managerial sustainment of the system. This project has addressed the need for a comprehensive, customizable, low- to no-cost, open-source LIS to serve the public health systems with initial attention to HIV clients and later expansion to cover the general population. This

descriptive case study presents the first published summary of original work which has been ongoing since 2009 in Côte d'Ivoire to transform the laboratory information management systems and processes nationally.

Impact: OpenELIS is now in use at 106 laboratories across Côte d'Ivoire. This article describes the iterative planning, design, and implementation process of OpenELIS in Côte d'Ivoire, and the evolving leadership, ownership, and capacity of the Ivorian MOH in sustaining the system. This original work synthesizes lessons learned from this 13-year experience towards strengthening laboratory information systems in other low resource settings.

2.2 Background

In low- and middle-income countries (LMICs), inadequate infrastructure including limited availability and use of electronic laboratory information systems (LIS) has hindered quality laboratory service delivery for communities.[1] International development efforts such as the U.S. President's Emergency Fund for AIDS Relief (PEPFAR) have aimed to strengthen national laboratory systems by modernizing infrastructure and diagnostic testing methods including automated analyzers that require computer connectivity for data management. The increase in the quantity and complexity of data generated from high-throughput analyzers and sophisticated diagnostics necessitates the transition from paper records to LIS.

Compared to paper-based systems, LIS are more efficient and enable better quality control in collecting, processing, managing, synthesizing, and reporting large amounts of data (Table 1).[1,7] The COVID-19 pandemic has highlighted the acute

importance of digital health including LIS in providing data and enabling rapid data exchange and sharing to facilitate public health surveillance and data-driven decision-making.[41]

However, LIS uptake and routine usage in low- and middle-income countries (LMICs) remains low due to several barriers. LIS ownership, development, and maintenance can be perceived as bearing high costs of financial and human resources. Numerous proprietary LIS exist but may not be ideally suited for LMICs where financial resources are limited and, most often, ongoing software support relies on long-term service contracts with private companies. Although some LMICs have implemented proprietary systems,[13,15,16] these systems are vulnerable to market changes and can leave users unsupported if a company suspends its operations or modifies its service terms. Health information systems (HIS), including LIS, that use open-source code and are supported by communities of practice (CoPs) offer an attractive alternative in LMICs. Open-source CoPs have a vested interest in capacity building of software developers and users including those from LMICs.[42] Besides time and effort, there are no licensing fees, and all software code created is in public ownership which enables others to customize and improve functionality.[43] Several open-source LISs are currently in use in LMICs in Africa and Asia with varied scale.[44]

Another barrier to sustained, wide-scale usage of LIS is that LIS initiatives are often international-donor-driven and may lack close collaborations with ministries of health (MOHs) in LMICs. Engaging the MOH in the initial design and feature prioritization stage, building local capacity to own and maintain the software, and securing resource commitment after phaseout of donor support are time- and labor-

intensive.[45] Power asymmetries between donors and LMIC stakeholders may discount local priorities, requirements, and innovations.[46] However, successful experiences of implementing LIS in LMICs at the national scale have shown that strengthening MOH leadership and cultivating mutually beneficial partnerships are essential to impactful and sustainable laboratory system strengthening.[13,14]

Since 2009, the University of Washington's (UW) International Training and Education Center for Health (I-TECH), has worked in partnership with the Côte d'Ivoire Ministry of Health and Public Hygiene (Ministère de la Santé et de l'Hygiène Publique, or MSHP) to implement a comprehensive set of activities aimed at strengthening the laboratory system. PEPFAR and the U.S. Centers for Disease Control and Prevention (CDC) have funded the partnership. One of the key activities is the sustainable development, expansion, and technical support of an open-source enterprise-level LIS, the OpenELIS system, with the long-term goal of Ivorian technical support and managerial sustainment of the system. The software serves as both an effective laboratory information management solution and a business operations framework for the laboratory service units (Figure 1). The collaboration has addressed the need for a comprehensive, customizable, low- to no-cost, open-source LIS to serve the public health systems with initial attention to HIV clients and later expansion to cover the general population.

Côte d'Ivoire has a tiered public health laboratory system of 9 reference laboratories, 77 laboratories at regional and general hospitals, and 100 laboratories among 1,486 district health centers. Prior to 2009 most laboratories used paper registers and reports to collect and report laboratory data to clinicians and national

disease monitoring programs. The only LIS was a bespoke database located at the national HIV reference laboratory (called RETRO-CI), and this system was paired with commercial software.

The objectives of this case study are to: 1) present the iterative implementation process of OpenELIS in Côte d'Ivoire; 2) describe the evolving leadership, ownership, and capacity of the Côte d'Ivoire MSHP in sustaining routine use of OpenELIS; and 3) synthesize lessons learned for strengthening LIS in other LMICs.

2.3 Methods

We used qualitative methods in this case study to describe the implementation and collaboration around OpenELIS and its supporting activities.[14,47] We reviewed monthly and annual project reports from the implementers, activity and trip reports from technical experts and government and donor representatives, and software development roadmap and technical documentation from 2009 to 2020. This project was determined to be non-research by the University of Washington and has been approved by Côte d'Ivoire Comité National d'Ethique des Sciences de la Vie et de la Santé (CNESVS, Ivorian Institutional Review Board; reference number 006-21/MSHP/CNESVS-km) and the U.S. CDC.

Information abstracted from the project documents was initially summarized in chronological order and later coded deductively and inductively. Next, we coded the summaries deductively using the components of the Stages of Continuous Improvement (SOCI) Framework for Health Information Systems.[48] The SOCI Framework has previously been used in Uganda and Cameroon to assess the maturity

of digital health tools.[48–50] In addition to deductive codes, we also created new codes inductively where the SOCI Framework did not apply. Inductive codes captured the different steps of OpenELIS implementation and evolving collaboration among stakeholders. When coding was complete, codes and their corresponding excerpts from the summaries were organized into themes. YH coded the summaries. The other co-authors reviewed and verified the coding and analysis to ensure accuracy. The coding and thematic analysis took place in ATLAS.ti 8 Windows.

To ensure that LIS implementation translates into high-quality health services and population health benefits,[51] it is important to monitor how data systems mature over time. As such, the SOCI Framework outlines 13 components and 39 subcomponents within five domains, i.e., HIS leadership and governance, management and workforce, infrastructure, standards and interoperability, and data quality and use.[52,53]

2.4 Results

2.4.1 Design and development

OpenELIS was initially designed and implemented at two state public health laboratories in Minnesota and Iowa, U.S.[54] Its implementation in global health began as part of a collaborative effort between the U.S. CDC and the Government of Vietnam to strengthen HIV service delivery and laboratory systems in 2005.[14] As part of the open-source medical record system (OpenMRS) consortium of partners,[55] UW I-TECH received the OpenELIS source code and joined the development of the OpenELIS codebase in 2009.

An agile software design and development methodology was adopted by UW I-TECH for OpenELIS to enable an inclusive, iterative approach to software creation together with the local stakeholders in Côte d'Ivoire.[56] Since its introduction and adaptation in Côte d'Ivoire in 2009, OpenELIS has evolved through multiple iterations of improving functionality and flexibility and through new releases twice per year. The first versions of OpenELIS were limited in scope and focused primarily on HIV care. It provided pre-defined forms and reports for common HIV-related tests such as early infant diagnosis of HIV (EID), CD4 counts, and HIV genotyping.

In 2011 UW I-TECH merged all versions of OpenELIS for different laboratories into one core, i.e., OpenELIS Global 1.4, greatly reducing the burden of maintenance and update. Before 2011 we created a customized copy of OpenELIS for each laboratory. This approach was manageable when OpenELIS was implemented in four national laboratories in Côte d'Ivoire and Haiti. However, as OpenELIS expanded to new laboratories, the time burden of maintaining and updating the software across different versions became excessive. The shift to a common code base shortened the software testing cycle for each new version from approximately 200 hours to 40 hours and permitted a more thorough software testing process and a higher quality final release.

The core software improvements also enabled greater customizability and made it possible for a lab to install and configure OpenELIS without engaging a software developer to customize elements. We added test catalog management features, allowing laboratories to modify catalogs between version releases. Laboratories could make changes to existing tests or add new tests or panels without a software developer adding them manually to the system. New analyzer interfaces were added so that

laboratories could import data from analyzers beyond those related to HIV. The core software could be deployed without impacting previous local customizations and further adapted to any setting without code re-write or maintenance. This allowed for countries and laboratories to have more control over what features to include in the software.

In 2018 UW I-TECH began an extensive review of the OpenELIS application and identified where the older technology had become obsolete and presented data security risks. OpenELIS Global 2.0, completed in 2019, upgraded the core framework to mitigate security risks (Table 2).

Many expansions and improvements in later iterations of OpenELIS stemmed from close collaboration between UW I-TECH and the multi-stakeholder OpenELIS technical working group (TWG) in Côte d'Ivoire, convened in 2015. The TWG consists of representatives from the MSHP, I-TECH Côte d'Ivoire, PEPFAR's NGO implementing partners (IPs), and CDC. UW I-TECH and the design team within the TWG would lead design workshops that start with needs gathering at regional and district hospitals and laboratories using a standardized questionnaire. After reconvening, group members would share the findings on identified needs and gaps in LIS functionality and reporting, prioritizing design features, adding the designs to the roadmap,[57] and writing software specifications.

The software development process followed a similar collaborative trajectory as the design process. Before 2014 UW I-TECH conducted all software development, mostly by one senior software developer and joined later by a second developer. All reports, enhancements, and changes relied on the two developers and was dependent

on the next release. Starting in 2015 UW I-TECH has provided software development training in Côte d'Ivoire and created a more collaborative workflow with Ivorian developers so that both design and development have become more localized.

2.4.2 Deploy, scale-up, and support

OpenELIS deployment and scale-up took place in several stages since 2009 (Table 3), and the respective roles of the MSHP and I-TECH in the process evolved over time. Before 2015 I-TECH led the deployment process. The deployment at a laboratory began with a team of I-TECH staff from Côte d'Ivoire and Seattle conducting an initial laboratory assessment. Then, during a second visit, the team deployed a customized version. By the end of 2015 OpenELIS had been deployed at 11 laboratories, covering the entire network of laboratories performing viral load testing at the time (Figure 2).

In 2015, after the MSHP defined and ratified LIS requirements, they determined that OpenELIS satisfied most of these requirements and would be the system deployed at laboratories throughout the country. The MSHP became the owner of OpenELIS in Côte d'Ivoire and started collaborating with I-TECH closely in deployment to roll out OpenELIS. The scale-up first prioritized regional referral laboratories that newly started providing viral load testing as part of a MSHP- and CDC-led initiative to scale-up viral load testing. OpenELIS was then deployed in hospitals at the district and local level to support their collection and management of data on routine laboratory testing for both HIV and non-HIV clients. As of 2021, 111 laboratories in Côte d'Ivoire had implemented OpenELIS (Figure 2). OpenELIS currently supports testing of hematology, biochemistry, molecular biology, serology, and testing of microbiology, pathology, and immunohistochemistry will be available in January 2023.

The collaborative deployment and scale-up process started with a series of deployment workshops with relevant stakeholders from the OpenELIS TWG in 2015. Participants received hands-on training on setting up servers and workstations, conducting maintenance and updates, and troubleshooting. During the deployment wave each year starting from 2015, a team of MSHP implementation, I-TECH Côte d'Ivoire staff, and IP representatives would organize a week-long implementation trip to deploy the software and perform the initial training of laboratory staff. The team would follow-up with the laboratories by phone weekly and conduct a coaching and review visit 1-3 months after the deployment and training.

Starting in 2020 the MSHP began leading the deployment process with minimal support from I-TECH. The MSHP team conducts all follow-up visits, and the training is facilitated by MSHP trainers with co-facilitation by I-TECH Côte d’Ivoire. The MSHP also independently operates the OpenELIS Technical Assistance Unit (Cellule d'Assistance Technique de OpenELIS, or CATOE), the technical support call center for OpenELIS. Established in 2016 within the MSHP, CATOE provides direct, real-time technical support to OpenELIS users. CATOE technicians hold bidirectional call services with laboratories to conduct monthly check-ins that proactively probe for issues and to respond to technical assistance requests. CATOE consists of four MSHP staff members who were recruited from the participants of the first OpenELIS implementers' workshop in 2015. The technicians received targeted training on providing real-time support, equipment, phone credits, and a 6-month mentorship with the primary support and development staff at I-TECH. CATOE meets monthly with the OpenELIS TWG to review activities and findings from the support calls, feeding information into the software roadmap.

2.4.3 Strengthening local leadership and ownership

The Côte d'Ivoire MSHP started collaborating with I-TECH in OpenELIS implementation more actively in 2015. The MSHP initiated a reorganization process in 2014 that spurred the creation of the Department of Informatics and Health Information (Direction de l'Informatique et de l'Information Sanitaire, or DIIS) in 2015 to consolidate and coordinate health informatics activities in the country. This designation signaled a leadership commitment to ownership of HIS development, implementation, and management activities nationally. In 2017 the MSHP incorporated the designation of OpenELIS and its scale-up in the National Strategic Plan for the Development of Medical Biology Laboratories 2017-2020.[58]

The continuous strengthening of MSHP leadership demonstrates comprehensive ownership of not only the software and hardware but also the essential knowledge, skills, and processes to sustain routine OpenELIS implementation. Before 2015 the MSHP was only involved in site selection for OpenELIS. After the formation of DIIS, the MSHP joined I-TECH throughout the implementation process from forming the TWG, gathering needs, and training developers and technicians to deploying the software and providing technical support. By 2020 the DIIS was conducting follow-up visits and operating CATOE independently, leading the deployment process, configuration of servers, and training of new and existing users.

2.4.4 Building local capacity

Building local capacity for implementing OpenELIS in Côte d'Ivoire is critical in addition to providing the software and hardware and strengthening local leadership. Training on various topics along the software development pipeline and in various

formats has happened in Côte d'Ivoire to equip Ivorian policymakers and technicians with necessary knowledge and skills for routine OpenELIS implementation and maintenance.

Before 2015 UW I-TECH staff initially provided on-the-job training (OJT) on OpenELIS deployment and upgrade to selected staff at the MSHP, national laboratories, and IPs. In 2014 a targeted month-long training on OpenELIS development took place in Seattle for software developers with background in Java from the MSHP, Institut Pasteur Côte d'Ivoire, Institut National Polytechnique Félix Houphouët-Boigny (INPHB; a public polytechnic institute of higher education), and I-TECH Côte d'Ivoire. After participants returned to Côte d'Ivoire, UW I-TECH staff provided remote mentoring and exercises. While the results of the OJT and targeted training were promising, the time and resources for replicating these formats became unsustainably high as the OpenELIS scale-up started in 2015.

In response, UW I-TECH started collaborating with the MSHP in 2015 to develop a full suite of materials for OpenELIS including a package for trainers and users, and to lead a series of training of trainers (TOT) sessions within Côte d'Ivoire. The week-long TOTs used theoretical and practical activities and took a holistic technical approach covering a range of topics from design, planning, development, and programming to implementation and support. Among the participants at the first TOT, one became the deputy director of DIIS, and most joined the OpenELIS TWG. The TOT participants later conducted cascade training led by the MSHP during the OpenELIS scale-up. Cascade training participants provided largely positive ratings, appreciating the theoretical and practical exercises. The TOTs and cascade trainings have been an integral part of the

deployment and scale-up process since 2015 and formed a cadre of trained teams in Côte d'Ivoire to ensure sustainable OpenELIS deployment and support.

The collaboration between I-TECH and INPHB incorporated OpenELIS into the computer science curriculum and started the OpenELIS internship at INPHB. In 2016 two INPHB faculty received training on OpenELIS software development from UW I-TECH, and they started using OpenELIS as an example LIS to teach students in computer science. In 2018 the OpenELIS internship program started with three students studying at INPHB and working with I-TECH Côte d'Ivoire simultaneously to practice OpenELIS software development, deployment, and technical support. The training program and assessment process became standardized in 2019, and two interns per year embedded with I-TECH or MSHP teams for one year. Ten interns have graduated from the program, and one was eventually hired as I-TECH Côte d'Ivoire staff.

In addition to periodic training and the internship program, software developer retreats and opportunities to attend and present at international and regional conferences for HIV/AIDS or health informatics have also been part of capacity building.

2.4.5 Supporting data-driven decision-making in HIV/AIDS

To transform data stored in OpenELIS into information that is meaningful for decision-making, I-TECH built the online data dashboard that displays aggregate data on viral load testing and EID imported from OpenELIS.[59] The dashboard imports data from OpenELIS and create visualizations that help the MSHP, IPs, and CDC monitor performance along the HIV care cascade and make programmatic decisions to improve quality of care. For example, the viral load dashboard helped discover a large group of

clients who only had initial HIV diagnostic and viral load tests but no follow-up tests across multiple regions in Côte d'Ivoire. This issue would have been hidden before the dashboarding process cleaned, consolidated, and visualized the data. The MSHP and CDC based their directions for the regions and IPs on the discovery from the dashboard.

I-TECH also developed the pediatric HIV case management tool that combined OpenELIS data of pediatric HIV clients with those from the HIV electronic medical records (EMR) system in Côte d'Ivoire. This tool helped health facilities and districts identify and follow-up with lost-to-follow-up pediatric clients and parents and those whose viral load test results indicated a decline in antiretroviral regimen effectiveness. OpenELIS's pivotal role as an essential public health tool was solidified.

2.4.6 Networking, interoperability between systems, and expansion

To respond to emerging needs from the MSHP and laboratories, the OpenELIS project will always have room for adaptation and growth. Current activities include transitioning from a series of individual instances of OpenELIS to a more interconnected national laboratory information system through system networking. The pilot of a consolidated server for the national laboratory data warehouse began in 2021, bringing all laboratory data to one central location for reporting and real-time decision-making by the MSHP. The continuous demands from laboratories to add more testing modules to OpenELIS motivated the project to start developing modules for tuberculosis, COVID-19, and enhanced support for molecular biology and bidirectional analyzer interfacing. A reference testing workflow has been developed, allowing results to be sent between OpenELIS instances and providing laboratory results instantly between laboratories and reference laboratories to aid diagnosis and allow for faster treatment.

Programmatically, I-TECH will continue to work with the Côte d'Ivoire MSHP to provide necessary assistance for the full transition.

2.5 Discussion

To our knowledge, this is the first case study of best practices and lessons learned from the implementation of a LIS in a tiered laboratory system in West Africa. This case study illustrates the development, implementation, and capacity building process for OpenELIS in Côte d'Ivoire since 2009, with support from PEPFAR, as part of an initiative to strengthen the national laboratory system. The open-source nature of OpenELIS coupled with the close partnership between the MSHP and I-TECH have facilitated the collaborative, iterative process of designing, developing, deploying, and scaling up OpenELIS in Côte d'Ivoire. Strong local leadership and ownership of OpenELIS implementation contributed to the scaling and sustainment of routine use of OpenELIS at laboratories nationwide beyond the first 13 years. The improved capacity and talent pool for OpenELIS implementation and support, resulting from continuous training efforts, also facilitated scaling and sustainment. OpenELIS and its dependent data dashboard have already demonstrated value in supporting the MSHP and other stakeholders in data-driven decision-making.

2.5.1 Open-source design and CoPs-supported software adoption, implementation, sustainability, and innovation

The open-source nature and the resulting potential for in-country capacity building and ownership of OpenELIS were the main reasons why the Côte d'Ivoire MSHP decided to adopt it. Reports from open-source LIS software projects in other settings,

including the OpenELIS project in Vietnam,[14] a LIS pilot for tuberculosis in Peru,[18] and a LIS pilot for HIV in Malawi,[21] have also underscored the value of open-source software in LMICs. Open-source software provide flexibility and agility so that governments can start with a pilot project and gradually build in more functions as use cases evolve and expand. The open-source nature invites collaboration and cultivates local capacity so that costs of development and maintenance will decrease over time, contributing to sustainability. Digital Square, a global consortium for promoting health equity through digital health, designated OpenELIS in 2018 as a digital "global good".[60] A CoP was also developed to support the advancement and implementation of OpenELIS globally. As of October 2020, over 270 laboratories in 18 LMICs in sub-Saharan Africa, Asia, and the Caribbean use OpenELIS.

Continuous maintenance and funding support for software is crucial after the initial launch,[61] and the OpenELIS CoP worldwide is a model that facilitates sustainable implementation, meaningful collaboration, and local ownership. There are three common models for implementing open-source software in LMICs, namely software as a service (SaaS),[62] donor investment in the core global good,[63,64] and CoP.[65] The first two models keep the knowledge and maintenance responsibility with the developers who are usually in high-income countries, and funding can be highly donor-driven. On the contrary, the CoP model brings a variety of actors and resources to a shared table to support the core stewardship and maintenance of the global good. The large-scale adoption of OpenELIS through different funding streams, not just PEPFAR, has led to a broader set of features and more sustainable cost-sharing, including recent co-investment from LMICs and the U.S. in 2021. Each implementing country benefits from

features developed for other use cases due to the single code base and flexible administrative options. The OpenELIS CoP continuously supports the development of innovations and flexible design that can be used across use cases.[42]

2.5.2 Collaboration, capacity building, and local ownership are the key to sustainable implementation

Numerous global health projects have struggled to continue beyond the pilot or trial phase, and one of the key barriers to scale-up and sustainability is lack of local ownership and leadership at each level of the system.[66,67] The collaboration between the MSHP and I-TECH is the nurturing ground for the decade-long OpenELIS project in Côte d'Ivoire. The open-source and global CoP of software such as OpenELIS naturally support technical collaboration and exchange.[68] However, without committed engagement and close partnership with the MSHP, the OpenELIS design and development process in Côte d'Ivoire would likely have been less participatory, less successful, and less sustainable.[69]

The improved local capacity of software development and maintenance for OpenELIS is an important contribution toward the vision of long-term, locally sustained implementation. Providing information technology without investing in human resources or building capacity would still be inadequate in addressing the gaps in the laboratory system.[7] Therefore, the policymakers and technicians trained in OpenELIS development and deployment as well as the interns embedded in MSHP teams to support OpenELIS implementation will ensure the medium- and long-term success of the project.

The collaboration has also strengthened local ownership of OpenELIS and leadership of relevant software development and support activities to achieve routine usage and nationwide scale. Although the OpenELIS project in Côte d'Ivoire is still receiving funding by the U.S. government as part of PEPFAR, and the Côte d'Ivoire MSHP has not committed to completely taking over the continuous implementation of OpenELIS, there has at least been progress towards this goal. Transition of all OpenELIS-related planning, design, development, and implementation to the MSHP has been underway as of March 2022.

