

Determinants of scaled implementation for electronic laboratory information systems in 27 clinical laboratories in Côte d'Ivoire: A mixed-methods study applying the Consolidated Framework for Implementation Research (CFIR)

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Abstract

Background

Electronic laboratory information systems (LIS) are critical for promoting data quality and improving laboratory performance, but sustained implementation following system deployment in resource-limited settings can be challenging. The OpenELIS project in Côte d'Ivoire seeks to promote routine use of the OpenELIS software at 108 clinical laboratories. This study assessed the sustainment of OpenELIS routine use at laboratories, identified implementation facilitators and barriers, and explained how high-sustainment laboratories differed 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 in 2021. We collected and analyzed de-identified routine testing data from OpenELIS servers to describe the sustained use of OpenELIS 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 determinants and to summarize differences between laboratories of high-, medium-, and low-sustainment. We used deductive and inductive approaches to code the interview data and conduct thematic analysis.

Results

OpenELIS was used during 9.0–99.3% of calendar days, and high-sustainment sites performed more routine tests. Common facilitators of sustainment included receiving positive comments about OpenELIS from external high-level leaders and partners; appreciating advantages of OpenELIS; and perceiving high accessibility of knowledge and information. Common barriers included low adaptability, power outages, server failure, space limitations, and printing costs. Participants of low-sustainment laboratories reported lower motivation and capability in using OpenELIS, perceived more complexity and lower software design quality, 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.

Conclusions

Ensuring infrastructure stability may benefit all laboratories. Refresher training, increased frequency of support visits, and staffing plans may help low-sustainment laboratories to increase their routine LIS use. Further research that tests implementation strategies may be beneficial for addressing the barriers and extend the facilitators to other settings.

1. 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. (1, 2) LIS are recommended by the World Health Organization and the International Organization for Standardization to digitize the typical paper-based records systems in low- and middle-income countries (LMICs) and improve service delivery and clinical outcomes.(3–5) Routine use of LIS can help remove obstacles to ensuring quality laboratory services, patient safety, and disease surveillance.(2, 6–9)

Sustained LIS use at clinical laboratories, defined as the continued use of LIS within routine practice is a determinant for sustaining the improvements in laboratory data quality and clinical decision-making.(10) Implementing LIS in diverse practice settings can be challenging, and sustaining them in real-world, resource-limited contexts is even more difficult. (11) While there is evidence on how use of electronic medical records could become routine in hospitals,(12, 13) little evidence exists on determinants of sustained implementation of LIS in clinical laboratories. This evidence is crucial for informing LIS sustainment beyond piloting or initial deployment, and this study aims to supply such evidence.

We reviewed multiple models and frameworks for determinants of LIS and health information systems (HIS) implementation.(14–23) To guide our inquiry, we selected the Consolidated Framework for Implementation Research (CFIR) which offers a holistic lens. The CFIR is a meta-theoretical framework that considers a comprehensive list of implementation determinants including the ones mentioned above.(24, 25) The CFIR is designed to explain how a variety of implementation strategies such as LIS work across different contexts and to identify determinants of program implementation.(24, 25) 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.(24, 25) 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.(26) The CFIR facilitates comparisons across clinical laboratories with different data quality, service capacity, and organizational and geographical characteristics. Such comparisons highlight the 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 hematology, biochemistry, molecular biology, serology, microbiology, pathology, and immunohistochemistry for all patients.(27)

In addition to OpenELIS software, the project provided necessary information and communication technology (ICT) infrastructure such as computers, local networks, and servers; annual national training workshop of super users who are laboratory personnel; maintenance services and remote support from MOH call center agents; and on-site coaching by project collaborators.

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?

2. Methods

This was a mixed-methods study with a convergent parallel design. The convergent parallel design involves simultaneous collection of complementary qualitative and quantitative data, and researchers subsequently merge and compare the data sources to build evidence and theory around the central question.(28)

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 (Fig. 1). The purposive sampling was aligned with the evaluation aims of describing OpenELIS sustainment and implementation determinants rather than estimating population parameters. Selection criteria

considered adequate representation in geography, level in the health system (regional/district, referral/non-referral laboratories), and feasibility of data collection (travel, security, timing, and site approvals). The quantitative analysis assessed the sustainment of routine OpenELIS use at clinical laboratories. The qualitative thematic analysis identified facilitators and barriers to the implementation process, based on a post-hoc extreme case sample of five high-sustainment sites and five low-sustainment sites, to distill differences between the two sustainment groups.