2.5.3 Limitations

This case study represents the experiences of one LIS project in Côte d'Ivoire and thus may not be generalizable to other settings, though the lessons learned are relevant to many health information systems strengthening projects in LMICs. Evaluation research that uses rigorous quantitative, qualitative, or mixed methods is necessary to assess and demonstrate the reach, effectiveness, adoption, implementation, and maintenance of the project.[70] For example, using a quasi-experimental design to assess the effectiveness of improving laboratory testing data quality (e.g., data timeliness, data completeness, data validity) and service quality (e.g., turnaround time, testing validity) by comparing LIS to paper records; using a qualitative study to interview laboratory staff about the facilitators and barriers to LIS implementation.

2.6 Conclusion

The development and nationwide scale-up of OpenELIS in Côte d'Ivoire for over a decade have relied on the open-source software design, CoP support, close

collaboration with the Côte d'Ivoire MSHP, and cultivation of local ownership and capacity since inception. Other countries and supporting partners planning to adapt and nationally scale LIS may consider the importance of HIS workforce development, financial sustainability, and institutionalization of government ownership and technical leadership.

2.7 Tables and Figures

Table 1. Strengths of laboratory information systems compared to paper-based processes.

<table>
<tr><th></th><th>LIS Features</th><th>Actions</th><th>Impact</th></tr>
<tr><td>Reception</td><td>Batch entry; referral workflows</td><td>Accelerate the processing and recording of incoming work</td><td>Reduce turnaround time</td></tr>
<tr><td rowspan="2">Results Generation</td><td>Work plans</td><td>Help managers monitor workload and supply management</td><td>Ensure efficient operation of laboratories</td></tr>
<tr><td>Analyzer interfaces</td><td>Relay result quickly and accurately</td><td>Reduce turnaround time</td></tr>
<tr><td rowspan="4">Reporting</td><td>Interface with EMR</td><td>Communicate client laboratory history rapidly to clinicians in referral networks</td><td>Enable faster clinical decision-making regarding diagnosis, treatment, and prognosis;
Reduce turnaround time</td></tr>
<tr><td>Interface with client notification systems via SMS or email</td><td>Communicate test results to clients rapidly</td><td>Prompt immediate behavior augmentation and achieve better health outcomes (e.g., initiate self-quarantine in the case of COVID-19).</td></tr>
<tr><td>Interface with routine health information systems at the district, regional, and national levels</td><td>Enable faster aggregate data reporting</td><td>Facilitate data-driven policy making;
Reduce turnaround time</td></tr>
<tr><td>Reports of quality indicators such as turnaround time</td><td>Help managers monitor quality performance</td><td>Facilitate continuous quality improvement;
Increase testing quality</td></tr>
<tr><td rowspan="2">Overarching</td><td>Graphic widgets (e.g., drop-down menus, checkboxes), active logic and value checks, flags and reminders for potential issues, and automation</td><td>Reduce errors</td><td>Facilitate quality control;
Increase testing quality</td></tr>
<tr><td>Data storage and data query tools</td><td>Allow secure, long-term data retainment and easy data retrieval based on specific needs</td><td>Improve client privacy, long-term data availability, and data usage</td></tr>
</table>

EMR, electronic medical records; SMS, short message service

Table 2. Open-source components in OpenELIS

	OpenELIS Global 1.X series	OpenELIS Global 2.X series
Timeframe	Before 2011	After 2011
Operating System	Ubuntu 12	Ubuntu 20
Programming Framework	Java Struts 1	Java Spring
Web Application	Tomcat	Tomcat
Database	PostgreSQL	PostgreSQL
Interoperability	Mirth, HL7 2.5.1	FHIR R4, HL7 2.5.1, ASTM
Customization	Hard-coded multiple forks by developers for each use case	Core software with flexible customization by users

HL7, Health Level 7; FHIR, Fast Healthcare Interoperability Resources; ASTM, American Society of Testing and Materials

Table 3. Timeline of the OpenELIS scale-up in Côte d'Ivoire

	Number of laboratories implementing OpenELIS	
Year	New	Cumulative
2009-2012	3	3
2013-2015	8	11
2016	1	12
2017	31	43
2018	12	55
2019	13	68
2020	28	96
2021	15	111

Figure 1. OpenELIS laboratory software solution and business process framework

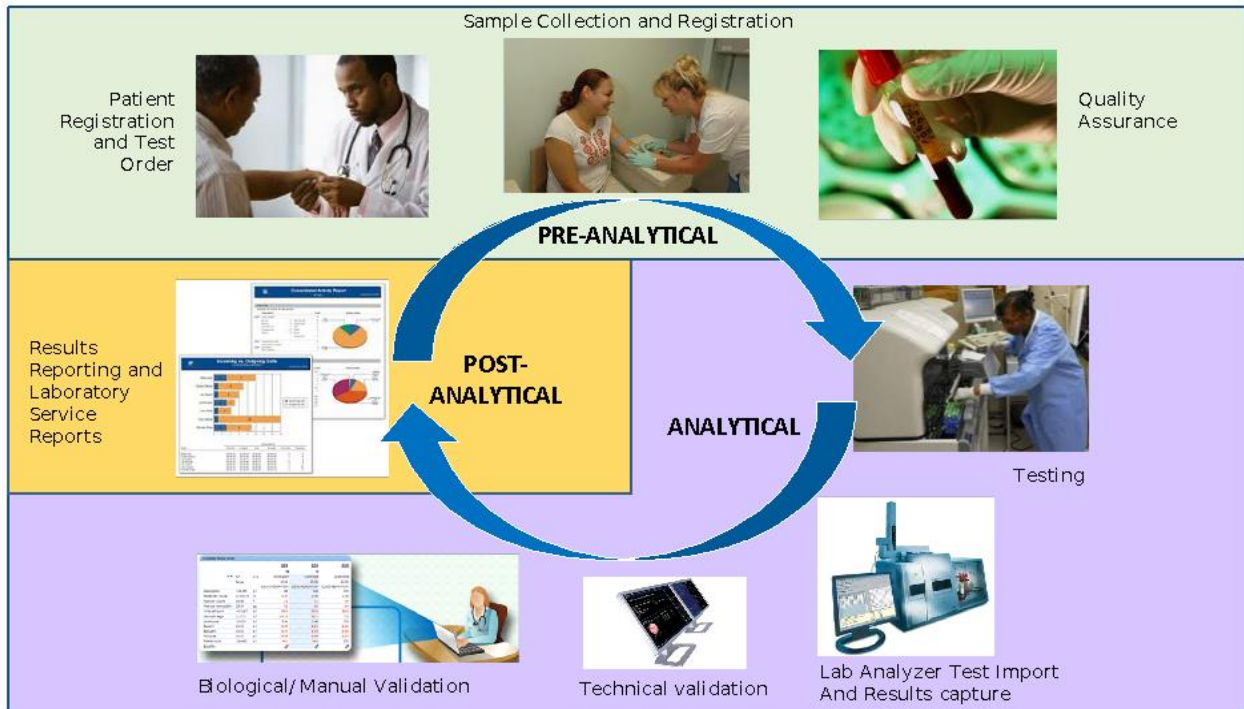
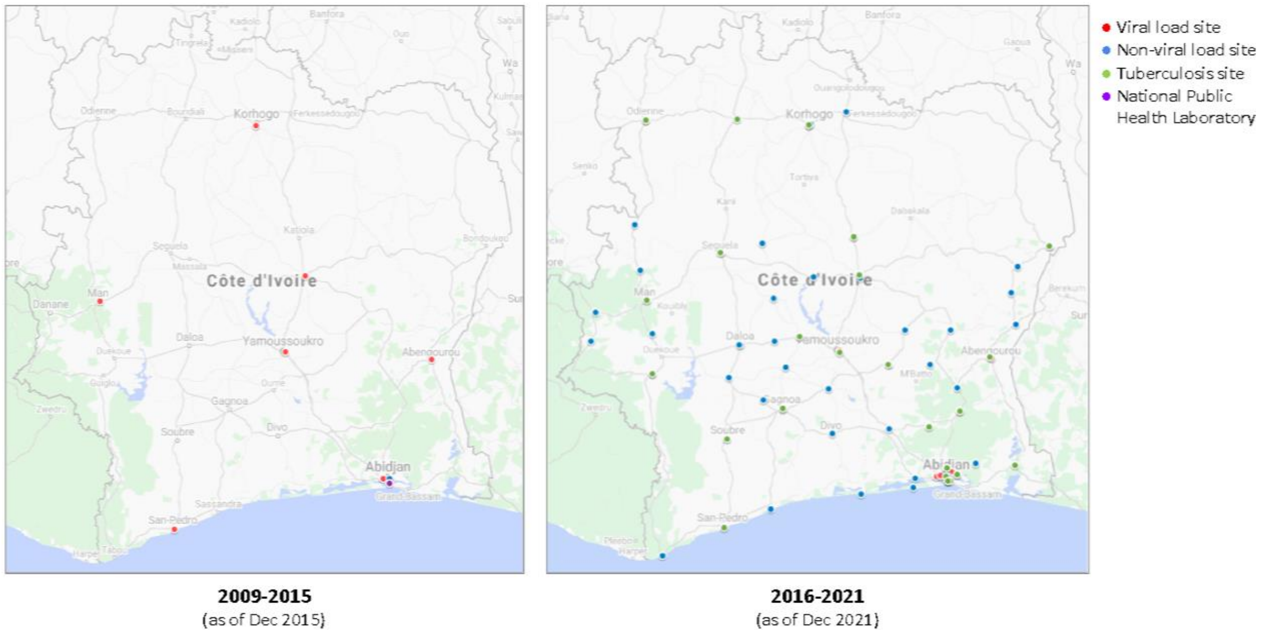


Figure 2. Laboratories in Côte d'Ivoire that implement OpenELIS before and after 2015.



Chapter 3. Laboratory data timeliness and completeness improves following implementation of an electronic laboratory information system in Côte d'Ivoire: An interrupted time series analysis on 21 clinical laboratories from 2014-2020

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3.1 Abstract

Introduction: The Ministry of Health in Côte d'Ivoire and the International Training and Education Center for Health at the University of Washington, funded by the United States President's Emergency Plan for AIDS Relief have been collaborating to develop and implement an open-source enterprise-level laboratory information system (OpenELIS) to improve HIV-related laboratory data management and strengthen quality management and capacity in clinical laboratories across the nation. This impact evaluation aimed to quantify the effects of implementing OpenELIS on data quality for laboratory tests related to care and treatment of people living with HIV.

Methods: This evaluation used a quasi-experimental design to perform an interrupted time series analysis to estimate the changes in the level and slope of three data quality indicators (timeliness, completeness, and validity) after OpenELIS implementation. CD4 testing records for 48 weeks before until 72 weeks after OpenELIS adoption were collected using paper and electronic records from 21 laboratories in 13 health regions that started using OpenELIS between 2014-2020. We analyzed the data at the laboratory facility level. We estimated odds ratios (ORs) comparing the observed outcomes with modeled counterfactual ones when the laboratories did not adopt OpenELIS.

Results: There was an immediate five-fold increase in timeliness (OR=5.27; 95% confidence interval [CI]: 4.33, 6.41; p<0.001) and an immediate 3.6-fold increase in completeness (OR=3.59; 95% CI: 2.40, 5.37; p<0.001). These immediate improvements were observed starting after OpenELIS installation and then sustained until 72 weeks after OpenELIS adoption. The weekly improvement in the post-implementation trend of completeness was significant (OR=1.03; 95% CI: 1.02, 1.05; p<0.001). The improvement in validity was not statistically significant (OR=1.34; 95% CI 0.69, 2.60; p=0.38), but validity did not fall below pre-OpenELIS levels.
Discussion: These results demonstrate the value of electronic laboratory information systems in improving laboratory data quality and supporting evidence-based decision-making in healthcare. These findings highlight the importance of OpenELIS in Côte d'Ivoire and the potential for adoption in other low- and middle-income countries with similar health systems.

3.2 Background

Clinical laboratories provide critically important data for disease investigations and supply timely information for clinical care and public health including helping to identify and characterize pathogens, conduct routine surveillance, and respond to communicable and non-communicable diseases. Effective and timely laboratory services help address national disease priorities and achieve national disease priority and global targets such as the Sustainable Development Goals and the 95-95-95 targets launched by the Joint United Nations Programme on HIV/AIDS.[1–3,71,72] In managing people living with the human immunodeficiency virus (HIV), CD4 testing is critical for

monitoring a client's immune status and risk of opportunistic infections as well as helping healthcare providers decide on differentiated care models and informing tuberculosis screening.[73] For a national HIV program to be highly successful and a country to reach their goal of reducing HIV-related deaths, the health system must integrate data from an effective clinical laboratory system. However, access to quality laboratory services remains a challenge low- and middle-income countries (LMICs) as many countries still rely on paper-based records that can often be unreliable.[6] Throughout the cascade of care, paper documents and records require a careful chain of possession, tracking, and version control, and their use and sometimes loss can impede an already complex process of service delivery. Problems in data quality could occur at every step of this manual process, jeopardizing quality of care.

Laboratory information systems (LIS) are part of the important infrastructure for laboratory operation and information management. According to the requirements for quality and competence of medical laboratories issued by the International Organization for Standardization (ISO), most of the information management requirements are for electronic systems.[74] This signals the high prevalence of electronic LIS at laboratories that meet or strive to reach ISO standards. The World Health Organization established the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist to guide clinical laboratories in Africa through continuous quality improvement and towards accreditation to international standards.[8] The SLIPTA checklist characterizes computerized LIS as integral to ensuring laboratory operation and fulfilling the criteria of laboratory information management on ensuring data quality, data

storage and back-up, and patient confidentiality.[8] Lack of effective electronic LIS is one of the barriers to quality laboratory service delivery in LMICs.[7]

LIS can also improve the quality of care, patient safety, and disease surveillance.[7,9–12] Compared to paper-based information systems, electronic LIS can provide more timely and more accurate monitoring and reporting of turnaround time, test failure rates, and other indicators, which improve the quality of the laboratory data that informs clinical care.[7] Various features in OpenELIS intend to ensure data timeliness, completeness, and validity. Control elements and graphical widgets such as drop-down menus and radio buttons make data entry easier and faster, supporting data timeliness and validity. Required data fields must be completed to generate the laboratory result for a patient, assuring data completeness. Valid ranges displayed alongside each test result, the flags for manual review of out-of-range results, and the mandatory validation step before generating results help ensure data validity.

The International Training and Education Center for Health (I-TECH) has been collaborating with the Ministry of Health, Public Hygiene, and Universal Health Coverage (MSHPCMU) in Côte d'Ivoire since 2009 with funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR) to build a functional, accredited diagnostic and laboratory network for effective HIV care and treatment. One of the key program interventions is establishing and supporting the use of OpenELIS, an open-source enterprise-level laboratory information system interfacing with laboratory testing analyzers.[75] From 2009-2021 OpenELIS was installed at 108 laboratories in Côte d'Ivoire, including 68 sites that use it primarily for HIV data, one for food and drug safety

data, 27 for tuberculosis data only, and 12 sites that use OpenELIS for routine laboratory testing data.

This study aims to estimate the intervention effect of OpenELIS on data quality, namely data completeness, timeliness, and validity, using CD4 testing data. Specifically, we aimed to answer the following questions: (1) Did the use of OpenELIS in Côte d'Ivoire's clinical laboratories lead to statistically significant improvements in the data quality outcomes? (2) If so, what was the magnitude of the improvements compared to the counterfactual scenario in which the laboratories had not adopted OpenELIS? (3) Had the improvements persisted after the initial adoption of OpenELIS?

Beyond a single study of the effect of an LIS on laboratory turnaround time in Peru,[76] there is limited evidence on how LIS interventions enhance data quality in LMICs. Findings from our study will provide evidence on the impact of the OpenELIS intervention and inform policy recommendations and guidance for the Côte d'Ivoire MSHPCMU to adopt the best approaches for the future and for decision makers elsewhere to consider adopting OpenELIS in countries with a context similar to Côte d'Ivoire.

3.3 Methods

Study design and data sources

We conducted an interrupted time series (ITS) analysis using weekly time-series data from up to 48 weeks before a laboratory started using OpenELIS until up to 72 weeks after. The ITS analysis is a quasi-experimental design in the evaluation of healthcare interventions or policies that are introduced at a specific time.[77,78] We

hypothesized that the functions and features in OpenELIS would improve the efficiency and quality of laboratory data collection and management more than paper registries (Figure 1). The primary data quality outcomes were timeliness, completeness, and validity. Timeliness for this study was defined as the proportion of test results produced within one day upon receiving test samples; completeness was defined as the proportion of test results having complete data on all four required data fields, namely patient identifier, age, sex, and result date; and validity is the proportion of test results on CD4 cell counts that were within the valid range (0-2,000 cells/mm^3).

We collected data from 21 clinical laboratories across 13 health regions in Côte d'Ivoire (Figure 2). This sampling considered adequate representation in terms of geography and service capacity, as well as the feasibility of data collection. Five sites were regional reference laboratories that provided HIV viral load testing services, three were regional laboratories, and 13 were either at general hospitals or urban hospitals that provided HIV- related laboratory services at the district level. Patient data for all outcomes were de-identified and individual-level data abstracted from laboratory paper registries for the pre-implementation period and from local servers for the post-implementation period. Data were aggregated by laboratory and organized by week for modeling the outcomes in the analyses. The number of laboratories whose data were incorporated in the analyses for timeliness, completeness, and validity was eight, 21, and 20, respectively.

The availability of data on each outcome for both the pre- and post-implementation periods is described below. The number of laboratory weeks differed for each outcome because some laboratories did not have the required paper records

on sample reception and test results that contained data for estimating pre-implementation trends. The most common reasons why paper records were missing were that accidents such as fire or flood destroyed them or that laboratories destroyed the paper records older than five years because the national policy only requires five years for archiving paper-based records.

Statistical analysis

We used a logistic regression model in the unadjusted analysis to examine the trend of each of the primary outcomes and their changes associated with OpenELIS implementation. We estimated crude odds ratios (ORs) representing weekly outcomes compared with outcomes that would have occurred had the laboratories not adopted OpenELIS. We reported both the level change and slope change. We specifically investigated the abrupt changes in outcomes observed during the first week of OpenELIS implementation and the weekly changes in the trend starting from the second week of OpenELIS implementation.

We used a mixed-effects logistic regression model in the adjusted analysis. We estimated odds ratios (ORs) as described above, adjusting for seasonal effects by including fixed-effect monthly indicator variables in the models. We included random intercepts to account for clustering at the laboratory levels and random slopes over time. We also accounted for the weekly number of HIV clients recorded at a given laboratory as weight. The adjusted model equation we utilized was:

$$log\ \left(E(\frac{Y_{it}}{1-Y_{it}})\right) = \alpha_{0i} + \beta_1 Time + \beta_2 OE_i + \beta_3 PostTime + \left(\sum_{m=2}^{12} \lambda_m Month\right)$$

where i indicates laboratory and t indicates week as the time unit. Y_{it} represents the proportion of laboratory records achieving each of the three primary outcomes comparing the factual to the counterfactual; α_{0i} represents the model intercept with a fixed effect and a random effect at the laboratory level; $Time_{it}$ counts the weeks from the earliest pre-implementation time point until the latest post-implementation time point; OE_i is the dummy variable indicating the weeks when a laboratory i was using OpenELIS (1 for the first week when a laboratory started using and thereafter, and 0 otherwise); $PostTime$ counts the weeks after the first week of implementation; $Month$ is an individual dummy variable indicating month of the year with January as the reference.

To develop expected counterfactual forecasts, we reran the logistic models to extend pre-implementation trends through 72 weeks after a laboratory started using OpenELIS as a counterfactual to the observed post-implementation trends. The mixed-effects models accounted for data that were missing at certain weeks using standard maximum likelihood estimation. To visualize the factual and counterfactual trends across time, we plotted the predicted proportions of testing results achieving the primary outcomes under the two scenarios, and the 95% prediction intervals for the factual estimates accounting for random variations at the laboratory level. All analyses were conducted using R 4.1.0 and a 2-sided alpha value of 0.05.

This study was determined to be non-human subjects research by the University of Washington Institutional Review Board and the United States Centers for Disease Control and Prevention (CDC). The study was approved by Côte d'Ivoire Comité National d'Ethique des Sciences de la Vie et de la Santé (CNESVS, Ivorian Institutional Review

Board; reference number 006-21/MSHP/CNESVS-km). The U.S. CDC reviewed this research and manuscript but had no influential role in the study design, data collection, analysis, and interpretation.

3.4 Results

The numbers of laboratory-weeks in the analyses were 613, 1,820, and 1,629 for timeliness, completeness, and validity, respectively. The analyses included an average of 34 weeks of pre-implementation data and 53 weeks of post-implementation data from each of the 21 laboratories. A total of 24,381 and 40,040 HIV client records from the pre- and post-implementation periods, respectively, were in the analysis (Table 1).

In respect to data availability, before laboratories adopted OpenELIS and when they used paper registries exclusively, only 3 of the 21 laboratories had all 48 weeks of complete data on sample reception, and only 10 had all 48 weeks of complete data on test results. After adopting OpenELIS, 19 of the 21 laboratories had all 72 weeks of complete data on both sample reception and test results.

According to the crude analysis, during the first week of OpenELIS implementation, the unadjusted odds of producing timely testing results were 3.36 times the odds had the laboratories not started using OpenELIS (OR=3.36; 95% confidence interval [CI]: 2.93, 3.85; $p<0.001$; Supplementary Figure 1A). The unadjusted odds of testing results having complete data for the required fields were 11.7 times the odds had the laboratories not started using OpenELIS (OR=11.7; 95% CI: 1.92, 70.7; $p<0.01$; Supplementary Figure 1B). The unadjusted odds ratio for data validity (OR=1.94; 95% CI 0.05, 69.9; $p=0.72$; Supplementary Figure 1C) and the differences in the weekly

change in the odds of the three primary outcomes after OpenELIS implementation were not statistically significant (timeliness: OR=1.00, 95% CI: 0.99, 1.01, p=0.96; completeness: OR=1.03, 95% CI: 0.97, 1.09, p=0.34; validity: OR=0.99, 95% CI: 0.89, 1.10, p=0.85).

According to the adjusted analysis, before adopting OpenELIS, a typical laboratory had minor improvements in the three data quality outcomes that were not statistically significant (timeliness: OR=1.03, 95% CI: 0.99, 1.07, p=0.12; completeness: OR=1.11, 95% CI: 0.93, 1.32, p=0.24; validity: OR=1.00, 95% CI: 0.99, 1.02, p=0.76; Table 2). However, immediately during the first week of OpenELIS implementation, we observed an immediate level change in data timeliness, completeness, and validity (Figure 3). The average odds of producing timely testing results were 5.27 times the odds had the laboratories not started using OpenELIS (OR=5.27; 95% CI: 4.33, 6.41; p<0.001; Table 2). The average odds of testing results having complete data for the required fields were 3.59 times the odds had the laboratories not started using OpenELIS (OR=3.59; 95% CI: 2.40, 5.37; p<0.001). The average odds of testing results being valid were 1.34 times the odds had the laboratories not started using OpenELIS (OR=1.34; 95% CI 0.69, 2.60; p=0.38). The immediate improvements in timeliness and completeness were both programmatically substantial and statistically significant.