2.1 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. (see formula below).

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

We collected de-identified data on routine hematology testing from OpenELIS servers at the laboratories. The period of the extracted data started when a laboratory began using OpenELIS and ended on December 31, 2020. We ranked the laboratories in routine use score 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.

2.2 Qualitative data collection and analysis

We conducted one semi-structured in-depth interview (IDI) at each laboratory. We invited the person who oversaw OpenELIS implementation at each laboratory to participate in the interview. If this person was absent, we instead interviewed a staff member who used OpenELIS. The laboratories received two notices for the data collection visit, one at one week before the visit and another one day prior. During the interviews we asked a single closed question about the maturity level of OpenELIS use at each laboratory to triangulate with the quantitative assessment of OpenELIS routine use described above.

Adapting validated tools of the 2009 version of the CFIR,(29, 30) we developed most 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, implementation program, and evaluation questions (Table 1).(31) We developed the interview guide in English and then translated it to French, reviewed and revised the French interview guide based on a pilot at two laboratories. We incorporated the feedback into the interview guide based on the pilot to remove repetition and clarify confusing terms in French.

Table 1
CFIR constructs of interest and example questions from the interview guide used in data collection

2009 CFIR constructs	2022 CFIR constructs	Example questions from the interview guide
1. Intervention characteristics	1. Innovation	• Why is OpenELIS being installed and used in your lab? How was the decision made to start using OpenELIS?
Intervention source	Innovation source	• What advantages and disadvantages does OpenELIS have compared to other data tools in your laboratory?
Relative advantage	Innovation relative advantage	
Adaptability	Innovation adaptability	
Complexity Design quality	Innovation complexity Innovation design	
2. Outer setting	2. Outer setting	• Were there financial or other incentives that influenced the decision to use OpenELIS? If so, what were they?
External policies and incentives	Policies and laws Financing Local conditions*	
3. Inner setting	3. Inner setting	• 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?
Structural characteristics	Structural characteristics - Physical infrastructure - Information technology infrastructure - Work infrastructure	
Implementation climate	Compatibility	
- Compatibility	Available resources	
Readiness of implementation	- Materials and equipment*	
- Available resources*	Access to knowledge and information	
- Access to knowledge and information		
4. Characteristics of individuals	4. Individuals	• How did you feel about the OpenELIS implementation in your lab? Any enthusiasm or stress? • Who are the key influential individuals to get on board with implementing OpenELIS?
Knowledge and beliefs about OpenELIS	Motivation	
Self-efficacy	Capability	
	High-level leaders	
5. Process	Implementation facilitators	
CFIR, Consolidated Framework for Implementation Research		
Note: Text in <i>italics</i> and bold indicates new constructs in the 2022 version of the CFIR(24)		

2009 CFIR constructs	2022 CFIR constructs	Example questions from the interview guide
Engaging - Opinion leaders - Formally appointed internal implementation leaders - Champions - External change agents	Implementation leads	
Reflecting and evaluating	5. Implementation process Reflecting and evaluating	• How have you assessed progress towards implementation goals?
CFIR, Consolidated Framework for Implementation Research		
Note: Text in italics and bold indicates new constructs in the 2022 version of the CFIR(24)		

* These constructs were not selected *a priori* for data collection and emerged during thematic analysis.

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. Interviews were audio-recorded, and detailed notes were taken on paper during the interviews. The average length of the IDIs was 29 minutes. The recordings were transcribed verbatim in French and translated into English. Data was 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.(32)

We applied the CFIR constructs as deductive codes and derived additional codes from the data that the CFIR constructs did not pertain to. We first chose five transcripts randomly to code with the initial codebook consisting of the CFIR codes only and to create new concept codes and valence codes to capture whether factors were facilitators or barriers. After coding the transcripts and writing memos that documented our thought processes 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 differences. We applied any changes in the codebook or coding approach to previously-coded transcripts. We conducted the coding and thematic analysis in ATLAS.ti (Windows Version 8.4.26.0).(33)

We summarized the quotes for each code and selected illustrative quotes. 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 sampled 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.(34)

Damschroder et al. updated the CFIR in 2022 after we finished the late-stage thematic analysis.(24) As we recognized the value of the updates and wanted to ensure longitudinal consistency of our results, we mapped the 2009 CFIR constructs that we chose *a priori* for our qualitative inquiry 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). All participants provided written informed consent.

3. Results

Among the 27 clinical laboratories in the sample, 8 (29.4%) were referral laboratories that were hubs that both performed the testing within their catchment areas and processed referral samples of HIV viral load testing and early infant diagnosis in the region. Sixteen laboratories (59.3%) were based in district hospitals that only treated patients within their respective health districts (Table 2). The median routine use score was 52.3% (interquartile range 33.1%). The laboratories had similar implementation durations (Table 2).

Table 2

Characteristics, routine OpenELIS use scores, and interview characteristics of the sampled laboratories in Côte d'Ivoire

Number (%) of laboratories	Overall	High sustainment	Medium sustainment	Low sustainment
	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)
Annual mean volume of routine tests	4631	12612	3188	1557
Median (IQR) number of days [months] of OpenELIS implementation = A	1068 (354) [35]	1067 (334) [35]	1170 (503) [38]	1068 (237) [35]
Median (IQR) number of days [months] during the implementation period with results recorded in OpenELIS = B	511 (576) [17]	1031 (331) [34]	511 (368) [17]	254 (152) [8]
Routine use score in percentage = $\frac{A}{B} \times 100\%$				
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				

Most interview participants were male, and half of the participants held positions of leadership at the laboratory (Table 2). The sex distribution was similar across the three sustainment groups; all five interview participants from 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 basics and needed more help.

We drew the following three themes about implementation determinants by integrating quantitative and qualitative data. The first two sections (3.1 and 3.2) illustrate the CFIR constructs which all laboratories converged on (Table 3), while the third section (3.3) 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 3.2.2.

Table 3

Convergence and divergence on the CFIR constructs as implementation determinants based on the interviews

CFIR Construct Name and Definition in the Context of This Study	Convergence ^a	Divergence in Perceiving a Construct as Facilitator or Barrier ^a	
		High-sustainment sites	Low-sustainment sites
I. INNOVATION: OpenELIS software and supporting activities such as training, coaching, and maintenance.			
A. Innovation source: The group that developed and/or visibly sponsored use of OpenELIS is reputable, credible, and/or trustable.	○		
B. Innovation relative advantage: OpenELIS is better than other available laboratory data management tools or paper registries.	☒		
C. Innovation adaptability: OpenELIS can be modified, tailored, or refined to fit local context or needs.	®		
D. Innovation complexity: OpenELIS is complicated, which is reflected by the number of steps it would take to perform tasks of data entry, retrieval, management, reporting, and analysis.		☒☒☒®	☒☒®☒
E. Innovation design: OpenELIS is well designed and packaged, including its interface, structure, and user guide.		☒☒☒ –	– – ®☒☒
II. OUTER SETTING: The space where units of the Ministry of Health function at the national, regional, and district level, as well as donors and non-governmental organizations			
A. Policies and laws: Legislation, policies, regulations, guidelines, or recommendations, or accreditation standards support implementation of OpenELIS.	○		
B. Financing: Funding from external entities (e.g., grants, reimbursement) is available to implement OpenELIS.	○		
C. Local conditions: Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation of OpenELIS.	®		
III. INNER SETTING: The setting in which OpenELIS is implemented, i.e., clinical laboratories within public hospitals, health centers, or clinics.			
A. Physical infrastructure: Layout and configuration of space and other tangible material features in the laboratories support functional performance of the Inner Setting.	®		
B. IT infrastructure: Technological systems for telecommunication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting.	®		
C. Work infrastructure: Organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting.		– – – – –	– ®☒☒☒
D. Compatibility: OpenELIS fits with workflows, systems, and processes.		☒☒☒®	– ®☒☒☒
IT: information technology			