Starting from the second week of OpenELIS implementation, we observed a slope change in the trend of completeness. The average odds of testing results having complete data for the required fields each week thereafter were 1.03 times the odds had the laboratories not started using OpenELIS (OR=1.03; 95% CI: 1.02, 1.05; p<0.001). In fact, the average proportion of testing results having complete data stayed at almost

100% after a laboratory started using OpenELIS, while the average proportion declined over time in the counterfactual had there been no OpenELIS (Figure 3B). There was no significant change in trend of timeliness and validity (timeliness: OR=1.01, 95% CI: 0.99, 1.02, p=0.49; validity: OR=0.99, 95% CI: 0.97, 1.01, p=0.55).

In terms of heterogeneity at the laboratory level that the adjusted analysis showed, laboratories at local general hospitals seemed to have more substantial improvements in timeliness immediately after starting to use OpenELIS and to have maintained the improvements better over time as compared to regional laboratories (Supplementary Figure 2A). Since a greater number of regional laboratories had less complete data than laboratories at general hospitals before OpenELIS implementation, immediate improvements in completeness were more obvious at regional laboratories, and the improvements also sustained over time (Supplementary Figure 2B).

3.5 Discussion

This study shows that data availability improved after clinical laboratories in Côte d'Ivoire adopted OpenELIS, and there was rapid and substantial improvement in data timeliness and completeness. Following the immediate post-OpenELIS implementation improvements, both timeliness and completeness remained close to 100% throughout time. Data validity was very close to 100% both before and after OpenELIS adoption. There was some heterogeneity in the results at the laboratory level, with laboratories at local general hospitals showing more substantial improvements in timeliness while regional laboratories showing more obvious immediate improvements in completeness.

To our knowledge, this is the first study to demonstrate the immediate and sustained impact of a scaled, multi-site laboratory information system on data quality in sub-Saharan Africa. There are limited studies from LMICs despite significant financial investments from the international donor community. Previous studies from LMICs took place on other continents or did not include as many laboratories or subnational geographic areas as ours did. The e-Chasqui LIS for tuberculosis testing data at 14 laboratories in Peru was the only one that was implemented and evaluated through a cluster randomized controlled trial.[18] The trial showed that the LIS decreased turnaround time and improved quality of care, but the study did not examine the impact on data quality.[18] Our study contributes to the evidence by quantifying the effect size of data quality improvement and its change over a period of 30 months at 21 clinical laboratories. The findings offer critical information for policy makers and digital health researchers in LMICs when considering real-world impact of the OpenELIS software or digitalization of a sub-Saharan African laboratory system.

Systematic LIS implementation across a national health system is rare in LMICs. A rapid literature review of peer-reviewed articles identified eight different LIS that six countries have implemented at a national or subnational scale, namely Ethiopia, Malawi, Namibia, South Africa, Peru, and Vietnam.[13–21,76,79] The LIS in South Africa is the only one that had the capacity of recording data on all laboratory testing services at all clinical laboratories.[80] It is likely that, as a result of the nationwide LIS adoption in South Africa, usage of laboratory data in research has also increased, since almost 20% of the rapid literature review search results from LMICs were epidemiological studies from South Africa using data from the LIS.[22–30]

Part of the success of OpenELIS in Côte d'Ivoire can be attributed to the systematic approach taken by I-TECH in establishing and supporting the use of OpenELIS. The approach included the endorsement by the MSHPCMU and locally trained technical staff who facilitated implementation and provided continuous technical support of the system to the laboratories and their users. The relative advantages of OpenELIS compared to paper registries in improving data timeliness and completeness as well as the ease of implementation and continuous technical support have facilitated routine use of OpenELIS. An experienced software development team designed various functional and interface features of the software specifically intended to improve data quality, e.g., dropdown menus for fast and accurate selections and automatic data completeness and validity checks. The decade-long development and implementation of OpenELIS in Côte d'Ivoire has been open-source, iterative, and collaborative so that feedback from users, laboratory managers, and governing bodies was directly incorporated into the software to match the needs of the users.[75]

Our study provides evidence for improving laboratory data quality which is important for the improvement of clinical care and treatment. A study from Kenya identified that reduced turnaround time and timely communication of laboratory test results are some of the key factors for improving HIV treatment retention.[10]

In addition, in terms of patient safety, LIS reduced the probability of errors in patient identification and subsequent inappropriate treatment by reducing manual clerical work through automation and user-friendly widgets.[7] A survey of clinicians in Malawi revealed that laboratories' poor documentation of test results was one of the reasons for having little trust in laboratory capability and not frequently using laboratory

test results in patient management.[11] Last but not least, LIS can also improve disease surveillance by making it easier to record accurate demographic data that informs disease classification, assessment of population-specific rates, and contact tracing for infectious diseases,[9] as well as to report laboratory-confirmed diagnoses to surveillance systems that allow more accurate estimation of disease burdens.[12]

This evaluation has many strengths and some limitations. The use of multiple data points before and after OpenELIS help capture the changes in time-varying variables through the data we used to generate the pre- and post-trends. However, since all sites that have been using OpenELIS, including the ones sampled in this evaluation, were purposefully selected due to their higher capacity, they might also have had a higher probability of adhering to the OpenELIS user instructions. The results may be generalizable to remaining clinical laboratories in Côte d'Ivoire that are at the same tiers in the health system as the sites sampled in this study, but generalizability to laboratories in other LMICs need further studies to demonstrate.

The implementation of a laboratory information system can have a significant impact on improving data quality in LMICs. This study found that the implementation of OpenELIS led to improved timeliness and completeness of laboratory data. The system also facilitated better data availability compared to paper registries, enabling healthcare providers to make informed decisions based on accurate and up-to-date information.

The effectiveness of a laboratory information system depends on many factors beyond the capabilities of the LIS itself, including systematic planning for adoption, supportive technical and implementation staff, attitudes of policy makers and users, presence of supportive policies, financial resources, infrastructure, and organizational

and individual readiness to adopt innovations. Future research is needed to explore the facilitators and barriers to implementing health information systems such as an LIS in LMICs.

3.6 Conclusion

This study underscores the positive impact of implementing OpenELIS on data quality in clinical laboratories in Côte d’Ivoire. The adoption of this LIS led to remarkable improvements in data timeliness and completeness, which were sustained over time; data validity did not regress below the pre-OpenELIS level. While this research presents significant strengths, further studies are necessary to explore the wider implementation of LIS in LMICs, considering multilevel facilitators and barriers.

3.7 Tables and Figures

Table 1. Background information on the clinical laboratories in Côte d'Ivoire included in this study, before and after the adoption of OpenELIS. The time period for this evaluation was from 2014-2020.

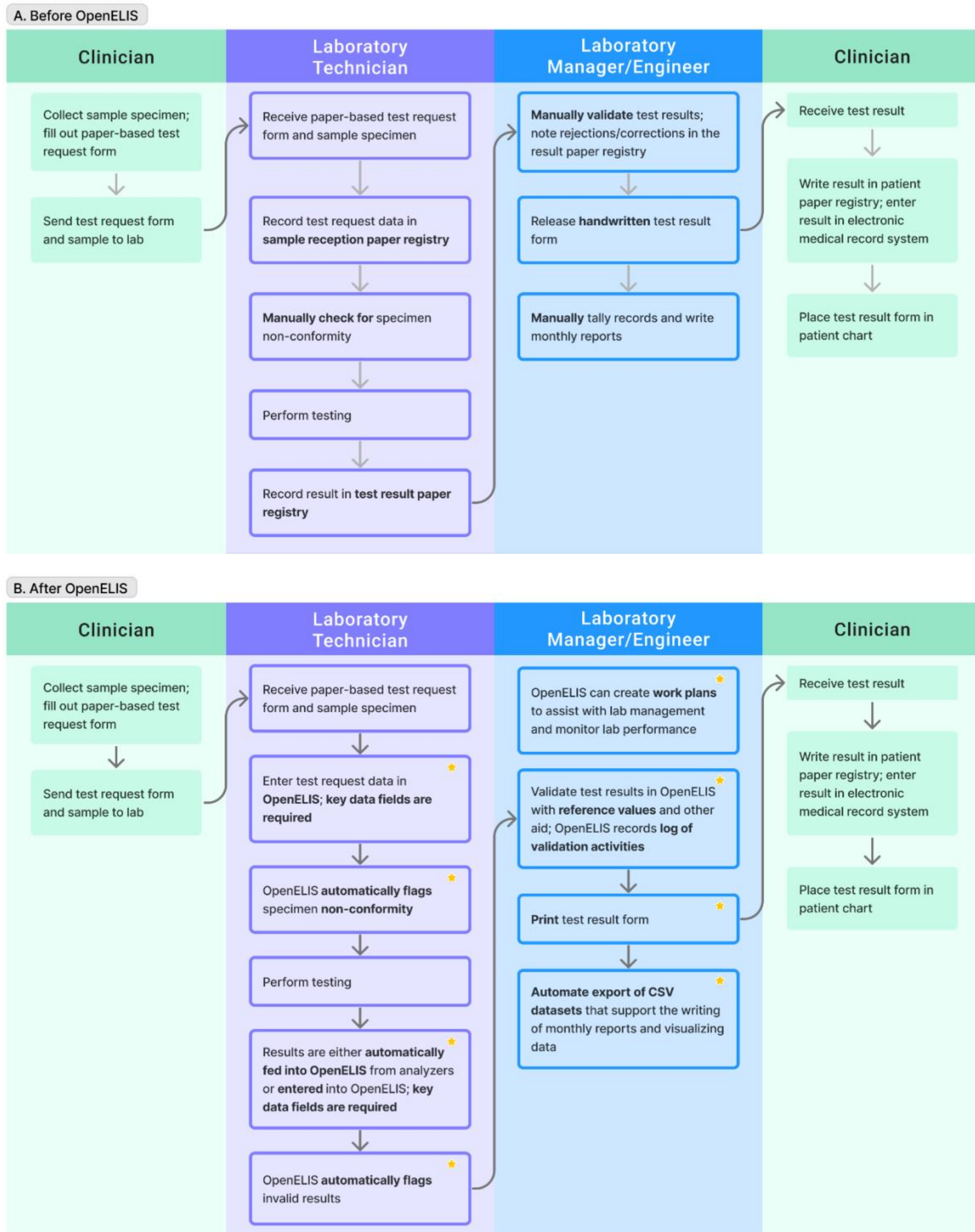
Health region	Number of clinical laboratories	Mean number of weeks of data collected		Number of HIV client records	
		Before	After	Before	After
All regions	21	34	53	24381	40040
Abidjan II	3	35	68	4780	10453
Agneby-Tiassa-Me	1	48	61	2022	1756
Cavally-Guemon	3	45	39	2718	1177
Gbeke	1	8	70	306	3505
Gbokle-Nawa-San Pedro	3	27	65	2769	8383
Goh	1	39	23	538	218
Hambol[a]	1	14	31	401	303
Haut Sassandra	1	32	69	1105	582
Indenie-Djuablin	2	32	51	4015	6857
Loh Djiboua	1	35	64	1164	1741
N'zi-Iffou	2	46	30	2995	888
Poro-Tchologo-Bagoue	1	44	42	719	503
Tonkpi	1	14	69	849	3674

Note: All laboratories had data that could be included in the analyses on completeness and validity unless otherwise noted.
[a] The laboratory sampled in this region did not have data that could be included in the analysis on validity.

Table 2. Estimated ratios comparing odds of achieving the quality outcomes of timeliness, completeness, or validity using specifically CD4 testing data, each week to the counterfactual scenario where the clinical laboratories in Côte d'Ivoire had not adopted OpenELIS. The time period for this evaluation was 2014-2020.

Time period	**Pre-adoption weekly change in the slope of the outcome**		**Immediate level change during first week of OpenELIS implementation**		**Post-adoption weekly change in slope of the outcome**	
Laboratory data quality outcomes	**OR (95% CI)**	**p-Value**	**OR (95% CI)**	**p-Value**	**OR (95% CI)**	**p-Value**
Timeliness	1.03 (0.99, 1.07)	0.12	5.27 (4.33, 6.41)	**<0.001**	1.01 (0.99, 1.02)	0.49
Completeness	1.11 (0.93, 1.32)	0.24	3.59 (2.40, 5.37)	**<0.001**	1.03 (1.02, 1.05)	**<0.001**
Validity	1.00 (0.99, 1.02)	0.76	1.34 (0.69, 2.60)	0.38	0.99 (0.97, 1.01)	0.55

Figure 1. Data flow process for a typical clinical laboratory test in Côte d'Ivoire before (A) and after (B) adopting OpenELIS.

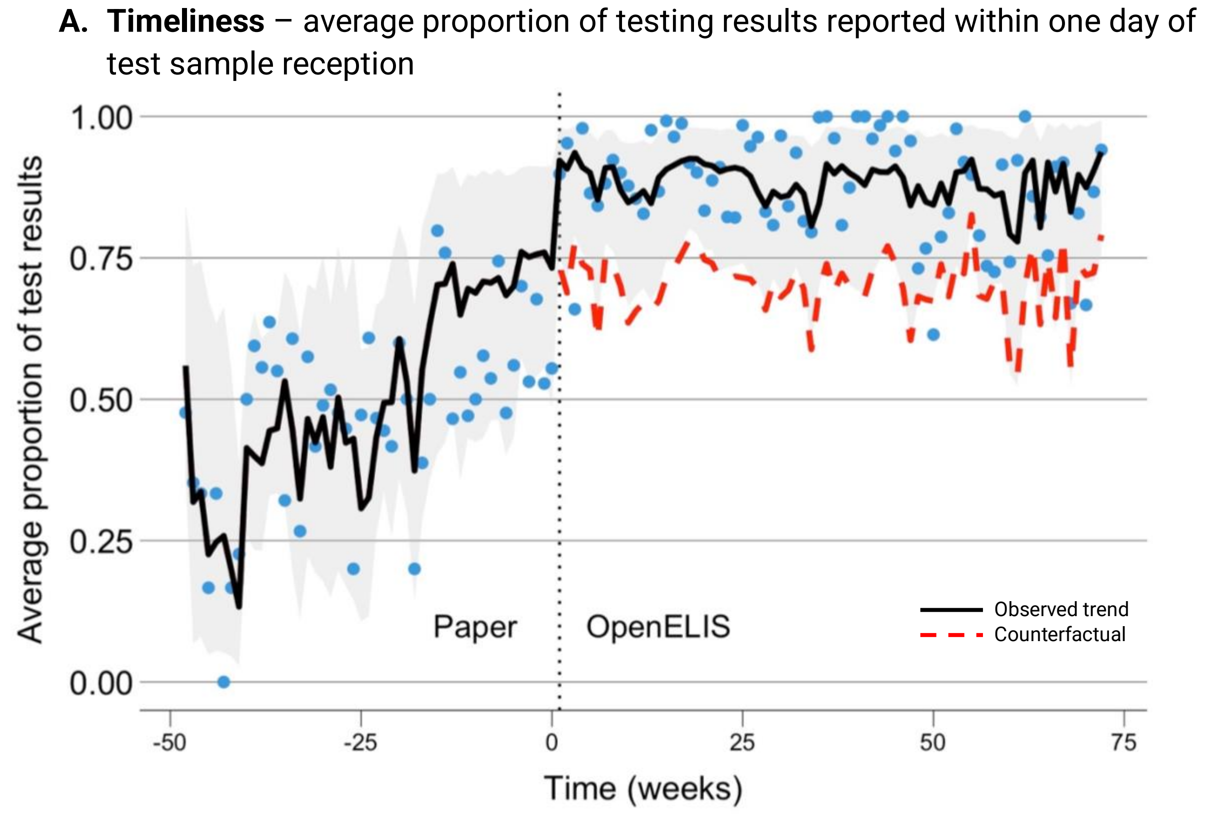


OpenELIS, open-source enterprise-level laboratory information system; CSV, comma-separated values
⋆ denotes the difference between OpenELIS and a paper-based laboratory information system

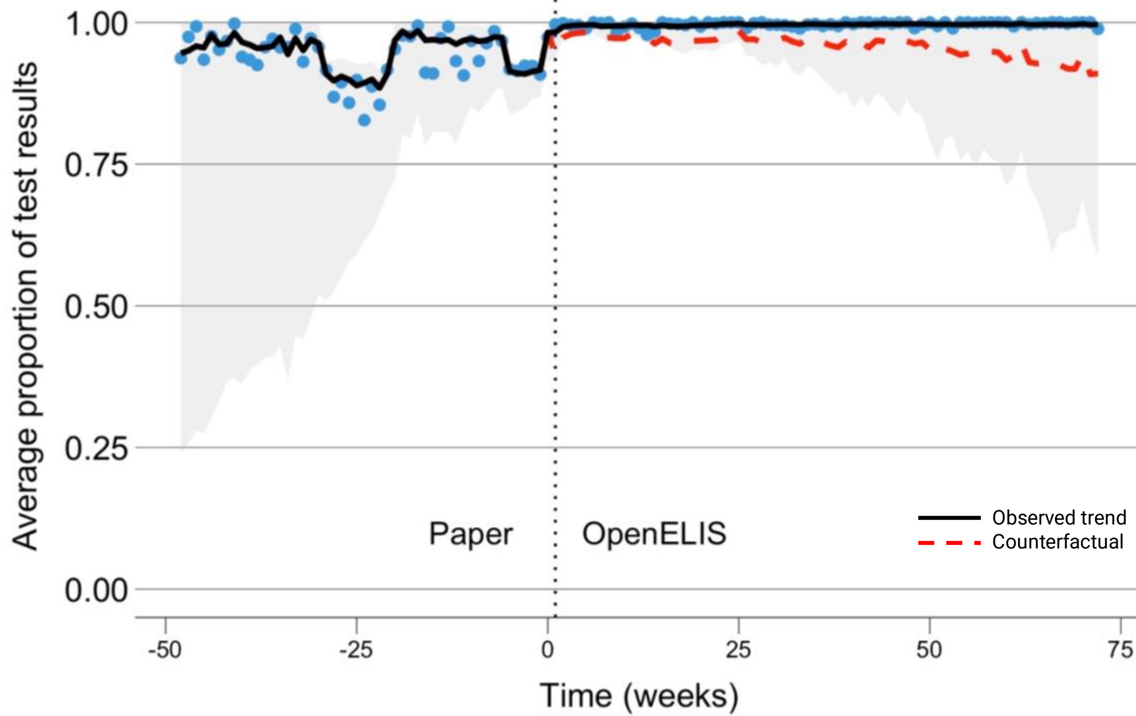
Figure 2. The 13 health regions in Côte d'Ivoire where data were collected from paper registries and OpenELIS for the evaluation of the effect of OpenELIS on data quality in Côte d'Ivoire from 2014-2020.

Figure 3. Laboratory test result timeliness, completeness, and validity from 48 weeks before OpenELIS implementation to 72 weeks after at clinical laboratories in Côte d'Ivoire, adjusted for monthly seasonality

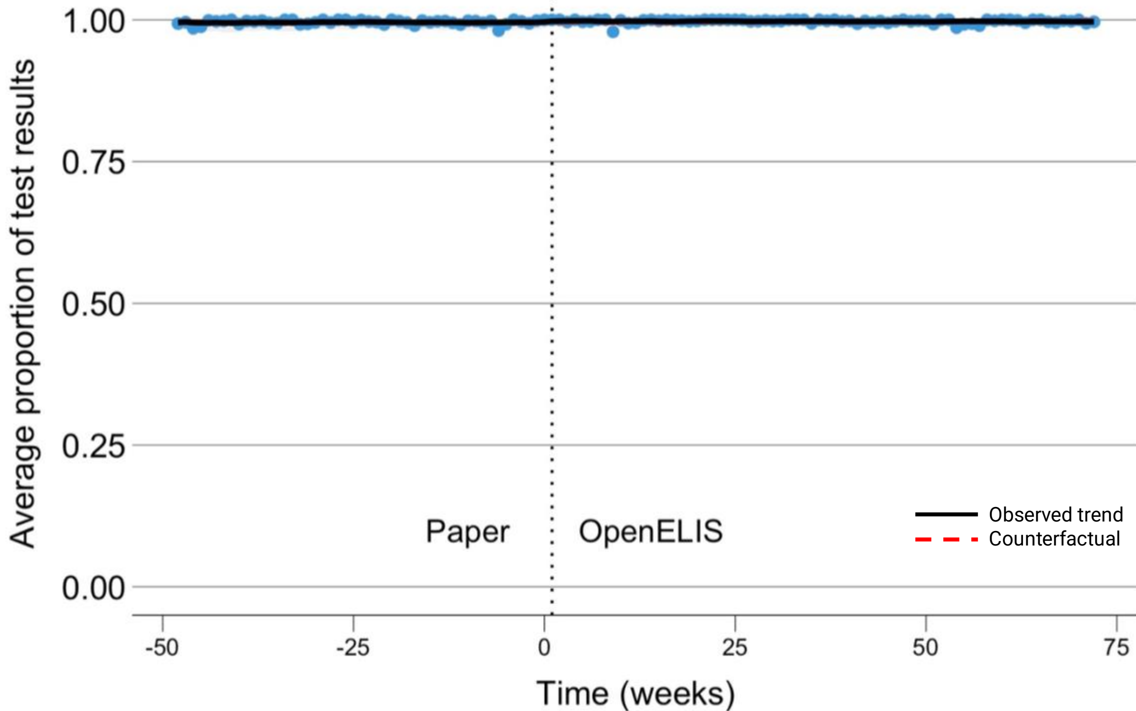
A. **Timeliness** – average proportion of testing results reported within one day of test sample reception



B. Completeness – average proportion of testing results having complete information for all required data fields



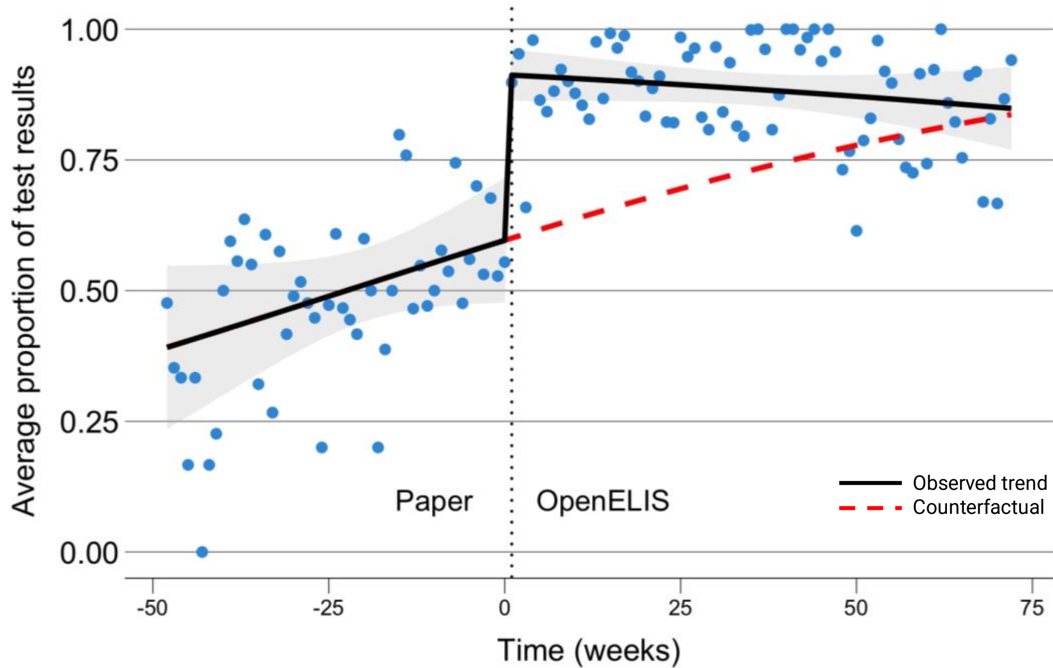
C. Validity – average proportion of testing results having valid results