CFIR Construct Name and Definition in the Context of This Study	Convergence ^a	Divergence in Perceiving a Construct as Facilitator or Barrier ^a	
		High-sustainment sites	Low-sustainment sites
E. Materials and equipment: Supplies are available to implement OpenELIS.	®		
F. Access to knowledge and information: Guidance and training are accessible to implement OpenELIS.	☒		
IV. INDIVIDUALS: The roles and characteristics of individuals.			
A. Motivation: The individual(s) is committed to fulfilling the role of using OpenELIS or supporting and supervising the use of OpenELIS.		☒☒☒☒®	☒☒®☒ –
B. Capability: The individual(s) has interpersonal competence, knowledge, and skills to fulfill the role of using OpenELIS or supporting and supervising the use of OpenELIS.		☒☒☒☒☒	– – ®☒☒
C. High-level leaders: Individuals with a high level of authority, including key decision-makers, executive leaders, or directors in the units of the Ministry of Health at national and subnational level.	☒		
D. Implementation facilitators: Individuals with subject matter expertise (e.g., from the main implementing partner of OpenELIS) who assist, coach, or support implementation.	☒		
E. Implementation leads: Individuals who lead efforts to implement OpenELIS.		☒☒☒ – –	– – – – –
V. IMPLEMENTATION PROCESS: The activities and strategies used to implement OpenELIS.			
A. Reflecting and evaluating: Collect and discuss quantitative and qualitative information about the success of implementation.		☒☒☒ – –	☒®☒☒☒
IT: information technology			

Table 4

Comparisons and supporting quotations for the constructs with high heterogeneity between high- and low-sustainment laboratories

Summary		Quote
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.	<i>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)</i>
Low-sustainment laboratories	Slightly higher complexity with the learning process and use; some lacked basic computer knowledge.	<i>A little difficult and long [to learn] because it requires a minimum [knowledge] of basic informatics. (low-sustainment site 4)</i>
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 malfunctions. All sites have been using the same versions of the software.		
High-sustainment laboratories	Satisfied with the design of OpenELIS, except for its low adaptability.	<i>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)</i>
Low-sustainment laboratories	Perceived more bugs and malfunctions in the software.	<i>We found some bugs. We have 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. (low-sustainment site 3)</i>
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 seemed to have overcome the challenges.	<i>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)</i>
Low-sustainment laboratories	Lack of personnel and difficulty adding data entry to existing staff's responsibilities and workload.	<i>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)</i>
	High staff turnover makes training new staff on OpenELIS challenging.	<i>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. (low-sustainment site 5)</i>
Individual 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	Motivated and enthusiastic to use OpenELIS due to its advantages, except for instances of power or server issues.	<i>It improved the reporting management and data quality. We usually have enthusiasm, [but] sometimes stressed during power outage problems. (high-sustainment site 3)</i>
Low-sustainment	Lower motivation, more stress, and distrust towards OpenELIS	<i>There is still the "whip" to put behind people because you have to be there to know who uses OpenELIS and</i>

Summary		Quote
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.		
laboratories		<i>motion people to use OpenELIS. (low-sustainment site 5)</i> <i>There is just distrust at the level of some laboratory staff members because [OpenELIS] is a new tool and method of work. (low-sustainment site 1)</i>
Individual 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.	<i>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)</i>
Low-sustainment laboratories	Self-perceived low capability of using OpenELIS and need for help.	<i>There are certain parameters that we still 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)</i>
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 national training, implementation leads shared positive comments about OpenELIS and expressed support, positively influencing the staff's attitudes.	<i>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)</i>
Low-sustainment laboratories	The participants did not recall any comments from implementation leads about OpenELIS. In a few cases, leads felt they had insufficient authority.	<i>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)</i>
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 verbal feedback from laboratory colleagues, physicians, and implementing partners.	<i>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)</i>
Low-sustainment laboratories	No participants reported that they had received ad hoc verbal feedback from anyone.	<i>No, no report received from my colleagues so far, no feedback from the implementing partner. (low-sustainment site 1)</i>

^a The arrow, circle, and dash icons represent the perception of whether a construct was a facilitator or barrier. The upward arrow in blue (↗) denotes facilitator; the downward arrow in red (↘) denotes barrier; the circle (○) denotes a perception of neither a facilitator or a barrier; and the dash (–) denotes that a site did not comment on whether a given construct was a facilitator or barrier. For constructs which the high- and low-sustainment sites diverge on, the arrow or dash icons represent the perception of each site.