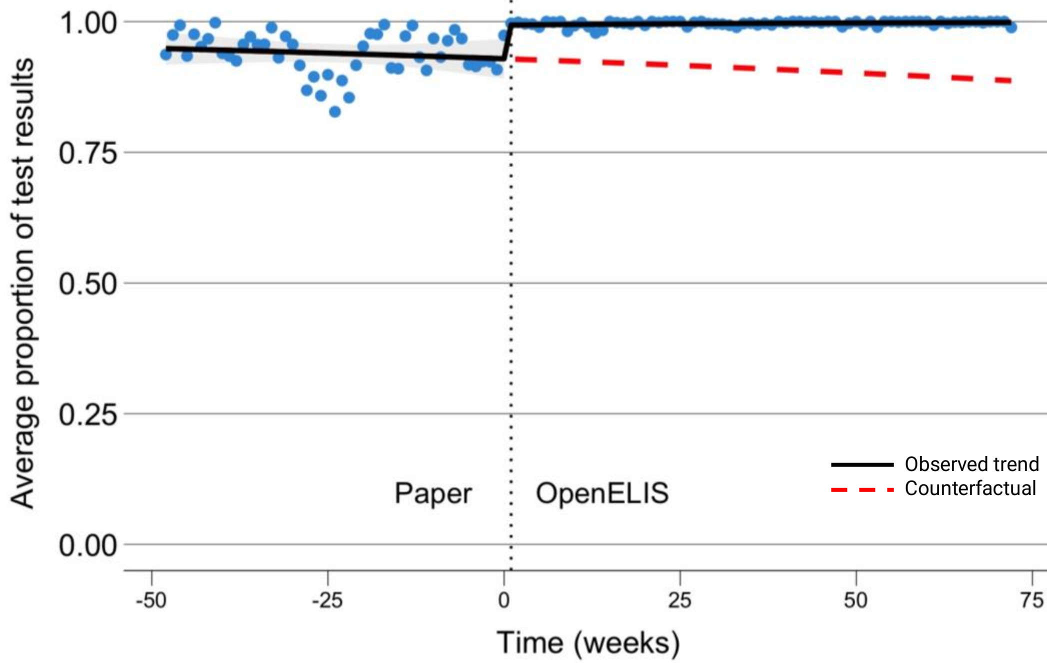
The vertical dotted line represents the first week when a laboratory started using OpenELIS. The blue dots represent the weekly grand means of the observed outcomes at all laboratories. The black solid line is the estimated trend around the observed data points, representing the factual. The light gray area around the solid black line represents the 95% prediction interval around the factual estimates. The red dashed line represents the counterfactual estimates if there were no OpenELIS implementation.

Supplementary Figure 1. Crude analysis of laboratory test result timeliness, completeness, and validity from 48 weeks before OpenELIS implementation to 72 weeks after at clinical laboratories in Côte d'Ivoire.

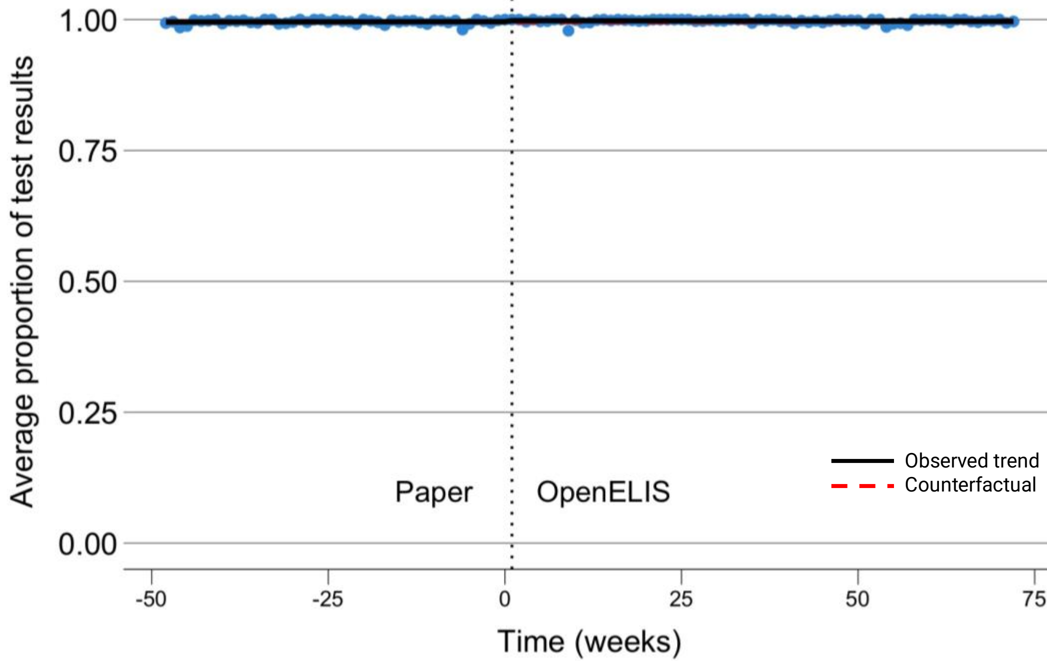
A. **Timeliness** – crude average proportion of testing results reported within one day of test sample reception



B. Completeness – crude average proportion of testing results having complete information for all required data fields



C. Validity – crude average proportion of testing results having valid results

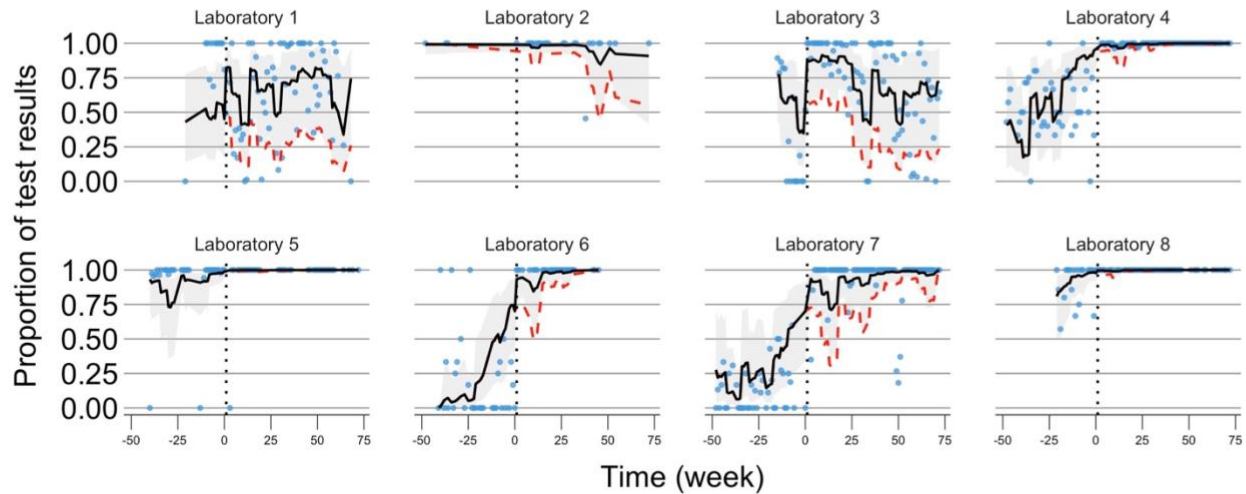


The vertical dotted line represents the first week when a laboratory started using OpenELIS. The blue dots represent the weekly grand means of the observed outcomes at all laboratories. The black solid line is the

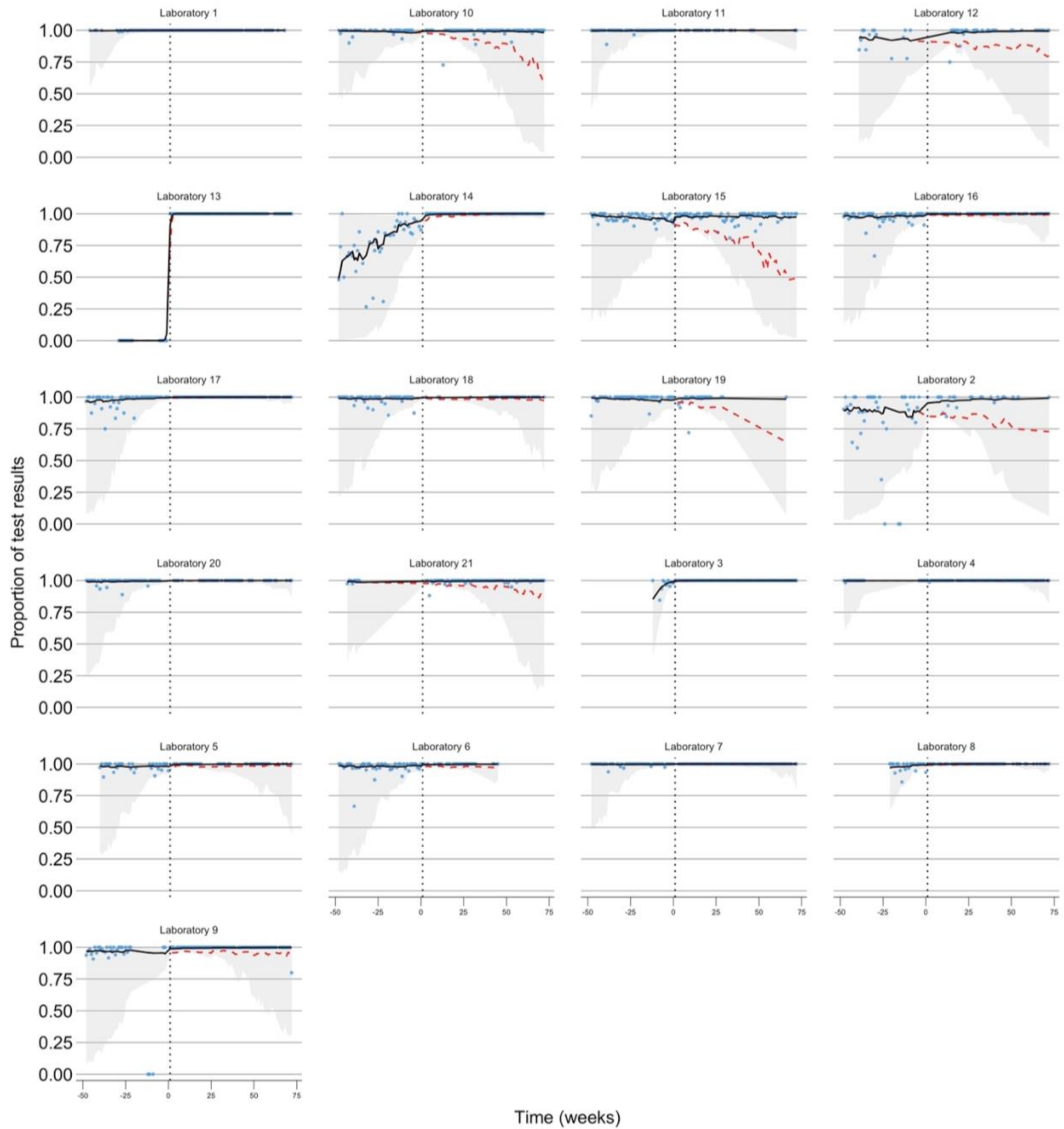
estimated trend around the observed data points, representing the factual. The light gray area around the solid black line represents the 95% confidence interval around the factual estimates. The red dashed line represents the counterfactual estimates if there were no OpenELIS implementation.

Supplementary Figure 2. Laboratory test result data timeliness, completeness, and validity at individual laboratories from 48 weeks before OpenELIS implementation to 72 weeks after at clinical laboratories in Côte d'Ivoire.

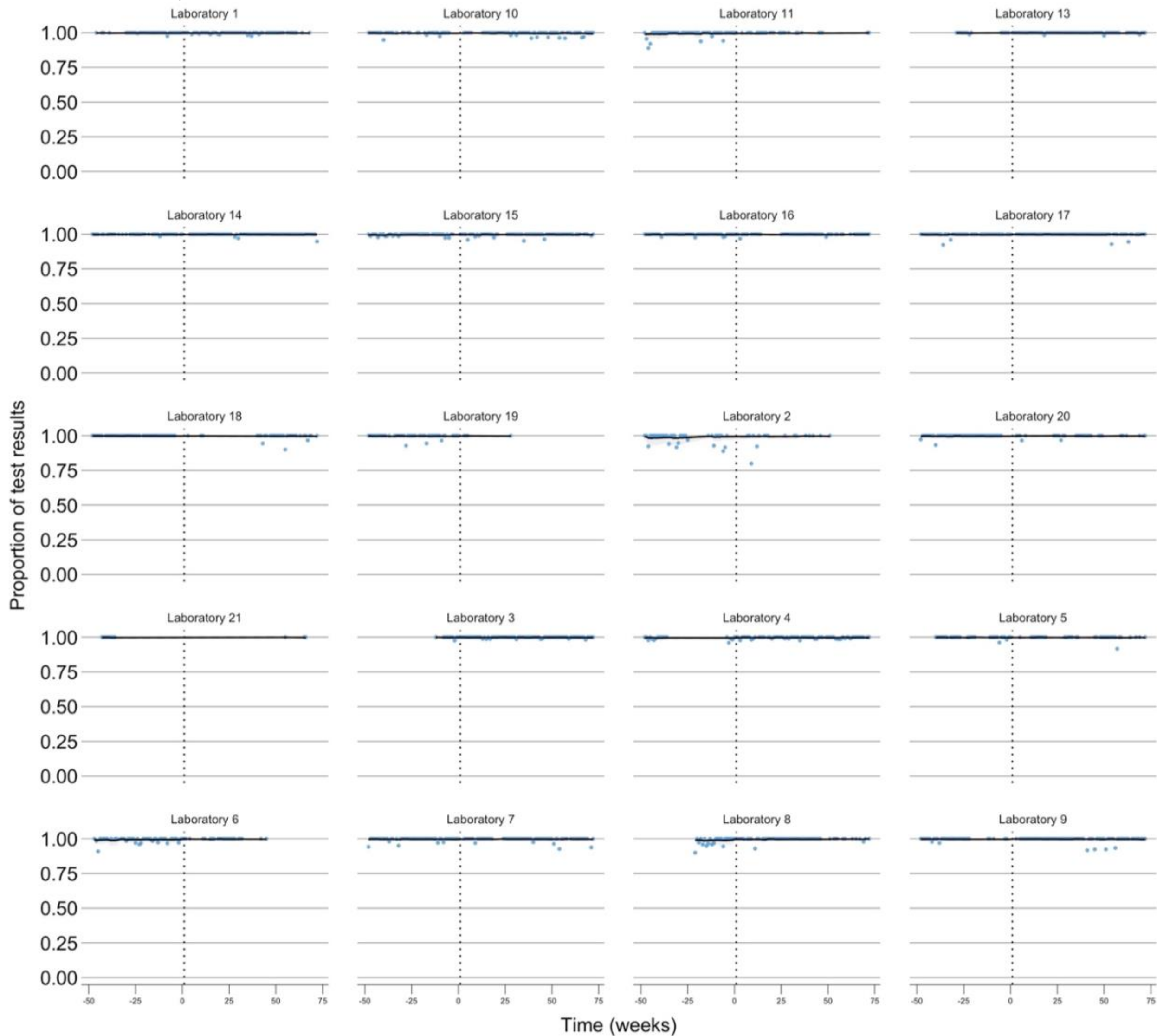
A. **Timeliness** – average proportion of results reported within one day of test sample reception



B. Completeness – average proportion of testing results having complete information for all required data fields



C. Validity – average proportion of testing results having valid results



The vertical dotted line represents the first week when a laboratory started using OpenELIS. The blue dots represent the weekly grand means of the observed outcomes at all laboratories. The black solid line is the estimated trend around the observed data points, representing the factual. The light gray area around the solid black line represents the 95% prediction interval around the factual estimates. The red dashed line represents the counterfactual estimates if there were no OpenELIS implementation.

Chapter 4. Determinants of implementation for electronic laboratory information systems in routine settings in Côte d'Ivoire: A mixed-methods study applying the Consolidated Framework for Implementation Research (CFIR)

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4.1 Abstract

Background: Electronic laboratory information systems (LIS) are critical for promoting data quality and improving laboratory performance, but successful LIS implementation and sustainment in resource-limited settings can be challenging. A collaboration between the Ministry of Health (MOH) and HIV program implementing partners, the OpenELIS project in Côte d'Ivoire seeks to promote routine use of the OpenELIS software at clinical laboratories for routine testing including hematology tests and urinalysis for all patients, while providing necessary hardware, training, and maintenance. This study assessed the sustainment of OpenELIS routine use at laboratories, identified implementation facilitators and barriers, and explained how high-sustainment laboratories differ from low-sustainment ones.

Methods: We conducted a convergent parallel mixed-methods study at 27 clinical laboratories across 15 health regions in Côte d'Ivoire. We collected de-identified routine testing data from OpenELIS servers to describe the sustainment of OpenELIS routine use at each laboratory by calculating the percentage of calendar days during the implementation period when test results were recorded in OpenELIS. We conducted interviews informed by the Consolidated Framework for Implementation Research with

laboratory staff to identify implementation facilitators and barriers and to summarize differences between laboratories of high- versus low-sustainment. We used deductive and inductive approaches to code the interview data and conduct thematic analysis.
Results: OpenELIS routine use at the laboratories ranged from 9.0% to 99.3%; the variation was not correlated with length of implementation or health system level. All participants perceived OpenELIS as originating from external sources without mandates or incentives. Facilitators included valuing positive comments about OpenELIS from external high-level leaders and external partners; appreciating advantages of OpenELIS relative to paper registries; and perceiving high accessibility of knowledge and information. Barriers to routine use included low adaptability; power outages, server failure, and space limitations; and printing costs. Participants of low-sustainment laboratories reported lower motivation and capability in using OpenELIS, perceived more complexity and lower design quality of the software, expressed more concerns about staffing challenges for data entry, received fewer positive comments about OpenELIS from internal leads, and had less reflection and feedback about implementation.
Discussion: Ensuring infrastructure stability may benefit all laboratories. Refresher training, increased frequency of support visits, and staffing plans may help low-sustainment laboratories. Further research is needed to identify determinants of OpenELIS sustainability in the health system.

4.2 Background

Electronic laboratory information systems (LIS) are part of the health systems building blocks and essential infrastructure for clinical laboratories that provide quality

laboratory information to support decision-making for diagnosis and treatment.[7,81] Electronic LIS are a recommended implementation strategy by the World Health Organization and the International Organization for Standardization that changes the usually paper-based records systems in low- and middle-income countries (LMICs) to improve service delivery and clinical outcomes.[8,74,82] Routine use of LIS can help remove obstacles to ensuring quality laboratory services, patient safety, and disease surveillance.[7,9–12]

Sustainment of LIS use at clinical laboratories, defined as the continued use of LIS within routine practice, is not only a desired implementation outcome,[83] but also a determinant for sustaining the improvements in laboratory data quality and clinical decision-making. Implementing effective strategies such as LIS in diverse practice settings can be challenging, and sustaining them in real-world, resource-limited contexts is even more difficult.[84] While there is evidence on explanations of how use of electronic medical records could become routine in hospitals,[85,86] little evidence exists on the determinants of sustained implementation of LIS in clinical laboratories. This evidence is crucial for informing LIS implementation program design in laboratory settings of LMICs that aims to scale up LIS or ensures LIS sustainability beyond the pilot phase, and this study aims to supply such evidence.

There are multiple models and frameworks that one could use to explain parts of the implementation process of a health information system (HIS) including an LIS.[87,88] For example, the Performance of Routine Information System Management (PRISM) framework identifies technical, behavioral, and organization determinants of HIS implementation;[39] a framework and a model explain HIS adoption;[89,90] an evaluation

design uses social network analysis to identify individual roles within an organization in terms of HIS use;[91] a model evaluates the design quality of an HIS intervention;[92] and a framework analyzes the inner and outer context of HIS implementation in a LMIC.[93] An evaluation framework for LIS is available for identifying factors of laboratory testing errors.[94] Although these models and frameworks could be useful to explain specific determinants or phases of an HIS implementation process, they do not offer a holistic lens, and using a combination of them might be cumbersome and still lead to gaps in findings.

The Consolidated Framework for Implementation Research (CFIR) is a meta-theoretical framework that considers a comprehensive list of implementation determinants including the ones mentioned above.[36,95] The CFIR is designed to explain how a variety of implementation strategies such as LIS work where across different contexts and to identify determinants of program implementation.[36,95] The CFIR uses multidisciplinary theories, including those from sociology, psychology, and organizational change, to determine innovation characteristics and contextual factors for various levels of implementation performance across diverse settings.[36,95] With a systems approach, the CFIR illustrates aspects of both the intervention and the implementation process that contribute to implementation success or failure and why.[96] Therefore, the CFIR has more nuanced constructs than the PRISM and other explanatory frameworks for HIS implementation, especially under the domains of outer setting, inner setting, individual, and implementation process. In addition, the CFIR offers validated data collection tools and analysis guides which facilitate comparisons across different implementation settings and with future studies that apply the CFIR to studying LIS

implementation.[97] The CFIR facilitates comparing across clinical laboratories with different performances in data quality, service capacity, and organizational and geographical characteristics. Such comparisons will highlight best practices and challenges in LIS implementation and provide informative evidence for future planning.

The International Training and Education Center for Health (I-TECH) has collaborated with the Ministry of Health, Public Hygiene, and Universal Health Coverage (MOH) in Côte d'Ivoire since 2009 to deploy OpenELIS, an open-source LIS. The nationwide software deployment at 108 clinical laboratories was part of a collaborative program funded by the United States President's Emergency Plan for AIDS Relief (PEPFAR) that aims to establish a functional, accredited diagnostic and laboratory network for effective HIV care and treatment. Although OpenELIS was originally designed to manage HIV-related laboratory testing data only, the software has expanded its scope to support testing of hematology, biochemistry, molecular biology, serology, microbiology, pathology, and immunohistochemistry for all patients.[75]

The LIS component of the laboratory strengthening program consists of the OpenELIS software; necessary information and communication technologies (ICT) infrastructure such as computers, local networks, and servers; installation support from PEPFAR partners including I-TECH and other HIV program implementing partners and the MOH informatics department; annual national training workshop of super users who are staff members of clinical laboratories; and ongoing maintenance services from I-TECH and remote support from the call center agents at the MOH informatics department.

This study aimed to answer three research questions: 1) What was the extent of sustaining OpenELIS routine use at clinical laboratories in Côte d'Ivoire? 2) What were the facilitators and barriers to OpenELIS routine implementation at all sites? 3) What implementation determinants differentiated high- versus low-sustainment sites?

4.3 Methods

This was a mixed-methods study with a convergent parallel design with a post-hoc extreme case sampling during qualitative data analysis. The convergent parallel design involves simultaneous collection of complementary qualitative and quantitative data and subsequently merges and compares the multiple data sources to build evidence and theory around the central question.[98] Both quantitative and qualitative data collection occurred from January-March 2021 at 27 clinical laboratories across 15 health regions that were purposefully sampled from 62 sites that used OpenELIS to manage routine testing data in Côte d'Ivoire at the time of data collection. The purposive sampling considered adequate representation in geography, level in the health system, and feasibility of data collection. The quantitative data collection and analysis aimed to assess the sustainment of routine use of OpenELIS at clinical laboratories as part of public hospitals in Côte d'Ivoire to manage data on routine testing including hematology tests and urinalysis. The qualitative data collection aimed to identify facilitators and barriers to the implementation process; the thematic analysis with a post-hoc extreme case sampling of five high-sustainment sites and five low-sustainment sites aimed to distill differences between the two sustainment groups.

3.3.1 Quantitative data collection and analysis

For the quantitative assessment of OpenELIS routine use, we conducted a descriptive analysis of the routine use score, namely the percentage of calendar days during the implementation period when routine test results were recorded in OpenELIS. The routine use score was the focus of this analysis because frequent and routine use of OpenELIS was an implementation outcome that the OpenELIS project aimed to achieve.

$$Routine\ use\ score = \frac{\#\ calendar\ days\ when\ any\ routine\ test\ result\ was\ recorded\ in\ OpenELIS}{\#\ calendar\ days\ of\ OpenELIS\ implementation\ period} \times 100\%$$

We collected de-identified routine testing data from OpenELIS servers at the laboratories. Routine testing at the time of data collection included hematology tests and urinalysis. The period of the extracted data started when a laboratory began using OpenELIS and ended on December 31, 2020. After calculating the routine use score from OpenELIS data for each laboratory, we ranked the laboratories and categorized the five laboratories with the highest routine use scores as high-sustainment; the five laboratories with the lowest routine use scores as low-sustainment; and the remaining 17 laboratories as medium-sustainment.

3.3.2 Qualitative data collection and analysis

We conducted one semi-structured in-depth interview (IDI) at each of the sampled laboratories. The laboratories received a notice for the data collection site visit at least twice, once at one week before the visit and another at one day prior. The person who oversaw OpenELIS implementation at a given laboratory was invited to

participate in the interview. If this person was absent, we interviewed a staff member who used OpenELIS instead.

During the interviews we asked a question on the maturity level of OpenELIS use at the laboratories, with the following response options: a) OpenELIS is still very new to us, we have a lot to learn; b) we know the basics, but we still need a lot of help with specific problems; c) the use of OpenELIS is now part of the routine, although we still have issues sometimes, we can troubleshoot some on our own; d) other, please specify. We intended to use the responses to this question to validate and triangulate with the quantitative assessment of OpenELIS routine use described above.

Adapting validated tools of the 2009 version of the Consolidated Framework for Implementation Research (CFIR),[35,99] we developed the rest of the questions in the semi-structured interview guide. The chosen constructs are compatible to the LMIC context (i.e., more emphasis on factors of health systems and organizations rather than individuals) and relevant to the intervention, the implementation program, and the evaluation questions (Table 1).[100] YH developed the interview guide in English and then translated it to French. PHA and YRK, native French speakers, reviewed and revised the French interview guide and piloted it at two laboratories. YH, PHA, and YRK discussed feedback from the pilot visits and revised the interview guides in English and French to remove repetition and clarify confusing terms.

PHA visited 14 sites, YRK visited 10 sites, and an Ivoirian data collection consultant visited three sites from the sample and conducted interviews in French. Interviews were conducted in person in an office at the laboratory, mostly with only the interviewer and interviewee, but on a few occasions other laboratory staff were present.

No repeat interviews were conducted. Interviews were audio-recorded, and detailed notes were taken on paper during the interviews. The average length of the IDIs were 29 minutes. Data were analyzed concurrently with data collection to ensure that *a priori* thematic saturation was reached, i.e., the degree to which chosen CFIR constructs were exemplified in the data.[101]

After each interview, PHA, YRK, and the consultant uploaded photos of informed consent forms, detailed notes, and audio recordings to a shared drive on the University of Washington Google Drive with restricted access. The recordings were transcribed verbatim in French and translated by YH, PHA, and YRK into English. The detailed notes were added to the transcripts to supply additional details.

The analysis team consisted of four members. YH, female and Chinese, is a Doctor of Philosophy student in global health implementation science at a university in the United States, with three years of experience in qualitative research and five years of experience working with health information systems in Côte d'Ivoire. RA, female, Palestinian and Jordanian, is a Master of Public Health student in global health at a university in the United States. PHA, male and Ivoirian, is the health information system specialist of the OpenELIS project and trained in informatics. YRK, male and Ivoirian, is the monitoring and evaluation specialist of the OpenELIS project and has a Master of Science degree in statistics. Some of the interviewees at the sampled laboratories had worked with PHA and YRK on previous activities related to OpenELIS implementation.

A combination of deductive (namely using the 2009 version of the CFIR)[35] and inductive approaches were used to analyze the data. Codes were created using the CFIR constructs as well as derived from the data that the CFIR constructs did not pertain to.

YH and RA were the primary coders of the interview transcripts. We first chose five transcripts randomly to code them with the initial codebook consisting of the CFIR codes only and to create new concept codes and valence codes to capture facilitating or hindering influences on perceptions or decisions regarding OpenELIS implementation. After coding the transcripts and writing memos that documented our thought processes and reasonings individually, we discussed the codes and approaches, recognized similarities, and resolved differences to reach consensus and update the codebook. We then each coded 11 of the remaining transcripts as the primary coder, reviewed the other person's coding and memos, and discussed and resolved key differences. Any changes in the codebook or coding approach were applied to transcripts that we had coded previously. We conducted the coding and thematic analysis in ATLAS.ti Window (Version 8.4.26.0).[102]

After finishing the coding process, we summarized the quotes for each code and selected representative quotes from the transcripts to illustrate the summaries. We characterized the CFIR construct codes as converging when we interpreted similarities in the quotes across the three sustainment groups. To illustrate differences between high- versus low-sustainment sites, we conducted a post-hoc extreme case sampling of the five high-sustainment sites and five low-sustainment sites and characterized the CFIR construct codes as diverging based on our interpretations. Differences between the high- and low-sustainment groups were organized into a table adapted from a joint display of a convergent design based on a theoretical framework.[103] PHA and YRK reviewed and provided their feedback on the findings, and all feedback was incorporated in the results and interpretation.

Damschroder et al. updated the CFIR in 2022 after we finished the late-stage thematic analysis.[36] As we recognized the value of the updates and wanted to ensure longitudinal consistency of our results interpretation, we mapped the 2009 CFIR constructs that we chose *a priori* for qualitative data collection and analysis to the corresponding 2022 CFIR constructs (Table 1), and presented the results and discussion with the 2022 constructs.

This study was determined to be non-human subjects research by the University of Washington Institutional Review Board and the U.S. Centers for Disease Control and Prevention (CDC), and was approved by Côte d'Ivoire Comité National d'Ethique des Sciences de la Vie et de la Santé (CNESVS, Ivorian Institutional Review Board; reference number 006-21/MSHP/CNESVS-km). The U.S. CDC has reviewed and authorized this publication but had no role in study design, data collection, analysis, and interpretation.

4.4 Results

Among the 27 clinical laboratories in the sample, 19 (70.4%) were not referral laboratories that processed referral samples of HIV viral load testing and early infant diagnosis, and 16 (59.3%) were laboratories based in district hospitals that only treated patients within their respective health districts (Table 2). The median OpenELIS implementation duration was 1,068 days or 35 months (interquartile range [IQR] 354 days).

The median routine use score in percentage across all sites was 52.3 (IQR 33.1). After ranking the 27 sites from the highest to lowest routine use score, we categorized the sites into three groups of high-, medium-, and low-sustainment (Supplementary

Table 1). On average, the laboratories in the three sustainment groups had similar implementation durations; a higher percentage of high-sustainment and low-sustainment sites were regional laboratories (Table 2). The five high-sustainment laboratories had a median routine use score of 98.1 (IQR 10.8); the 17 medium-sustainment laboratories had a median score of 52.3 (IQR 16.9); and the 5 low-sustainment laboratories had a median score of 26.2 (IQR 5.5).

Most interview participants were male (85.2%), and half of the participants held positions of leadership at the laboratory (Table 2; Supplementary Table 1). The gender distribution was similar across the three sustainment groups; all five interview participants at the high-sustainment site were laboratory heads or deputy heads, which was a higher proportion than at medium- or low-sustainment sites (Table 2).

After triangulating the quantitative assessment of routine implementation with the responses to the OpenELIS maturity question in the interviews, we were able to validate the routine use scores. Three of the five high-sustainment sites (60.0%) and seven of the 17 medium-sustainment sites (41.2%) reported routine use of OpenELIS and knowing how to troubleshoot common issues independently, whereas three of the five low-sustainment sites (60.0%) expressed that OpenELIS was very new to them or that they only understood the fundamentals of use and needed more help.

We drew the following three sections of findings about implementation determinants by integrating quantitative and qualitative data. The first two sections (3.4.1 and 3.4.2) illustrate the CFIR constructs which all laboratories converged on (Table 3), while the third section (3.4.3) illustrate the CFIR constructs which the high- and low-sustainment sites diverged on (Tables 3 and 4). All *a priori* CFIR constructs

were reflected in the findings. The two CFIR constructs that emerged during coding and thematic analysis were local conditions of power outages and available resources for printing materials and equipment under Section 3.4.2.2.

3.4.1 High- and low-sustainment sites commonly experienced no policy mandates or incentives for OpenELIS implementation and perceived OpenELIS as originating from an external source

Policies and law; financing

Participants from all laboratories, regardless of the extent of OpenELIS routine use, perceived the MOH and PEPFAR implementing partners including I-TECH and other non-governmental organizations as the source of the OpenELIS project ("this is a choice that was made by the Ministry and implementing partner on a certain number of hospitals" – medium-sustainment site 1).

All participants shared that they were not aware of any mandatory policies or financial incentives for implementing OpenELIS, although the participants of two sites shared that the regional health directors communicated about the importance of using OpenELIS ("The director of the health region had a meeting with the main actors to inform them about the importance of the use of this software." – low-sustainment site 4).

Innovation source

Two participants thought that their hospital management teams were also part of the intervention source. The participant of a high-sustainment site said, although the

staff were not aware of any explicit mandate, they felt resistant towards OpenELIS due to defiance towards the hospital management monitoring laboratory activities:

> My lab staff is usually very resistant to use OpenELIS. Because some technicians think that the management has imposed the software on us for the purpose of monitoring laboratory activities. (high-sustainment site 4)

Participants of all but one site thought that OpenELIS had no financial implications on laboratory revenues ("The fact that patients come or not is not related to OpenELIS because they come according to their state of health." – low-sustainment site 4).

All laboratories, regardless of the extent of OpenELIS sustainment, converged on the perceptions of an external intervention source, no mandate or incentive, and no financial implications. These perceptions did not seem to have facilitated or hindered the laboratories' decisions to adopt and continuously implement OpenELIS.

3.4.2 All laboratories converged on a set of facilitators and barriers for adoption and implementation of OpenELIS.

Facilitators that all laboratories shared were valuing positive comments about OpenELIS from external high-level leaders and implementation facilitators, recognizing the advantages of OpenELIS, and having ready access to knowledge and information about OpenELIS. The shared barriers included low adaptability of OpenELIS, power outages, server failures, space limitations, and printing costs.

3.4.2.1 Shared facilitators

High-level leaders; implementation facilitators

Positive comments about the usefulness of OpenELIS or motivating messages from high-level leaders and implementation facilitators were helpful for laboratories to adopt OpenELIS. Twenty-one participants (77.8%) shared that the people who were influential to OpenELIS adoption included external high-level leaders such as MOH officials at the national level or regional or district health management teams, as well as external implementation facilitators who were staff members of PEPFAR implementing partners.

> The National Public Health Laboratory sent agents to train us. They are people who are influential because they have motivated us to use the OpenELIS tool. (medium-sustainment site 2)
>
> The HIV implementing partner encouraged us to computerize our laboratory data management system. (low-sustainment site 2)

Innovation relative advantages

The various relative advantages of OpenELIS compared to paper registries contributed strongly to adopting and implementing OpenELIS. At adoption, all participants recognized the reason for adopting OpenELIS was that it would improve laboratory data management and quality of service.

During implementation all participants appreciated that OpenELIS improved data archive and prevention of data loss; enhanced data quality by improving data availability, completeness, and validity; and facilitated data use in patient follow-up, reports, and analyses by enabling searchability, traceability, and faster retrieval of patient records to easier and better data reporting.

> *On improved data retainment and availability:* The use of OE is very efficient in our laboratory because it allows us to save our data and reprint it at any time. We have no data loss. (medium-sustainment site 7)
>
> *On improved data completeness and validity:* There are certain parameters on OpenELIS which are mandatory, so if the doctors did not fill out [the test request form], we cannot record it on OpenELIS. In that case we ask the doctors to provide all the information of the patient, and at meetings they are reminded to fill in the fields. […] There are no reference values in the registries. You write the values, but you don't know if it is high or not. On OpenELIS it will tell you if the parameter is too low or high. (low-sustainment site 5)
>
> *On improved data use:* Before we have our paper registers with which we need to count [the records] one by one. Now OpenELIS facilitates us in our reports and stores our results well. Using data in OpenELIS is quick and easy because the papers are very cumbersome. The fact that we can save our data electronically is a great advantage, and it made searching easy, and the doctors have appreciated the results. (medium-sustainment site 2)

Access to knowledge and information

All but one participant shared that they had access to useful knowledge and information for OpenELIS implementation through training workshops, on-the-job coaching, and remote support. The workshops trained select laboratory staff members as super users. The super users conducted cascade training and on-the-job coaching for other staff members in the laboratory ("Not everyone went to the central training – only people who were appointed went, but when we came back, we shared the training with others, since the objective is that everyone uses OpenELIS." – medium-sustainment site 10). The call center or I-TECH provided remote support regularly or as needed ("The call center agents call regularly to inquire about software difficulties, so we think the program is going very well." – low-sustainment site 2).

The participant from low-sustainment site 5 shared that all current staff members at the laboratory had not participated in any training or coaching in OpenELIS

due to staff turnover ("All those who have been trained have practically left, and those who are here have not had any retraining." – low-sustainment site 5). The degree to which the training and coaching strategies occurred during implementation was directly associated with the structural characteristic of staffing, influencing OpenELIS routine use. We explain how staffing was more likely to be a barrier to routine implementation at low-sustainment sites under section 3.4.3.

3.4.2.2 Shared barriers

Innovation adaptability

Eighteen participants (66.7%) shared that, as OpenELIS use continued at their laboratories, staff members started wanting to use it for recording all laboratory tests rather than only those for HIV clients and a few other routine tests for non-HIV clients. However, the software was not easily configurable or adaptable by laboratory personnel to enable additional modules. Laboratories had to adapt to the software configurations provided and contact I-TECH so that software developers could incorporate suggestions in the next software update.

> Initially [OpenELIS] was for a number of tests specifically related to people living with HIV. We in the use of this software realized that it could be useful for the routine examination. We asked [an I-TECH staff member] so that he can insert the other exams except micro-bio which has not yet been taken into account. The changes so far have been done successfully. (medium-sustainment site 1)

> OpenELIS can be expanded to collect and report data on more types of laboratory tests, but also it must be connected to the analyzers to be able to pull the forms directly. (low-sustainment site 1)

Four participants also suggested that OpenELIS should improve the reporting function so that they can directly generate a monthly report with MOH-required format and information but also have options to edit the report ("the software is very good, but we want OpenELIS to output our reports directly to make things easier for us." – medium-sustainment site 7).

Local conditions; physical infrastructure; information technology infrastructure

A key barrier to OpenELIS implementation that all participants mentioned was unstable electricity and server network performance. These common issues that all laboratories experienced in information technology infrastructure were a source of inconvenience or stress sometimes.

> I [feel] stress when there is a network problem because you are validating [the test results] and you press the save button, you see that it has not happened! (medium-sustainment site 11)

Physical infrastructure also posed challenges to implementation. Ten participants (37.0%) shared that the space in their laboratories was already too small to accommodate more equipment or workstations, but the laboratory staff found solutions eventually.

> Our laboratory is not spacious enough, so already to deploy the equipment we had space concerns. That's why we had to put the server high up. (medium-sustainment site 2)

Materials and equipment

The participants shared that the cost of the printer, ink, and paper for printing test result forms produced from OpenELIS was a disadvantage of the software compared to

paper registries (“A disadvantage to OpenELIS compared to registries is the lack of ink and paper” – medium-sustainment site 9). Since neither the MOH nor the PEPFAR implementing partners provided earmarked resources to support the printing function, the laboratories had to find their own resources. At a laboratory where the team could not afford a printer, the staff had to revert to the traditional way of writing down test results manually (“There is no printer, so we had to write the result on a form. This slowed us down. This is a hindrance.” – medium-sustainment site 12).

3.4.3 Low-sustainment sites experienced more implementation barriers than high-sustainment sites.

The five high- and five low-sustainment laboratories diverged on the following seven CFIR constructs: OpenELIS complexity, OpenELIS design, work infrastructure, compatibility, motivation, capability, implementation leads, and reflecting and evaluating (Table 3). More participants at low-sustainment sites mentioned these eight constructs as barriers to routine implementation of OpenELIS. Table 4 provides detailed summaries and supporting quotations for the contrasts between the two sustainment groups in each of the seven constructs.

Innovation complexity

Four participants at high-sustainment laboratories found OpenELIS easy to learn and use routinely, while three at low-sustainment laboratories perceived slightly higher complexity and needed more time to learn and more training to refresh their knowledge of OpenELIS use. According to the participants at two low-sustainment laboratories, a

reason why they needed more time to learn was that they had to first acquire basic knowledge of using computers.

Innovation design

While four participants at high-sustainment sites were satisfied with the design quality of the OpenELIS software except for the low adaptability as discussed under section 3.4.2.2, three participants at low-sustainment sites complained more about software bugs and malfunctions. All laboratories used the same versions of OpenELIS and received the same updates when they became available. Therefore, the difference in the perception of design quality might correspond to maturity and capability of OpenELIS use.

Work infrastructure; compatibility

When asked about potential barriers to OpenELIS implementation that were related to work infrastructure and compatibility, four participants at low-sustainment laboratories mentioned challenges in dedicating staff to data entry or incorporating data entry duties into the existing workflow. The challenges stemmed from lack of personnel in general so that it was difficult to add data entry to any existing staff member's responsibilities and workload, as well as high staff turnover so that staff members who knew how to use OpenELIS left before new members joined and received coaching on OpenELIS. In contrast, no participant at high-sustainment laboratories mentioned staffing challenges, even if the laboratories in both high- and low-sustainment groups were at similar levels of the health system and thus had similar sizes of staff (Table 2).

Three low-sustainment laboratories tried the same strategy to mitigate the staffing issues, namely rotating data entry responsibilities.

> There is a person dedicated to entering results and all. Everything is going well as if nothing had happened. And that person is changed every day. (low-sustainment site 5)

Although participants thought these strategies successfully solved the data entry issue and helped OpenELIS integrate with their workflows, we did not observe high OpenELIS sustainment according to the quantitative analysis.

Motivation

Four participants at high-sustainment laboratories expressed high enthusiasm towards OpenELIS except for moments of power or server outages, reflecting high motivation to use OpenELIS. However, participants at low-sustainment laboratories expressed lower motivation, more stress, and distrust towards OpenELIS. The quote from the participant at a low-sustainment site exemplifies the lack of motivation and necessity to direct staff to use OpenELIS:

> There is still the “whip” to put behind people because you have to be there to know who uses OpenELIS and motion people to use OpenELIS. (low-sustainment site 5)

The participant at low-sustainment site 1 said OpenELIS created distrust among some staff due to its novelty, deterring implementation (“There is just distrust at the level of some laboratory staff members due to the fact that [OpenELIS] is a new tool and method of work.”).

Capability

All participants at high-sustainment laboratories showed high confidence in their capabilities of using OpenELIS and coaching someone new to start using OpenELIS,

while three participants at low-sustainment laboratories showed low confidence. This corresponds well to the quantitative findings of routine use as well as the maturity levels of OpenELIS use described above.

Implementation leads

All participants reported that their laboratories had internal leaders of OpenELIS implementation. Most of the leaders were appointed because of their higher status in laboratory management (e.g., laboratory head, deputy head) or their participation in central training workshops on OpenELIS. When asked about what internal implementation leads said about OpenELIS that could have influenced implementation, the participants at high-sustainment laboratories recalled that their implementation leads shared positive comments about OpenELIS, especially at the time of adoption. However, these comments seemed to be absent at low-sustainment laboratories where the participants did not recall any comment from their implementation leads about OpenELIS.

Reflecting and evaluating

Regardless of the extent of sustainment, no site conducted regular internal reflections or assessments of the software or implementation process. Three participants at high-sustainment sites received ad hoc feedback reports from PEPFAR implementing partners through supervision visits and internal actors such as laboratory staff and doctors, whereas only one participant at a low-sustainment site received an ad hoc evaluation from the PEPFAR implementing partner.

> An evaluation carried out by the implementing partner to verify the conformity between data entered into OpenELIS and data on paper. The comparison turned out to be fair. (low-sustainment site 3)

4.5 Discussion

Sustainment of routine OpenELIS use varied widely across the 27 sampled clinical laboratories in Côte d'Ivoire, ranging from the highest-sustainment site recording routine testing results in OpenELIS during 99.3% of the implementation period to the lowest-sustainment site with 9.0%. Regardless of sustainment, OpenELIS implementation facilitators shared by all sites included positive comments from external leaders or partners, advantages over paper registries, and accessibility of knowledge. Shared barriers included low adaptability, ICT infrastructure issues, and printing costs. Compared with high-sustainment sites, low-sustainment sites experienced barriers in lower motivation, capability, perceived complexity of the software, staffing challenges, and less reflection and feedback.