3.1 Policy mandates and external incentives

Participants from all laboratories, regardless of the extent of OpenELIS routine use, perceived the MOH and PEPFAR implementing partners as the source of the OpenELIS project. 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.” – a low-sustainment site). These perceptions did not seem to have facilitated or hindered the laboratories’ decisions to adopt and continuously implement OpenELIS.

3.2 Convergence across the laboratories

3.2.1 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.

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; 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 completeness and validity

“There are certain parameters on OpenELIS which are mandatory, so if the doctors did not fill out [certain data fields on the test request form], [...] we ask the doctors to provide all the information about the patient.” (low-sustainment site 5)

On improved data validity by helping technicians check whether test results fall within the reference values and are therefore valid

“There are no reference values in the paper registries. 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 helps us with our reports and stores our results well. The papers are very cumbersome. [OpenELIS] made searching easy, and the doctors 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 who conducted cascade training and on-the-job coaching for other staff members in the laboratory (“Not everyone went to the national training, but when we came back, we shared the training with others, since the objective is that everyone uses OpenELIS.” – a medium-sustainment site). 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.” – a low-sustainment site).

The participant from a low-sustainment site shared that all current staff members at the laboratory had not participated in any training or coaching in OpenELIS due to staff turnover. 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 3.3.

3.2.2 Shared barriers

Innovation adaptability

Eighteen participants (66.7%) shared that, as OpenELIS implementation 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 non-HIV routine tests. 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.

“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.” (a medium-sustainment site)

Four participants also suggested that OpenELIS should improve the reporting function so that they can directly generate a monthly report with the 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.” – a medium-sustainment site).

Local conditions; information technology infrastructure ; physical infrastructure

A key barrier to OpenELIS implementation that all participants mentioned was unstable electricity and server network. These common issues that all laboratories experienced 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, but you see nothing has happened!” – a medium-sustainment site).

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

Materials and equipment

The participants shared that the cost of the printer, ink, and paper for printing test results produced from OpenELIS was a disadvantage of the software compared to paper registries. 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.” – a medium-sustainment site).

3.3 Compared to high-sustainment sites, low-sustainment sites experienced more implementation barriers in willingness and capability of using OpenELIS and staff shortage and turnover.

The five high- and five low-sustainment laboratories diverged on the following seven determinants: 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 constructs as barriers to routine OpenELIS implementation. Table 4 provides detailed summaries and supporting quotations for the contrasts between the two sustainment groups in each of the seven constructs.

[Table 4 is included at the end of this document]

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. The participants at two low-sustainment laboratories shared they needed more time to learn because 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 3.2.2, three participants at low-sustainment sites complained more about software malfunctions. All laboratories used the same version of OpenELIS and received the same updates. Therefore, the difference in the perception of design quality might correspond to maturity and capability of OpenELIS use.

Work infrastructure; compatibility

Four participants at the low-sustainment laboratories mentioned challenges in dedicating staff to data entry or incorporating data entry duties into the existing workflow. The challenges stemmed from a general lack of personnel so that it was difficult to add data entry to 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 participants at the high-sustainment laboratories mentioned staffing challenges, even if both groups were at similar levels in the health system and thus had similar sizes of staff (Table 2).

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." (a low-sustainment site)

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 finding 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 management or their participation in national training workshops on OpenELIS. 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.

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 doctors and laboratory staff, whereas only one participant at a low-sustainment site received an ad hoc evaluation from the PEPFAR implementing partner.

4. Discussion

OpenELIS sustainment varied widely across the 27 sampled clinical laboratories in Côte d'Ivoire. Regardless of sustainment, OpenELIS implementation facilitators shared by all sites included positive comments from external leaders or partners, advantages over paper registries, and access to knowledge about using OpenELIS. 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 to apply the CFIR, an implementation science framework, to assess determinants of sustainment. Evaluations of comprehensive LIS at a national level are uncommon in LMICs. Our rapid literature review identified six countries, including Ethiopia,(35) Malawi,(36, 37) Namibia,(38) South Africa,(39) Peru,(40–44) and Vietnam,(45) that have implemented 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,(39) but there is no published research on implementation determinants. Reports on LIS in Ethiopia,(35) in Malawi,(36, 37) and in Peru were pilot projects at fewer than 15 clinical laboratories;(41) with no published evidence on sustainment since the pilots ended. Our study addresses this gap by examining implementation determinants in a routine, post-pilot setting.