To our knowledge, this is the first study to examine the sustainment of LIS implementation in routine settings and apply the CFIR, an implementation science framework, to identify implementation determinants. Implementation of comprehensive laboratory information systems (LIS) at a national level is uncommon in LMICs. Our rapid literature review identified six countries, including Ethiopia,[16] Malawi,[20,21] Namibia,[15] South Africa,[13] Peru,[17–19,76,79] and Vietnam,[14] that have implemented various LIS at a national or subnational scale. Among these, the LIS in South Africa stood out as the only system capable of recording data on all laboratory testing services across all clinical laboratories in the country,[13] but there is no published research on implementation determinants. The LIS in Ethiopia,[16] the one in Malawi,[20,21] and the one in Peru were pilot projects at fewer than 15 clinical laboratories;[17] there is no published evidence on how sustained the LIS implementation has been since the pilots ended.

Our study contributes to the evidence by quantifying the sustainment of LIS implementation in routine settings beyond the pilot or initial intensive period of implementation; determining implementation facilitators and barriers shared by all sites; and identifying implementation determinants that distinguish high- and low-sustainment sites. The findings provide critical information for policy makers, investors, implementers, and researchers in LIS when considering software and real-world factors that affect LIS adoption, sustainability, and other implementation outcomes.

3.5.1 Convergent implementation determinants

All participants perceived OpenELIS as originating from the MOH and PEPFAR partners. Although the participants did not share whether this perception facilitated or hindered adoption and implementation of OpenELIS, the influence might have been positive. Other research in low-resource settings suggests that an external source has the potential to showcase the value of the intervention and enhance the chances of future local buy-in.[104]

The extent of OpenELIS sustainment might have been even greater if there were explicit policies and laws that formally institutionalize OpenELIS use in the operational processes of clinical laboratories in Côte d'Ivoire. External policies, regulations, mandates, guidelines, or directives from the government or other external entity with legitimacy facilitate implementation directly.[105–111]

The lack of financing to support individual laboratory staff members to use OpenELIS might not have hindered implementation, and monetary incentives from outside the laboratories that might facilitate implementation in other scenarios might

not be helpful or sustainable.[112] Business planning to identify total cost of ownership and, eventually, a government budget for sustaining OpenELIS beyond PEPFAR commitments would be crucial for ensuring OpenELIS sustainability and addressing the barriers of power instability, ICT and physical infrastructure, and printing materials and equipment.[113]

The participants' strong perception of the various relative advantages of OpenELIS compared to paper registries contributed positively to adoption and implementation. For successful implementation, it is crucial that all users recognize and acknowledge the relative advantage of an innovation. The relative advantage is an essential prerequisite for adoption and implementation.[114]

The perceived high accessibility of relevant knowledge was helpful for the OpenELIS users to implement successfully.[114,115] The central training workshops transmitted digestible information the super users and allowed them to practice while following the live demonstration, helping them become committed to the software.[112,114,116–118] The laboratory-level on-the-job coaching from the super users to fellow staff also facilitated implementation.[114]

Positive remarks about OpenELIS from external high-level leaders and implementation facilitators were helpful. In this study we defined high-level leaders as regional or district health directors from the MOH and implementation facilitators as program staff from I-TECH and other PEPFAR implementing partners. Exhibits of active interest from high-level leaders strengthen the implementation climate which contributes to greater implementation effectiveness.[116,117,119] Implementation facilitators are individuals with subject matter expertise who can play a critical role in

supporting and guiding implementation efforts, influencing decision-making and aiding the Implementation Leads or Teams throughout the process.[120–122]

Over two-thirds of the participants shared that the staff members at their laboratories wished OpenELIS could be more flexible and expand its use case from viral load and routine testing (e.g., CD4 cell count) for HIV clients only to all laboratory tests for all patients. This need for higher adaptability demonstrated that the users recognized the usefulness of the software beyond its original scope and were willing to incorporate this tool into routine workflow completely. The software developers in Côte d'Ivoire and the U.S. have in fact learned of these evolving needs over the past 13 years of OpenELIS implementation, and the scope of the software has evolved from just HIV-related testing to testing of hematology, biochemistry, molecular biology, serology, microbiology, pathology, and immunohistochemistry for all patients as of 2023.[75] While the software still has a core that users cannot change, incorporating user-centered design principles, adapting testing modules to the users' needs, and allowing more flexible configurations by users would improve the fit between the software and the implementation setting and positively influence implementation.[83,123–126]

The barriers that all laboratories experienced were in local conditions of unstable power supply, underperforming infrastructure, and insufficient printing materials and equipment, which is a common phenomenon in LMICs.[100,127] The use of OpenELIS relies on the outer setting to provide stable electricity to sustain normal use of the computers and servers. Power fluctuation damages servers and other electronics which are required for OpenELIS and thus important for successful implementation.[128] Inconvenient layout or configuration of space could hinder functional performance of

the laboratory.[115,129] Provision of necessary materials and equipment is positively linked with implementation.[108,115,129,130] Therefore, working with the MOH to ensure a functioning enabling environment in and outside clinical laboratories would support sustainment of OpenELIS us and benefit all laboratories.[127]

3.5.2 Implementation barriers for low-sustainment sites

The co-occurrence of higher complexity, worse design, and lower capability was high among participants at low-sustainment sites, but capability might be the more underlying determinant among the three. OpenELIS might need to be simplified, since simple innovations tend to be more successful as they enhance user satisfaction and help users gain capability of using the innovations,[114,117,123] The software design might also need to be improved to fix all bugs, since low design quality and reliability impacts satisfaction and use negatively.[116,117] However, participants at high-sustainment sites who used the same version of the software for almost the same amount of time did not find OpenELIS complex or experience numerous bugs and reported high capability. Therefore, the more targeted strategy might be providing more refresher training and on-the-job coaching to low-sustainment sites to increase their capability which would contribute to higher quality and sustainability of implementation.[115,129] This is particularly important for the low-sustainment sites with staff members who lacked basic computer knowledge, since existing knowledge or familiarity with the innovation helps build capability.[131]

Issues in work infrastructure and perceptions of incompatibility were also highly correlated in our findings about the low-sustainment sites. Inadequate staff or high

turnover at the low-sustainment sites might be the precursor to incompatibility, since deficiencies in work infrastructure made it challenging to allocate data entry tasks and incorporate them into existing workflows.[111] Higher likelihood of implementation success is associated with stable teams where there is low turnover and members remain in the team for a sufficient duration.[132] Once the team is stable, the tangible fit between the software and existing workflows would be improved, driving sustained outcomes.[83,114,133–135] Working with the MOH to conduct staffing needs assessments and develop budgeted staffing plans that the MOH owns might address work infrastructure issues and facilitate routine OpenELIS implementation.

Lower motivation and more stress and distrust at low-sustainment sites might have impacted how committed individual staff members were to using OpenELIS.[115,129] Opinions from internal implementation leads may have contributed to lower motivation, since we observed high co-occurrence of low motivation and lack of encouraging comments about OpenELIS from internal leads at low-sustainment sites. While positive opinions shared by internal leads and peers about the innovation could create enthusiasm,[136] negative opinions could generate resistance.[137,138]

Internal implementation leads of OpenELIS not only influenced the motivation and attitudes of others towards OpenELIS,[114] but may also have facilitated or hindered the implementation directly through their project management, critical thinking, and leadership style.[139,140] According to the study participants, most of the implementation leads were formally appointed, but team members who volunteer to lead may be more successful than those who received a top-down assignment.[139] A potential strategy during future scale-up of OpenELIS could be to identify and equip internal leads who are

committed to supporting, promoting, and driving the implementation forward, overcoming any indifference or resistance that may arise within the laboratory towards OpenELIS.[82,141] For sites that already have implementation leads, engaging the leads more might be useful for understanding and addressing their needs and concerns.

The lack of effective reflecting and evaluating at low-sustainment sites about OpenELIS implementation, even its issues or failures, at low-sustainment sites did not facilitate shared learning and improvements.[117,132] To foster a learning climate around OpenELIS implementation, I-TECH and the MOH could collaborate to increase the frequency of support visits to low-sustainment sites to facilitate internal audits and provide timely feedback.[82,115] Providing feedback on progress is an important behavior change strategy in various theories and models of individual behavior change,[142,143] also facilitating organizational-level changes.[114]

Since we did not sample the study participants based on representativeness, the generalizability of specific findings to other clinical laboratories in Côte d'Ivoire and other LMICs requires additional research for confirmation. However, the methods of assessing software sustainment quantitatively and using interviews and the CFIR to identify implementation determinants and explain high- versus low-sustainment may be useful for studying implementation of health informatics in other LMICs.

Limitations

The interviews were conducted by I-TECH staff who also facilitated the OpenELIS implementation at these sites, which may reduce the reporting of barriers or issues in implementation due to social desirability bias. However, we also observed unreserved

expressions of negative emotions and constructive suggestions from some participants. This reflected that some participants had a familiar working relationship with the interviewers because they collaborated on laboratory strengthening projects for multiple years. Other limitations may be due to poor recall or misunderstanding of the questions. These limitations were partially mitigated by providing necessary prompts and explanations of the interview questions and triangulating interview responses with the quantitative analysis.

4.6 Conclusion

This study provides novel insights into the sustained, routine use of OpenELIS, a laboratory information system, in clinical laboratories in Côte d'Ivoire. We observed varied sustainment rates among sampled laboratories, highlighting shared facilitators such as advantages of OpenELIS compared to paper registries, and barriers including adaptability challenges and infrastructure issues. Our research contributes to the field by quantifying the long-term implementation of comprehensive laboratory information systems beyond pilot phases, identifying determinants for successful implementation, and shedding light on factors that distinguish high- from low-sustainment sites. These findings offer crucial guidance for creating appropriate implementation strategies for further supporting implementation facilitators and overcoming implementation barriers.

4.7 Tables and Figures

Table 1. The constructs of interest from the Consolidated Framework for Implementation Research (CFIR), mapped between the 2009 and 2022 versions, and example questions from the interview guide used in the qualitative data collection at 27 clinical laboratories in Côte d'Ivoire in 2021

2009 CFIR constructs	2022 CFIR constructs	Example questions from the interview guide
1. Intervention characteristics Intervention source Relative advantage Adaptability Complexity Design quality	**1. Innovation** Innovation source Innovation relative advantage Innovation adaptability Innovation complexity Innovation design	• Why is OpenELIS being installed and used in your lab? How was the decision made to start using OpenELIS? • What advantages and disadvantages does OpenELIS have compared to other data tools in your laboratory?
2. Outer setting External policies and incentives	**2. Outer setting** Policies and laws Financing ***Local conditions******	• Were there financial or other incentives that influenced the decision to use OpenELIS? If so, what were they?
3. Inner setting Structural characteristics Implementation climate - Compatibility Readiness of implementation - Available resources* - Access to knowledge and information	**3. Inner setting** Structural characteristics - ***Physical infrastructure*** - ***Information technology infrastructure*** - ***Work infrastructure*** Compatibility Available resources - ***Materials and equipment**** Access to knowledge and information	• How do you think the infrastructure/characteristics of your lab (level in the health system, number of years in operation, number of staff, size, or physical layout) affects the use of OpenELIS? • How well has OpenELIS fit within existing work processes and practices in your lab?
4. Characteristics of individuals Knowledge and beliefs about OpenELIS Self-efficacy	**4. Individuals** ***Motivation*** ***Capability***	• How did you feel about the OpenELIS implementation in your lab? Any enthusiasm or stress?
5. Process Engaging - Opinion leaders - Formally appointed internal implementation leaders - Champions - External change agents	***High-level leaders*** ***Implementation facilitators*** ***Implementation leads***	• Who are the key influential individuals to get on board with implementing OpenELIS?
Reflecting and evaluating	**5. Implementation process** Reflecting and evaluating	• How have you assessed progress towards implementation goals?

Note: Text in italics and bold indicates new constructs in the 2022 version of the CFIR[36]
* These constructs were not selected *a priori* for data collection and emerged during thematic analysis.

Table 2. Characteristics, routine OpenELIS implementation scores, and interview characteristics of the 27 clinical laboratories in Côte d'Ivoire in 2021

	Overall	High sustainment	Medium sustainment	Low sustainment
Number (%) of laboratories	27 (100.0)	5 (18.5)	17 (63.0)	5 (18.5)
Number (%) of referral laboratories				
Yes	8 (29.6)	2 (40.0)	5 (29.4)	1 (20.0)
No	19 (70.4)	3 (60.0)	12 (70.6)	4 (80.0)
Number (%) of laboratories at different health system levels				
Regional	11 (40.7)	2 (40.0)	6 (35.3)	3 (60.0)
District	16 (59.3)	3 (60.0)	11 (64.7)	2 (40.0)
Median (IQR) number of days [months] of OpenELIS implementation = *A*	1,068 (354) [35]	1,067 (334) [35]	1,170 (503) [38]	1,068 (237) [35]
Median (IQR) number of days [months] during the implementation period with results recorded in OpenELIS = *B*	511 (576) [17]	1,031 (331) [34]	511 (368) [17]	254 (152) [8]
Routine score in percentage = $\frac{B}{A} \times 100\%$				
Median (IQR)	52.3 (33.1)	98.1 (10.8)	52.3 (16.9)	26.2 (5.5)
Mean	54.5	94.1	51.7	24.5
Interview characteristics				
Number (%) of female participants	4 (14.8)	1 (20.0)	2 (11.8)	1 (20.0)
Number (%) of participants who were laboratory heads or deputy heads	13 (48.1)	5 (100.0)	6 (35.3)	2 (40.0)
Mean recording length (mm:ss)	29:01	23:57	28:45	34:01

IQR: interquartile range
mm: minutes; ss: seconds

Table 3. Convergence and divergence on the constructs from the Consolidated Framework for Implementation Research (CFIR) as implementation determinants based on interviews with representatives at 27 clinical laboratories in Côte d'Ivoire in 2021

2022 CFIR constructs	**Convergence**			**Divergence in perceptions of a construct as a facilitator or barrier**[a]	
	Neither a facilitator nor a barrier	Facilitator	Barrier	High-sustainment sites	Low-sustainment sites
I. Innovation					
Innovation source	✓				
Innovation relative advantage		✓			
Innovation adaptability			✓		
Innovation complexity				↑↑↑↑↓	↑↑↓↓↓
Innovation design				↑↑↑↑ –	– – ↓↓↓
II. Outer setting					
Policies and laws	✓				
Financing	✓				
Local conditions			✓		
III. Inner setting					
Physical infrastructure			✓		
IT infrastructure			✓		
Work infrastructure				– – – – –	– ↓↓↓↓
Compatibility				↑↑↑↑↓	– ↓↓↓↓
Materials and equipment			✓		
Access to knowledge and information		✓			
IV. Individuals					
Motivation				↑↑↑↑↓	↑↑↓↓ –
Capability				↑↑↑↑↑	– – ↓↓↓
High-level leaders		✓			
Implementation facilitators		✓			
Implementation leads				↑↑↑ – –	– – – – –
V. Implementation process					
Reflecting and evaluating				↑↑↑ – –	↑↓↓↓↓

IT: information technology

[a] For constructs which the high- and low-sustainment sites diverge on, the arrow or dash icons represent the perception of each site. Blue upward arrows denote facilitators; red downward arrows denote barriers;

and black dashes denote that a site did not comment whether a given construct was a facilitator or barrier.

Table 4. Comparisons and supporting quotations for the constructs that had high distinguishment between high- and low-sustainment laboratories

	Summary	Quote
INNOVATION		
Innovation complexity		
High-sustainment site participants found OpenELIS easy to learn and use, while low-sustainment site participants perceived it as more complex and required additional time and training, partly due to the need to acquire basic computer skills.		
High-sustainment laboratories	Little time was spent on learning OpenELIS; it was easy to use.	*The operation is simple. The number of steps involved in using OpenELIS is reasonable. All technicians use and master the OpenELIS software.* (high-sustainment site 2)
Low-sustainment laboratories	Slightly higher complexity with the learning process and use; some participants shared that lack of basic computer knowledge might be a barrier.	*A little difficult and long [to learn] because it requires a minimum [knowledge] of basic informatics.* (low-sustainment site 4)
Innovation design		
High-sustainment site participants were generally satisfied with the design quality of the OpenELIS software, whereas low-sustainment site participants complained more about software bugs and malfunctions. All sites have been using the same versions of the software.		
High-sustainment laboratories	Mostly satisfied with the design of OpenELIS, except for its low adaptability.	*The software development and technical work done on OpenELIS is good. It's a software that makes it easier for us.* (high-sustainment site 1)
Low-sustainment laboratories	Perceived more bugs and malfunctions in the software.	*We found some bugs. For example, we have results parameters that are in panels where they should not be. Sometimes when you click to generate the lab code, it does not come automatically, and once you click again, several codes are generated at the same time.* (low-sustainment site 3)
INNER SETTING		
Work infrastructure and compatibility		
More participants at low-sustainment sites expressed concerns over staffing challenges that affect data entry, namely lack of personnel, difficulty with assigning existing personnel to data entry, and high staff turnover.		
High-sustainment laboratories	Lack of personnel was rarely reported; when it was, the laboratory seems to have overcome the challenges with high motivation.	*OpenELIS has integrated well because it has become a key element for all laboratory examinations. No complications, OpenELIS did not conflict with our existing process.* (high-sustainment site 3)
Low-sustainment laboratories	Lack of personnel and difficulty adding data entry to any existing staff member's responsibilities and workload.	*There was no one to take care of data entry because we did not have enough staff, and everyone had a role already to accomplish.* (low-sustainment site 2)

	High staff turnover makes training new staff on OpenELIS challenging.	*I (the lab manager) was trained [here] on site, and it is because I wanted to learn, otherwise I did not receive training... All those who have been trained have practically left, and those who are here have not had any retraining, we are practically all new. It'd be better if there were more training and coaching from time to time so that the elders can recall and the new ones to retrain.* (low-sustainment site 5)
INDIVIDUALS		
Motivation		
Participants at high-sustainment sites showed enthusiasm and motivation towards using OpenELIS, while participants at low-sustainment sites expressed lower motivation, more stress, and distrust.		
High-sustainment laboratories	Generally motivated and enthusiastic to use OpenELIS due to its advantages, except for instances of power or server issues.	*It improved the reporting management and data quality. We usually have enthusiasm, [but] sometimes stressed during power outage problems.* (high-sustainment site 3)
Low-sustainment laboratories	Lower motivation, more stress, and distrust towards OpenELIS	*There is still the "whip" to put behind people because you have to be there to know who uses OpenELIS and motion people to use OpenELIS.* (low-sustainment site 5) *There is just distrust at the level of some laboratory staff members due to the fact that [OpenELIS] is a new tool and method of work.* (low-sustainment site 1)
Capability		
Participants at high-sustainment laboratories were confident in using and coaching others on OpenELIS, whereas low-sustainment site participants lacked confidence.		
High-sustainment laboratories	High confidence in their capability to use OpenELIS and teach someone new to start using OpenELIS quickly.	*OpenELIS is part of our routine. It's an integral part of laboratory information management. We have good command of computer tools.* (high-sustainment site 3)
Low-sustainment laboratories	Self-perceived low capability of using OpenELIS and need for help.	*Sometimes there are certain difficulties, for example […] there are still certain parameters that we cannot fully identify or determine. It was difficult so I have one of my brothers to show me how to use it.* (low-sustainment site 5)
Implementation leads		
High-sustainment participants remembered positive comments from their implementation leads about OpenELIS, while low-sustainment participants did not recall any specific messages from their implementation leads.		
High-sustainment laboratories	After returning from the central training, implementation leads shared positive comments about OpenELIS and expressed support, positively influencing the attitudes of laboratory staff.	*We are very receptive to the use of OpenELIS. After the training, I (the laboratory head) had an internal meeting in the lab. The decision [to use OpenELIS] was made unanimously by all the laboratory staff.* (high-sustainment site 1)
Low-sustainment laboratories	The participants did not recall any comments from implementation leads about OpenELIS. In a few cases, leads felt they did not have sufficient authority.	*I was appointed by [the hospital] management. […] I don't have much authority because it depends a lot on the management.* (low-sustainment site 13)

IMPLEMENTATION PROCESS		
Reflecting and evaluating		
High-sustainment laboratories received ad hoc feedback reports from HIV program implementing partners and internal stakeholders, while low-sustainment sites lacked feedback or reflection about the software or implementation process.		
High-sustainment laboratories	Participants at some high-sustainment sites received ad hoc feedback through verbal communication from laboratory colleagues, physicians, implementing partners.	*We have received verbal comments from lab staff. They were useful for improving OpenELIS. We communicated the comments to I-TECH to make the improvements.* (high-sustainment site 5)
Low-sustainment laboratories	No participants reported that they had received ad hoc verbal feedback from laboratory colleagues.	*No, no report received from my colleagues so far, no feedback from the implementing partner.* (low-sustainment site 1)

Supplementary Table 1. OpenELIS implementation duration, routine use score, and characteristics of the interviews at the sampled 27 clinical laboratories in Côte d'Ivoire

Laboratory Identifier	Referral laboratory	Level in the health system	OpenELIS implementation timeline			Routine use score = B/A*100%	Interviews		
			Year of adoption	A = Number of days of implementation period[a]	B = Number of days during the implementation period[a] with results recorded		Participant gender	Participant job position in the laboratory	Recording length (mm:ss)
High-sustainment site 1	Yes	Regional	2018	1067	1060	99.3	Female	Head	21:54
High-sustainment site 2	Yes	District	2017	1228	1211	98.6	Male	Head	N/A[b]
High-sustainment site 3	No	District	2019	528	518	98.1	Male	Deputy head	27:57
High-sustainment site 4	No	Regional	2017	1174	1031	87.8	Male	Head	19:16
High-sustainment site 5	No	District	2018	840	729	86.8	Male	Head	26:40
Medium-sustainment site 1	Yes	Regional	2015	1862	1380	74.1	Male	Major	39:55
Medium-sustainment site 2	No	District	2019	532	391	73.5	Male	Head	48:06
Medium-sustainment site 3	No	Regional	2018	828	511	61.7	Female	Other staff	16:13
Medium-sustainment site 4	No	District	2017	1172	719	61.3	Male	Major	26:20
Medium-sustainment site 5	Yes	Regional	2015	1913	1130	59.1	Male	Other staff	25:15
Medium-sustainment site 6	No	District	2017	1170	682	58.3	Male	Head	22:39
Medium-sustainment site 7	No	District	2018	834	481	57.7	Male	Other staff	30:07

Medium-sustainment site 8	Yes	Regional	2015	2108	1166	55.3	Male	Deputy head	29:44
Medium-sustainment site 9	No	District	2017	1172	613	52.3	Male	Other staff	N/A[b]
Medium-sustainment site 10	Yes	Regional	2014	2523	1318	52.2	Female	Head	36:06
Medium-sustainment site 11	No	Regional	2017	1194	594	49.7	Male	Major	28:29
Medium-sustainment site 12	No	District	2019	531	227	42.7	Male	Major	24:55
Medium-sustainment site 13	No	District	2018	833	351	42.1	Male	Other staff	30:28
Medium-sustainment site 14	No	District	2018	835	309	37.0	Male	Head	20:02
Medium-sustainment site 15	No	Regional	2019	529	185	35.0	Male	Major	27:35
Medium-sustainment site 16	Yes	District	2017	1331	452	34.0	Male	Deputy head	33:04
Medium-sustainment site 17	No	District	2019	526	171	32.5	Male	Other staff	20:58
Low-sustainment site 1	Yes	Regional	2018	1068	340	31.8	Male	Other staff	28:17
Low-sustainment site 2	No	District	2018	834	254	30.5	Male	Head	41:04
Low-sustainment site 3	No	District	2017	1144	300	26.2	Male	Other staff	47:32
Low-sustainment site 4	No	Regional	2019	592	148	25.0	Male	Major	30:13
Low-sustainment site 5	No	Regional	2018	1071	96	9.0	Female	Head	22:59

[a] Implementation period is from when a laboratory first started using OpenELIS for recording routine test results until December 31, 2020.
[b] Recording lengths were not available (N/A) at two sites because the interview participants consented to the interviews but refused to be recorded.
Major: usually the third highest ranking staff member after the head and deputy head in a clinical laboratory in Côte d'Ivoire

Chapter 5. Perceptions and experiences of data-driven decision-making and data dashboard for HIV viral load testing and early infant diagnosis in Côte d'Ivoire

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5.1 Abstract

Background: Data dashboards are popular tools for supporting routine monitoring and decision-making in public health. Per the request from the Côte d'Ivoire Ministry of Health (MOH) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), a data dashboard has been developed since 2017 for monitoring performance of HIV viral load (VL) testing and early infant diagnosis (EID). This study assessed the values, attitudes, and experiences regarding data-driven decision-making and the VL and EID dashboard among existing and potential dashboard users in Côte d'Ivoire.

Methods: We conducted a qualitative study including two focus group discussions (FGDs) and 12 in-depth interviews (IDIs) with 22 unique existing and potential users of the VL and EID dashboard. The Conceptual Framework for the Use of Health Data in Decision Making guided the FGDs, and the Consolidated Framework for Implementation Research informed the IDIs. We used deductive and inductive approaches to code and analyze the interview data.

Results: The 22 unique participants were from 17 organizations; 10 (45.5%) were female. The study found that data-driven decision-making was valued by participants and that leaders exhibited concrete behaviors of using data. The VL and EID data

dashboard were considered useful tools for monitoring performances and making decisions for HIV service delivery and HIV-related laboratory operations. Existing users used the dashboard regularly, while potential users expressed interest in their speed and ability to track progress. The participants considered the dashboard simple and straightforward compared to other analytical tools. Participants suggested improving the dashboard by updating data more frequently, adding additional useful information, and enhancing the interface design.

Discussion: The study highlighted the importance of a supportive data culture, especially among leaders, and the potential of dashboards to promote data use. However, challenges such as data quality and equipment limitations for potential users need to be addressed.

5.2 Background

Progress around HIV/AIDS prevention and treatment has stagnated around the world,[144] and the fight against the HIV epidemic needs to be reinvigorated to achieve the 95-95-95 goals set by the Joint United Nations Programme on HIV/AIDS (UNAIDS).[72] HIV viral load (VL) suppression and early infant diagnosis (EID) are important health and service delivery outcomes to monitor for ensuring timely and effective treatment, preventing transmissions, and assessing prevention of mother-to-child transmission (PMTCT). In Côte d'Ivoire, 62% of people living with HIV (PLHIV) were estimated to have suppressed viral load, 53% of HIV-exposed children were estimated to have been tested for HIV by two months of age in 2022, and prompt improvements are necessary.[145] The national online data dashboard for VL and EID in Côte d'Ivoire intended to provide

relevant, up-to-date information that supports decision-making in HIV-related services and programs.

Using data and evidence strengthens the decision-making capacity of country leadership and contributes to successful HIV responses ultimately.[146] Timely, high-quality data are critical to guide decision-making in public health, e.g., setting priorities, planning and budgeting, allocating and utilizing health resources effectively, and implementing and enhancing service delivery and policymaking to increase healthcare utilization and improve health outcomes.[38,147]

Understanding the context, culture, and behavior around data demand and use is important to ensure effectiveness of interventions or tools that aim to support data-driven decision-making, especially in low- and middle-income countries (LMICs). According to a 2023 literature review, the main barriers to data-driven decision-making in LMICs include insufficient data use competencies; low data quality; inadequate data availability; lack of systems design and user-centered design; disconnect between data producers and users; unsupportive leaders of data-driven decision-making; absence of organizational supports; misalignment in data needs between donors and local stakeholders; weak data use culture; and low individual motivation.[38] Evidence is limited on whether and how these barriers influence data-driven decision-making in HIV responses in Côte d’Ivoire, and such evidence will provide useful context for understanding the successes and issues with the VL and EID dashboard.

The Conceptual Framework for the Use of Health Data in Decision Making,[38] building on the literature review mentioned above and the Performance of Routine Information System Management (PRISM) framework,[39] highlights key factors that

most directly influence data demand and use. We will use this conceptual framework to assess the values, attitudes, and experiences of using data in decision-making among the existing and potential users of the VL and EID data dashboard in Côte d'Ivoire.

Data dashboards are tools designed to support data-driven decision-making by visualizing quantitative data and supplying audit and feedback to decision makers and service providers.[82,148] Applications of data dashboards are ubiquitous in public health, and the purposes range from disease surveillance,[149–151] monitoring of quality and efficiency,[152–156] clinical decision support,[157–160] to stock management and more.[161,162] Articles that describe dashboards that display HIV-related data including VL and PMTCT are also not uncommon.[163–169]

To respond to the need for a tool that consolidates and presents VL data in an accessible format, the International Teaching and Education Center for Health (I-TECH) collaborated in October 2017 with the Côte d'Ivoire MOH, PEPFAR, the United States Centers for Disease Control and Prevention (CDC, the United States Agency for International Development, Clinton Health Access Initiative, and the Kenyan MOH to develop the VL online data dashboard (https://chargevirale.openelisci.org/vl_dashboard/).[59,170] I-TECH obtained the software source code for the Kenyan VL dashboard (https://viralload.nascop.org/) and adapted it for the Ivorian context to visualize monthly aggregate VL data from OpenELIS, the electronic laboratory information system in Côte d'Ivoire.[75,171]

The use case is to provide analyzed, critical information for monitoring program performance and progress towards achieving the goals for viral load testing and suppression and EID. The target users are the U.S. CDC, and the PEPFAR implementing

partners, policymakers at different levels of the MOH in Côte d'Ivoire, and clinical and laboratory service providers.

Data visualizations of the VL dashboard include stacked bar chart of the national average turnaround time of tests by sample type (i.e., dry blood spot [DBS] or EDTA/plasma); stacked bar chart of the number of test samples by sample type; pie chart of the number of clients by viral load (undetectable, <1,000 copies/ml, >=1,000 copies/ml, invalid result); stacked bar chart of the number of clients by viral load suppression (suppressed, unsuppressed) and the following disaggregation: gender (female, male), age group in years (<2, 2-9, 10-14, 15-19, 20-24, >25), and region. All but the charts on the national average turnaround time can be disaggregated by specification of month, region, district, health facility or clinical laboratory, PEPFAR implementing partners. Users can access the disaggregated visualizations through the navigation tabs at the top of the data dashboard webpage. A dedicated tab shows charts about viral suppression by gender (female, male, no data), age group (infants [<10 years], adolescents [10-19 years], adults [>20 years], no data), reason for the test request, and treatment regimen. All data visualizations are globally accessible and available for download as four different formats of image files, and the source datasets are available for download as comma separated values files and Microsoft Excel files. A data dashboard user guide document is available for download through a navigation tab. In 2020 the EID dashboard (https://chargevirale.openelisci.org/eid_dashboard/fr/) was created based on the VL one to display monthly aggregate EID data from OpenELIS.[172] The types of visualizations and functions are similar to those described above for the VL dashboard. More details about the development process, information

visualized, and types of visualizations of the VL and EID dashboard were described elsewhere.[59]

Despite the proliferation of data dashboards in public health, studies that assessed data needs and user experience of dashboard users are limited. After reviewing 1,191 papers, the authors of a systematic review on public health dashboards identified only 18 user studies, while most of the remaining papers reviewed were only about the design and technical development process of a specific dashboard.[32] Only a few of the 18 user studies considered data demands and self-efficacy in dashboard user experiences,[32] highlighting a notable gap in research that other reviews already identified previously.[33,34]

This study aimed to fill the research gaps described above by answering the following questions:

1) What were the values, attitudes, and experiences of existing and potential dashboard users on data-driven decision-making in their organizations?
2) What were the participants' impressions of the VL and EID data dashboard?

5.3 Methods

We conducted a qualitative study including two focus group discussions (FGDs) to answer the first research question and 12 semi-structured in-depth interviews (IDIs) to answer the second research question (Table 1). The FGDs intended to gather general perspectives which the group members converged or diverged on about data-driven decision-making and the VL and EID data dashboard. The IDIs intended to draw detailed responses about data-driven decision-making and the dashboard from individual

participants based on the perspectives of themselves and their organizations. Data collection took place from September 2021 to April 2022 through in-person or online meetings.

The study population was existing and potential users of the VL and EID dashboard. Existing users were staff members of the MOH, the U.S. Centers for Disease Control and Prevention (CDC) office in Côte d’Ivoire, PEPFAR implementing partners, and national and regional clinical laboratories. Potential users were from MOH divisions and clinical laboratories which the I-TECH project team and existing users thought would find the dashboard useful but had not used them.

To collect data from existing users, we purposefully sampled individuals who we knew were already using the dashboard to participate in the first FGD and subsequent IDIs. Nine participants from six organizations participated in FGD1, including two from the U.S. CDC and seven from the PEPFAR implementing partners (e.g., clinical program manager or strategic information director) in Côte d'Ivoire. We then used snowball sampling to ask FGD1 participants to introduce us to other existing users from additional organizations to participate in the IDIs. Seven existing users from national and regional referral laboratories as well as PEPFAR implementing partners participated in the IDIs (Supplementary Table 1).

To collect data from potential users through the second FGD (FGD2) and IDIs, we purposefully sampled a staff member of the Programme National de Lutte contre le Sida (PNLS; National AIDS Control Program) who had not used the dashboard and had a convenience sample of five individuals who had not used the dashboard and were heads or deputy heads of the regional clinical laboratories in Côte d’Ivoire. We

purposefully chose PNLS because, as the national technical group created by the MOH to guide the national response to fight the HIV epidemic, PNLS knew of the dashboard but did not routinely use them. Regional laboratories might also be interested in the dashboard because they are referral sites that process all VL and EID samples referred from other laboratories in the region. Five potential users participated in FGD2, and five different potential users participated in the IDIs (Supplementary Table 1).

The Conceptual Framework for the Use of Health Data in Decision Making informed the interview guides for the two FGDs,[38,40] and the relevant CFIR constructs informed the interview guides for the IDIs (Table 1).[35,36] The Conceptual Framework for the Use of Health Data in Decision Making builds on the Performance of Routine Information System Management (PRISM) framework created by the MEASURE Evaluation group.[38–40] This conceptual framework highlights key activities that most directly influence data demand and use and subsequently influence the building blocks in the health system and ultimately health outcomes. We chose to focus on the activities that would influence data demand and use to see if and how they were reflected in the participants' responses. The CFIR is a meta-theoretical framework designed to explain how innovations such as the data dashboard work across different contexts.[35,36]

The interview guides were initially developed in English by YH and later translated into French. PHA and YRK, native French speakers, reviewed and edited the French interview guides for grammar, word choice, and logical coherence. The FGDs and IDIs were conducted online in French using Zoom by YRK, PHA, and YH. The sessions were

recorded, and comprehensive notes were taken. On average, the FGDs lasted 59 minutes, while the IDIs lasted 32 minutes. No additional sessions were held.

After each session, YRK, PHA, and YH uploaded photos or electronic copies of informed consent forms that were signed by the participants, detailed notes, and audio recordings to a shared drive on the University of Washington Google Drive with restricted access. The recordings were transcribed verbatim in French and translated by YH, PHA, and YRK into English. The detailed notes were added to the transcripts to supply additional details.

YH conducted the analysis described below. YH was female and a Chinese Doctor of Philosophy student in global health implementation science at a university in the United States, with three years of experience in qualitative research and five years of experience working with health information systems in Côte d'Ivoire.

A combination of deductive (namely using the two conceptual frameworks mentioned above) and inductive approaches were used to analyze the data. Codes were created using the activities that influence data demand and use from the Conceptual Framework for the Use of Health Data in Decision Making, the CFIR constructs, as well as derived from the data that the two frameworks did not pertain to. YH was the primary coder of the transcripts. YH first chose one FGD transcript and one IDI transcript to code with the initial codebook that consisted of the deductive codes. After adding inductive codes to the codebook, YH revised the coding in the first three transcripts and continued coding the rest of the transcripts. Any subsequent changes in the codebook or coding approach were applied to transcripts that had been coded previously. The coding and thematic analysis were conducted in ATLAS.ti 8 Windows.

After finishing the coding process, we summarized the themes that correspond to the research questions and selected corresponding quotes when the participants' own words conveyed the information more effectively than a summary. The two frameworks served as the basis for the themes, with additional themes derived from the data that did not fit the components or constructs of the two frameworks. We mapped the 2009 CFIR constructs that we chose *a priori* for qualitative data collection and analysis to the corresponding 2022 CFIR constructs (Table 1),[36] and presented the results and discussion with the 2022 constructs.

This study was determined to be non-human subjects research by the University of Washington Institutional Review Board and has been approved by Côte d'Ivoire Comité National d'Ethique des Sciences de la Vie et de la Santé (CNESVS, Ivorian Institutional Review Board; reference number 006-21/MSHP/CNESVS-km). The U.S. CDC reviewed the paper but had no role in study design, data collection, analysis, and interpretation.

5.4 Results

We conducted one FGD (FGD1) with nine existing users from six different organizations; a second FGD (FGD2) with five potential users from five organizations; seven IDIs with existing users from six organizations; and five IDIs with potential users from four organizations (Table 2). The number of unique participants was 22; 10 (45.5%) were female; 17 unique organizations were represented. The FGD1 participants were two CDC officers in clinical and laboratory programs and PEPFAR implementing partner staff in clinical programs and strategic information. The FGD2 participants were

one CDC officer in EID and prevention of mother-to-child transmission programs and heads and deputy heads of national and regional referral laboratories. The IDIs with existing and potential users included one staff member of PNLS, two PEPFAR implementing partner staff, and nine heads and deputy heads of national and regional referral laboratories (Supplementary Table 1).

4.4.1 Data-driven decision-making

Data use context

According to all the participants in the FGDs and IDIs, their organizations used data in decision-making. The participants of both FGDs converged on the importance of data-driven decision-making. Not only would the leaders use data in decision-making, but different units and levels within each organization also used data in their work, even if some units or levels were not seen as decision makers. Data were used routinely to monitor performances as well as ad hoc under special circumstances to assess the situation, identify problems or needs, and make decisions to solve problems or make improvements. The most common areas where the participants used data to monitor were laboratory operational processes (e.g., non-conformity of samples, sample flows, turnaround time) and lost-to-follow-up clients for HIV viral load testing.

> Data is our essence, we use the data [in our decision-making process]. There's technical data, validation data, operational data; so everyone at their level uses their data, and we centralize everything as a technique to know the number of samples has arrived, what is out, what is the reason for the delay, and after the operational data we share not only for our decision-making but at the same time we share with the [MOH], the partner, the PNLS. (IDI with existing user 3)
>
> When we took the decision regarding the contingency plan in relation to the COVID-19 crisis, we looked a little in terms of the data on stock availability.

> Starting from the quantification of the needs, it was on the basis of factual data that we took decisions. (IDI with potential user 1)

<u>Data use context: attitude of leaders and staff members towards using data</u>

When asked specifically about the attitude of the leaders versus staff members towards using data in decision-making, all IDI participants shared that the leaders in their organizations were supportive and exhibited concrete behaviors of using data in decision-making.

> Our leader is very committed to using data for improvement and decision-making in the lab because we are an accredited lab, so we value data-driven decision-making at the highest quality. (IDI with existing user 4)
>
> The leadership monitor the performance of technicians by analyzing data on the lab process, suggest changes to improve the performance; the same with monitoring the equipment. We discuss data analyses at meetings to find solutions. (IDI with potential user 5)

In fact, the whole team of staff members, not just the leaders shared the same attitude and data use behavior.

> Everyone is absolutely interested and motivated to use data. I think that at this lab there are 2 levels of interest. The first level is for biologists, data managers, and managerial staff, for top management use, data for the programming is very important, for the follow-up of the patient. Now those who are at the technical level are more interested in data management to see the activity and the flow of samples so that there are not too many samples waiting. (IDI with existing user 2)
>
> The whole team, not just the leaders, uses data to inform their decisions. Because even outside the monthly meeting [with the hospital management], there is a small group that also meets to be able to see what difficulties we are having especially with patients, and we try to discuss. (IDI with potential user 4)

Data use context: external pressure

The participants from PEPFAR implementing partners and the Retro-CI laboratory established and directly funded by the U.S. CDC shared that how they used data in decision-making was heavily influenced by PEPFAR and the MOH. The rest of the participants from the other laboratories shared that their data use behavior was only influenced by external donors and partners in the areas that external funding supported, e.g., HIV viral load testing, donated equipment. An existing user stated:

> No, external donors and other organizations don't really influence how we use data in decision-making. […] Our center here is supported by PEPFAR via [an implementing partner], to which we report the data every month, but it's really not them who influence our activity. We also have standards internally in terms of turnaround times, all that, but it generally falls within their objectives as well. (IDI with existing user 2)

Data demand and use infrastructure, data users and data producers

The FGD with existing users revealed convergence among PEPFAR implementing partners in demands for data, data use infrastructure, and internal processes that engaged data users and producers (Tables 3, 4). PEPFAR implementing partners, not directly providing services, used both laboratory and clinical data to monitor laboratory operational processes and progress of HIV program implementation. Laboratory data were from OpenELIS and clinical data were exported from the electronic health record for HIV clients into Microsoft Excel spreadsheets. These organizations had data management units that compiled and validated the data collected from the clinical laboratories in the implementing districts. The programmatic units then received the processed data and conducted data analyses to monitor or evaluate progress

achievements and shortfalls. The analyses informed leaders in deciding how their organizations could support the clinical laboratories to address areas of improvement.

While three referral laboratories used data to inform laboratory operations as well as participate in clinical decision-making, four other laboratories used data only for laboratory operations (Tables 3, 4). Three participants from two national referral laboratories and one regional referral laboratory shared that they not only used operational data from OpenELIS to monitor non-conformities and improve sample flows and result validation, but they also actively contributed to clinical decision-making by examining data on testing results and whether a client was on time for a test. The participants from the rest of the referral laboratories were only interested in laboratory operational data and viewed themselves as suppliers of data to the clinicians for making decisions ("It's the clinician who prescribes, we give him his result so it's a chain of which we play a part in." – IDI with existing user 1).

Data quality

When asked how data quality issues affect how often they used data for decision-making, the participants shared that data timeliness had a more direct impact on the frequency of data use. All existing users that participated in the first FGD shared that they had internal processes to ensure data quality. Four participants from the second FGD with potential users shared that, since they had technical validations, the data quality should be fine. However, one participant disagreed that, despite the processes and units that intended to ensure data quality, there were still missing data or poorly documented data on paper forms that decreased data quality.

4.4.2 VL and EID data dashboard

We present the summaries for two non-CFIR constructs that emerged from the FGD and IDIs with existing users, namely the frequency and reasons for using the dashboard. We then present the summaries for the CFIR constructs and finally a non-CFIR construct on suggestions for improving the dashboard.

Frequency of using the dashboard

Three existing users shared that they used the dashboard monthly; two said quarterly; and one said every six months because they were most interested in stock shortages, but they said that the dashboard was not up to date on stock. One existing user said they did not use the dashboard in a systematic way because the dashboard was not updated as frequently as they preferred.

Reason for using the dashboard

The general impression that the existing users had on the dashboard was that they were good tools to consult themselves and show to others about performance, useful for identifying and raising awareness of problems and deciding on solutions.

> The dashboard has the advantage of presenting us with the results collected on the sites, so it is an element that is very present in our daily lives, and allows us to have the reality of the results available for our area to be able to make decisions and solve certain problems. It is a very effective element that allows all parties to agree. (IDI with existing user 5)

Two existing users reported that they used the dashboard as important references to communicate with other laboratories that they worked with. An existing user from a national referral laboratory felt excited and relieved that the dashboard was

available because they provided direct evidence of laboratory performances, and there was no need to guess how the performances had been:

> I will say excitement and relief [about the dashboard], because when we visit the sites inside the country, we don't have to talk too much, we go to the dashboard and show them what they are doing in the laboratory, they are happy to see the work they are doing, the dashboard is a relief. [IDI existing user 4])

An existing user at a PEPFAR implementing partner agency was interested in the performances of other similar organizations which the dashboard showed so that they could cross compare.

> The dashboard shows us the work that is done on laboratories that we don't have access to, for example on other partners' laboratories. They show us how the activity takes place throughout the national territory, what the volume of activities is at other laboratories. So we can see how we can boost our platforms to work more. (IDI with existing user 6)

This person also mentioned that they trusted the quality of the data presented in the dashboard because they knew the data had been processed and checked. They felt comfortable and motivated to use this quality information in decision-making ("I tell myself that this information has been processed, it is quality information, this is what led me to use." – IDI with existing user 6)

After examining the dashboard briefly during the FGD and IDIs, potential users shared the reasons that would motivate them to use the dashboard were serving as a model to other peers, accessing information quickly for decision-making, and monitoring progress towards targets.

A potential user at a regional referral laboratory shared their motivation and enthusiasm for using the dashboard stemmed from the potential for being a model that others would want to copy:

> The dashboard will be useful not only to ourselves and to other units. We can show the dashboard to the hospital director and even the heads of units so that the people outside the laboratory can copy us and seek to get in touch with us to see how we have achieved this. We can be a model. I think I know an innovation." (IDI with potential user 5)

A potential user mentioned in the FGD that they were interested in using the dashboard because of the speed of accessing information and making decisions subsequently ("When we want to see our performance and see if there are any problems, we will look and very quickly we know where it gets stuck and what quick decision to take." – FGD potential user 5).

Two potential users thought that the dashboard would be helpful in tracking progress towards meeting quality standards or achieving targets set by the national directives. ("[The dashboard] is useful for the work, in terms of the implementation of the national directive for the biological monitoring of PLHIV, it is true that the directives have been drawn up, but it is also good to know that we have feedback from the implementation of the guidelines." – IDI with potential user 1).

<u>Capacity – facilitator</u>

All existing users were confident that they themselves and the colleagues who used the dashboard routinely in work were capable of using the dashboard.

Innovation source – facilitator

Two existing users shared that the need for the VL and EID data dashboard was common across the PEPFAR implementing partners and the U.S. CDC, so the dashboard in Kenya were adapted for Côte d'Ivoire.

Innovation relative advantage – facilitator

The existing and potential users shared that the relative advantages of the dashboard compared to other data analysis and visualization tools such as Microsoft Excel or Microsoft Power BI were simplicity and straightforwardness. Compared to static data spreadsheets, the visualizations on the dashboard showed a lot more information in an interactive way.

In terms of simplicity and straightforwardness, three existing users perceived the dashboard as useful for data visualization and supporting decision-making and problem solving for specific laboratories or areas. The participants explained that, since the configurations and structures of the interface were predefined, accessing specific information was faster and easier for people who monitor performances routinely. One potential user at a regional referral laboratory thought that, compared to Excel which could also visualize data, the dashboard was faster and more straightforward, and it was also a direct way to convey information to others who wanted to learn about the VL and EID activities of the laboratory or the region.

One potential user and one existing user found it useful to have an interactive tool that can quickly provide information that they were interested in, e.g., meaningful disaggregation by population groups, whereas Excel spreadsheets were static.

> It's a little livelier, we have the possibility of being able to search for the information we want with a simple click, for example on the desired period, the desired laboratory, and then we have all the information that appears at the same time for a given laboratory. It is an advantage over having a static Excel file which will give us in a tab the number of viral load tests. We instead have a graphic visual [in the dashboard], it is good to have a graph, a diagram allows us to have an idea at the same time of what we are looking for, we do not need to go and redo the calculations again to be able to assess the information, I think that is the advantage that the Excel file does not have. (IDI with potential user 1)

Although one existing user perceived Excel and Power BI as more versatile in analyzing data exported from OpenELIS, she acknowledged that the dashboard was "accessible" (IDI with existing user 4). Sometimes if she "had not finished analyzing [data exported from OpenELIS], [she] will take the information from the dashboard," indicating that the dashboard provided faster access to analyzed information that was useful for decision-making.

Innovation design – facilitator

The FGD participants converged within each group that the design of the dashboard was fine, the colors were beautiful and distinct, and the layout was clear and easily readable.

Market pressure – facilitator

The existing users converged during the first FGD that they were aware of other organizations, especially PEPFAR implementing partners, that were using the dashboard. In the subsequent IDI an existing user shared that "generally all the partners

in Côte d'Ivoire use the dashboard, I exchange with colleagues in other organizations, and everyone refers to the dashboard" (IDI with existing user 5).

All but one potential user did not know of any organization that used the dashboard. The only participant who had prior knowledge came from PNLS which oversees all HIV-related activities in the country:

> I know organizations such as PEPFAR implementing partners and Retro-CI practically use the dashboard, and even providers are supposed to be used because they were told about it during the demand optimization sessions for viral load testing. (IDI with potential user 1)

Materials and equipment – potential barrier

Three existing users shared that, although they were able to use the dashboard without difficulty, they were concerned that new users might need Internet connection and computers or tablets to access these online dashboard.

Access to knowledge and information – potential barrier

Both existing and potential users would like to have more information and training or coaching on using the dashboard ("Perhaps if there are resources [that provide more information], it will allow us to optimize the use of dashboard and therefore decision-making at the level of our organization." – IDI with existing user 6). One existing user thought that training or coaching would be useful for new users to orient themselves around the layout and functions of the dashboard ("As we have already used the dashboard, it is easy for us. But for people who are discovering this for the first time, they may be impressed, but the use will be difficult, they need explanations and coaching." – IDI with existing user 4).

Suggestions for improving the data dashboard

The suggestions for improving the data dashboard were in three categories, namely updating the data more frequently, adding more useful information, and improving the interface design to improve user friendliness.

The most mentioned suggestion was updating the data displayed in the dashboard more frequently. Four existing users and three potential users suggested updating at least every other week and the more near real-time the better. One potential user cautioned the others during the FGD about having an ideal world with near real-time data updates, since there was a natural trade-off between the speed of posting data and the necessary biological and technical validations in the laboratory operational process. Therefore, weekly updates might be the most ideal scenario that the dashboard could realistically achieve (FGD potential user 5).

The participants also suggested various information to add to the dashboard so they can meet the needs of the organizations better. Three existing users and two potential users would like to have more indicators about the laboratory operational process and service quality, e.g., the volume of samples received, number of non-compliant samples, number of rejected samples, testing validity, and number of tests completed within deadlines. Information on when and why major disruptions in laboratory services happened was highly requested by all but two existing users to display next to the charts and provide context to changes in the trends. One existing user from a PEPFAR implementing partner would like the VL dashboard to disaggregate data by key populations to support programs for sex workers, men who have sex with

men, etc. The potential user from PNLS would like the dashboard to extend to all laboratory testing related to people living with HIV rather than just VL and EID.

A reason why a potential user would like to see more information displayed was that they preferred using a comprehensive platform to consulting many different tools and databases ("If we have too many tools, it will be complicated to use them. Apart from the dashboard we have other databases and data visualizations. If [the dashboard] is a tool that is detailed, it's better than having several tools." – FGD potential user 1).

Two existing users suggested during the FGD that the dashboard should display individual level data to enable more precise and timelier follow-up with individual clients. A third existing user dissented that this publicly accessible platform would not be the appropriate place to display any individual level data due to potential privacy and confidentiality issues.

The most common suggestion regarding the design of the dashboard was to tailor the information shown more specifically to what a user chose to see. Four existing users shared that, after choosing a specific time period, some charts on the dashboard did not seem to change in response to the time period selection, leading to confusion. The users suggested making all charts change according to the user's specification.

5.5 Discussion

This study explored the values, attitudes, and experiences related to data-driven decision-making and the usage of HIV VL testing and EID data dashboard among existing and potential dashboard users in Côte d'Ivoire. We found that the participants valued data-driven decision-making and perceived utility of the VL and EID dashboard in

monitoring performances and informing decisions. Future iterations of the dashboard can benefit from the suggestions from the participants.

The findings contributed to the literature by providing a better understanding of the values and attitudes towards data-driven decision-making among HIV programmatic staff and service providers in Côte d'Ivoire, specifically in data use context, data demand and use infrastructure, data users and producers, and data quality.

The participants not only recognized the importance of data but also reported concrete behaviors of using data in decision-making. The recognition and behaviors were shared by both leaders and other staff members in an organization. This data culture, especially among leadership, seemed to be more supportive than some LMIC settings reported in other studies.[173,174] However, the study sample was biased towards valuing data, since more than half of the participants were existing dashboard users and had monitoring and evaluation as one of their key job functions.

As the supportive data culture would promote data use, the dashboard displaying data across all clinical laboratories in Côte d'Ivoire that processed VL and EID samples would further promote a data use culture, creating a virtuous cycle. MOH supervisors can use the dashboard to provide regular feedback and comparative results to health facilities and laboratories, showcasing how the submitted data were used and enhancing the value of data collection and use.[175–177]

The participants at clinical laboratories shared that they submitted data to PEPFAR implementing partners monthly in addition to the routine data collection and use process. This indicates parallel data systems due to donors' data demands which may have been burdensome and led service providers to view themselves only as data

producers.[38,178] Having access to useful tool such as the VL and EID dashboard that visualize the data that the laboratories submitted might motivate them to assume the role of data users.[179]

All participants reported that their organizations had processes to validate data or ensure data quality, which seemed to give them confidence in the quality of the data they collected, reported, and used. However, as one study participant and various existing evidence suggested, quality issues were not rare in data reported from frontline health facilities, since health workers often lacked time and motivation to ensure data quality.[173] Therefore, more targeted research is necessary to assess data quality, users' confidence in the quality, and actual data use behaviors.

The findings about how the study participants viewed the data dashboard conformed with what other studies reported, but the multilevel explorations of user perceptions informed by the CFIR were an addition to the evidence. The reasons for existing and potential users to the VL and EID dashboard align with those identified through a systematic review about public health data dashboards.[32] The strongest advantages of the dashboard relative to other data visualization tools were higher user-friendliness, which the study participants defined as simplicity and straightforwardness, and faster speed of accessing digested information. Ease of use was one of the most assessed dashboard characteristics.[32] Indeed, simple innovations have a higher likelihood of effectiveness, due to their ability to enhance user satisfaction and shorten the learning curve.[114,117,123] For data dashboards that intend to simplify the data synthesis and analysis process for users, low complexity is an important determinant to effectiveness. Most participants mentioned that they were satisfied with the colors in

the dashboard, which corresponds to the findings from other dashboard user studies.[32,180]

The market pressure from peer organizations may have motivated existing users to use the dashboard, and it would be interesting to explore if the same would apply when some potential users start using the dashboard while others do not. Late adopters often face significant pressure to implement innovations, especially when competitors or colleagues have already adopted them; when others in the field are using an innovation, individuals and organizations may feel compelled to follow suit.[181] However, if potential users of the dashboard do not see other users as competition,[114] mobilization strategies that exert market pressure might not be effective.

Although the existing dashboard users reported that they had the necessary materials and equipment as well as knowledge and capability to use the dashboard with ease, concerns were raised for potential users. The existing users, all based in Abidjan or other urban areas, were concerned that potential users in other regions of the country might not have the necessary equipment or Internet connection to access the online dashboard and that they might need training to learn to use the dashboard. It is important to ensure the precondition of necessary equipment is met for achieving the outcome of increased user pool in the future.[182] Providing training or a support hotline might also be useful strategies to engage potential users.[183]

Furthermore, participants offered valuable feedback for improving the dashboard. They emphasized the need for more frequent data updates, echoing what another dashboard user study found.[184] Additionally, participants suggested incorporating more indicators related to laboratory operational processes and service

quality to further improve the dashboard and support the data demands for decision-making.

Limitations

The FGDs and IDIs were carried out by I-TECH personnel who were involved in the development and implementation process of the data dashboard, potentially leading to social desirability bias in reporting barriers or issues. However, since we explained to the participants that the study was formative rather than evaluative, the social desirability bias might not have manifested to a great extent. Other limitations include potential difficulties in recall or misunderstanding of the questions. To partially address these limitations, we provided necessary prompts and explanations of the interview questions.

Future research could explore data demands and dashboard user experiences in other LMICs with the Conceptual Framework for the Use of Health Data in Decision Making and the CFIR to compare with our findings and identify cross-contextual patterns.

5.6 Conclusion

This study demonstrated that decision makers and program staff in Côte d'Ivoire's fight against HIV valued data-driven decision-making. They recognized the utility of the HIV viral load and EID data dashboard in monitoring performance and guiding decisions. The findings offered insights into data demand and use culture and

infrastructure in the HIV work in Côte d'Ivoire. These insights contribute to the broader understanding of effective data use and dashboard design.

5.7 Tables and Figures

Table 1. The *a priori* components of interest from the conceptual framework for the use of health data in decision-making and the Consolidated Framework for Implementation Research (CFIR)

Data collection method	Conceptual framework for the use of health data in decision-making	2019 CFIR constructs	2022 CFIR constructs
FGD1: existing dashboard users **FGD2:** potential dashboard users	• Data use context • Data demand and use infrastructure	None.	None.

IDIs with individual existing or potential dashboard users	• Data use context
	• Data demand and use infrastructure
	• Data users and data producers
	• Data quality
		• Intervention characteristics
		  ○ Relative advantage
		  ○ Adaptability
		  ○ Design quality and packaging
		• Outer setting
		  ○ Peer pressure
		  ○ External policy and incentives
		• Individual characteristics
		  ○ Self-efficacy
			• Innovation
			  ○ Relative advantage
			  ○ Adaptability
			  ○ Design
			• Inner setting
			  ○ Access to knowledge and information
			• Outer setting
			  ○ External pressure – market pressure
			  ○ Policies and laws
			  ○ Financing
			• Individuals
			  ○ Capability

FGD, focus group discussion; IDI, in-depth interview.

Table 2. Characteristics of the study participants who were existing or potential users of the HIV viral load and early infant diagnosis data dashboard in Côte d'Ivoire in 2021-2022.

	Overall	FGD1 with existing users	FGD2 with potential users	IDIs with existing users	IDIs with potential users
Number of unique participants	22	9	5	5	3
Number of participant-times from each type of organization	26	9	5	7	5
U.S. CDC	3	2	1	0	0
PEPFAR IP	9	7	0	2	0
PNLS	1	0	0	0	1
National referral laboratory	6	0	1	4	1
Regional referral laboratory	7	0	3	1	3
Number of organizations represented[a]	17	6	5	6	5
Number of female participant-times	10 (45.5%)	3 (33.3%)	2 (40.0%)	2 (28.6%)	4 (80.0%)
Mean recording length in minutes	36	70	48	36	26

FGD, focus group discussion; IDI, in-depth interview; U.S. CDC, United States Centers for Disease Control and Prevention; PEPFAR, United States President's Emergency Plan for AIDS Relief; IP, implementing partner; PNLS, Programme National de Lutte contre le Sida (National AIDS Control Program)
[a] Two participants of the IDIs with existing users and two of the IDIs with potential users already participated in the FGDs. Therefore, the number of unique organizations represented was 17.

Table 3. Data demanded, uses of data demanded, and data use infrastructure at two types of organizations where most participants of this study worked in Côte d'Ivoire in 2021-2022.

	CDC, PEPFAR implementing partners	**Referral laboratories**
Data demanded	• Lab data on VL, EID • Clinical data on active client case • Pharmacy data on filled prescriptions	• Data on lab operational process
Understand or address what with data	• Identify districts or labs with performance issues • Track lost-to-follow-up clients for VL testing or treatment • Identify clients with unsuppressed VL	• Bottlenecks in sample flow • Non-conforming samples • Turnaround time • Workload
Create what strategies with data	• Follow-up with specific districts, labs, or clients	• Improve workflow • Follow-up with satellite labs about non-conforming samples
Data use infrastructure	• OpenELIS • Clinical records (electronic health records for HIV clients; Excel spreadsheets)	• OpenELIS

PEPFAR: U.S. President's Emergency Plan for AIDS Relief; VL: viral load; EID: early infant diagnosis

Table 4. Details about the data demand, data use infrastructure, and internal data processes involving data users and producers at different organizations of participants of this study in Côte d’Ivoire in 2021-2022.

<table>
<tr><th></th><th>Data demand</th><th>Data use infrastructure</th><th>Internal data process involving data users and data producers</th></tr>
<tr><td colspan="4">PEPFAR implementing partners used both laboratory and clinical data to monitor program implementation and identify areas of improvement.</td></tr>
<tr><td>FGD1 existing users 3, 4, 8, 9</td><td>• Active client cases
• Viral load data for appointment reminder and scheduling, tracking loss-to-follow-up, identifying clients with unsuppressed viral load</td><td>• OpenELIS
• Clinical records of HIV clients in electronic format (e.g., online database, Excel spreadsheet)
• VL and EID data dashboard</td><td>1. IT unit and evaluation unit validate and consolidate the data from implementing sites, and supply the data to programmatic units.
2. Programmatic units produce analyses in three areas: 1) laboratory operational process (e.g., non-conformities, stocks, logistics); 2) program level M&E (e.g., for general population, key populations); 3) information for service providers to make clinical decisions.
3. Analyses are submitted to organization leaders for decision-making and assigning tasks to various units.</td></tr>
<tr><td colspan="4">Some referral laboratories used data to inform laboratory operations and contribute to clinical decision-making.</td></tr>
<tr><td>IDI existing user 2 (national referral laboratory 3)</td><td rowspan="3">• Laboratory operational data for monitoring sample flows, non-conformities, result validation, turnaround time
• Data on testing result and behavior (on-time or delayed testing)</td><td rowspan="3">• OpenELIS
• VL and EID data dashboard for the existing users</td><td>1. Technical staff were responsible for data entry and management; more interested in laboratory operational data.
2. The biologists and people in laboratory management were downstream in the data process; more interested in data that guide patient follow-up and inform clinical decision-making</td></tr>
<tr><td>IDI existing user 4 (national referral laboratory 4)</td><td>Request other referral laboratories to supply data, analyze data, determine areas and strategies of improvement.</td></tr>
<tr><td>IDI potential user 4 (regional referral laboratory 1)</td><td>1. Technicians do technical validation; the biologist or laboratory head do biological validation. Share results with clinicians.
2. Clinical departments including this laboratory supply the data (not just on VL and EID); the data manager and team for the whole hospital compile the data and make presentations based on the data for the monthly hospital-wide meetings; the department representatives discuss and make decisions based on the presentations. The laboratory and HIV-related services use the 90-90-90 targets as benchmarks.</td></tr>
<tr><td colspan="4">Other referral laboratories used data only to inform laboratory operations.</td></tr>
<tr><td>IDI existing user 1 (national referral laboratory 2)</td><td>• Laboratory operational data for monitoring sample flows, non-</td><td>• OpenELIS</td><td>Enter data into OpenELIS, review quality of raw data, supply validated data to clinicians to make clinical decisions.
“It's the clinician who prescribes, we give him his result so it's a chain of which we play a part in.”</td></tr>
</table>

IDI potential user 2 (national referral laboratory 5)	conformities, result validation, turnaround time		Export data from OpenELIS, analyze, and use analysis in decision-making about improving the laboratory operational process.
IDI potential user 3 (regional referral laboratory 5)			Consult the database, assess the laboratory operational process, and identify tasks to prioritize.
IDI potential user 5 (regional referral laboratory 2)			The laboratory head and deputy head could make decisions on their own or also discuss with technicians who would propose plans based on data analysis.

OpenELIS, open enterprise-level laboratory information system; VL, viral load; EID, early infant diagnosis

Supplementary Table 1. Characteristics of the study participants and their organizations in Côte d'Ivoire

Participant Identifier	Organization	Role	Gender	Recording length (minutes)
FGD1 with existing VL and EID data dashboard users				
Participant 1	CDC	Officer, clinical programs	Female	70
Participant 2	CDC	Officer, laboratory branch	Male	
Participant 3	PEPFAR IP 1	Staff, strategic information	Male	
Participant 4	PEPFAR IP 2	Lead, clinical programs	Female	
Participant 5	PEPFAR IP 2	Staff, strategic information	Male	
Participant 6	PEPFAR IP 2	Staff, clinical programs	Male	
Participant 7	PEPFAR IP 3	Lead, clinical programs	Female	
Participant 8	PEPFAR IP 4	Staff, strategic information	Male	
Participant 9	PEPFAR IP 5	Staff, strategic information	Male	
FGD2 with potential data dashboard users				
Participant 1	CDC	Officer, EID and PMTCT programs	Female	48
Participant 2	Regional referral laboratory 1	Head	Female	
Participant 3	Regional referral laboratory 2	Head	Male	
Participant 4	Regional referral laboratory 3	Deputy head	Male	
Participant 5	National referral laboratory 1	Deputy head	Male	
IDIs with existing users				
Participant 1	National referral laboratory 2	Deputy head	Female	44
Participant 2	National referral laboratory 3	Head	Male	26
Participant 3	National referral laboratory 3	Deputy head	Male	36
Participant 4	National referral laboratory 4	Deputy head	Female	55
Participant 5	PEPFAR IP 1	Staff, strategic information	Male	34
Participant 6	PEPFAR IP 4	Lead, clinical programs	Male	50
Participant 7	Regional referral laboratory 4	Head	Male	8
IDIs with potential users				
Participant 1	PNLS	Staff	Female	44
Participant 2	National referral laboratory 5	Head	Female	20
Participant 3	Regional referral laboratory 5	Deputy head	Female	28
Participant 4	Regional referral laboratory 1	Head	Female	23
Participant 5	Regional referral laboratory 2	Deputy head	Male	15

FGD: focus group discussion
VL: viral load
EID: early infant diagnosis
CDC: United States Centers for Disease Control and Prevention
PEPFAR: United States President's Emergency Plan for AIDS Relief
IP: implementing partner
IDI: in-depth interview
PMTCT: prevention of mother to child transmission
PNLS: Programme National de Lutte contre le Sida (National AIDS Control Program)

Chapter 6. Conclusion

This dissertation contributes to the literature by applying implementation science methods to understanding the implementation effectiveness and determinants of digital health strategies such as electronic laboratory information systems and data dashboards.

Aim 1 quantifies the immediate and sustained impact of an electronic laboratory information system (OpenELIS) on data quality in clinical laboratories in Côte d'Ivoire. The implementation of OpenELIS led to a remarkable five-fold increase in data timeliness and a 3.6-fold increase in data completeness, which remained close to 100% throughout the study period. Notably, data validity was consistently high both before and after OpenELIS adoption. The study contributes valuable evidence on the effectiveness of a scaled, multi-site laboratory information system in sub-Saharan Africa, offering critical information for policymakers and digital health implementers and researchers in LMICs. By filling this research gap, the findings underscore the potential impact of laboratory information digitalization in LMICs to improve data quality, clinical care, patient safety, and disease surveillance.

Aim 2 examines the sustainment of OpenELIS in routine settings in Côte d'Ivoire. Sustainment varied across 27 clinical laboratories, with some sites achieving high routine use while others struggled. The study identified shared facilitators (positive feedback from external leaders, advantages over paper registries, accessibility of knowledge) and barriers (low adaptability, ICT infrastructure issues, printing costs). Low-sustainment sites faced additional challenges, including lower motivation, capability, staff turnover, and lack of reflection and evaluation. This is the first study to

use the CFIR to identify determinants of LIS implementation. The findings provide valuable insights for policymakers, implementers, and researchers to improve LIS adoption and sustainability in LMICs, addressing key factors affecting implementation outcomes.

Aim 3 explores the values, attitudes, and experiences related to data-driven decision-making and the usage of data dashboard for HIV VL testing and EID in Côte d'Ivoire. The participants valued data-driven decision-making and found the dashboard useful for monitoring performances and informing decisions. The study provided insights into potential barriers to data-driven decision-making, including parallel data systems due to donor demands, concerns about data quality, and the need for more frequent data updates. Existing users appreciated the user-friendliness of the dashboard but also raised concerns for potential users about the lack of necessary equipment and training supporting dashboard use. The findings contribute to the understanding of data culture, data use, and the potential impact of data dashboards in Côte d’Ivoire, offering valuable suggestions for improving the dashboard to meet user needs.

Future research could explore a few different directions. Studies on the association between LIS implementation and clinical service delivery outcomes or health outcomes would be great contributions to the evidence base. Designing and testing strategies that amplify implementation facilitators and overcome barriers would be useful. More targeted research would be necessary to assess the relationship among data quality, data users’ confidence in data quality, and actual data use behaviors.

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