Our findings on shared implementation determinants align with broader research on digital health systems in LMICs. The perceived advantages of OpenELIS over paper registries contribute positively to adoption, which is consistent with studies showing relative advantage as a key facilitator for HIS implementation in both high- and low-income settings.(46, 47) High accessibility of knowledge through national training workshops and on-the-job coaching also facilitated implementation,(48, 49) reflecting that training and access to information are critical constructs for successful digital health adoption.(50–54) The extent of sustainment might have been even higher with explicit policies that institutionalize OpenELIS use formally in clinical laboratory operations, as external mandates from entities with legitimacy directly facilitate implementation.(55–61) Business planning to identify total cost of ownership and government budget allocation beyond PEPFAR commitments would be crucial for long-term sustainability.(62)

Over two-thirds of participants wished OpenELIS could expand beyond HIV related testing to all laboratory tests. This demand for adaptability demonstrates that users recognized the software's value and were willing to fully incorporate it into routine workflow, underscoring the importance of user-centered design principles in HIS implementation.(63, 64) While OpenELIS has evolved to include additional testing modules,(27) incorporating more flexible configurations would improve the fit between software and implementation setting.(10, 63–66) The shared barriers of unstable power, underperforming infrastructure, and insufficient printing materials reflect common challenges for digital health project implementation in

low-resource settings.(31, 53, 54, 67, 68) Working with the MOH to ensure a functioning enabling environment would support sustainment across laboratories.

For low-sustainment sites specifically, capability emerged as a more fundamental determinant than perceived complexity or design quality of OpenELIS. Participants at high-sustainment sites using the same software did not find it complex and reported high capability of using the software, suggesting that targeted refresher training and on-the-job coaching for low-sustainment sites, particularly those with staff lacking basic computer skills, may be more effective than software simplification alone.(49, 69, 70) This aligns with systematic reviews identifying training, capacity building, and ongoing support as critical for digital health program sustainability in low-resource settings.(53, 54, 68)

Staffing issues and perceived incompatibility between OpenELIS and existing workflows were highly present at low-sustainment sites. Inadequate staffing or high turnover made it challenging to allocate data entry tasks and incorporate them into workflows.(61) Higher implementation success is associated with stable teams where members remain for sufficient duration;(71) once stable, the fit between software and workflows improves, driving sustained outcomes.(10, 48, 72–74) Conducting staffing needs assessments and developing budgeted staffing plans owned by the MOH could address these work infrastructure issues. Handover manuals that departing staff can edit and share with successors may mitigate loss of OpenELIS expertise due to turnover.

Internal implementation leads influenced not only motivation and attitudes toward OpenELIS but also implementation directly through their leadership and project management.(48, 75, 76) A potential strategy during future scale-up is identifying and equipping internal leads who are committed to driving implementation forward, particularly those who volunteer rather than receive top-down assignments.(5, 75, 77) Moreover, the lack of effective reflecting and evaluating at low-sustainment sites hindered shared learning and improvement.(52, 71) Increasing the frequency of support visits to facilitate internal audits and provide timely feedback could foster a learning climate around implementation, consistent with literature on behavioral and organizational changes.(5, 48, 49, 78, 79)

Existing implementation strategies that facilitated adoption included the OpenELIS software and ICT infrastructure, super user training or training of trainers, centralized technical support, and on-site coaching for providing feedback. To address shared barriers, potential strategies include incorporating user-centered design workshops into training to improve adaptability, identifying funding from hospitals or MOH for IT infrastructure and printing costs, and conducting advocacy meetings with multiple ministries to improve electricity stability. For barriers specific to low-sustainment sites, potential strategies include providing additional training support, preparing handover manuals, adding hands-on training activities, pairing low-sustainment sites with higher-sustainment sites for knowledge exchange, identifying implementation leads, advocating for adequate staffing and integration of OpenELIS into job descriptions, facilitating meetings to discuss workflow integration and problem-solving, and building algorithms in OpenELIS to flag implementation and data quality issues.

Future research should examine whether the implementation determinants and strategies identified in this study apply to LIS implementation in other LMICs. Longitudinal studies tracking sustainment over time and evaluating the effectiveness of proposed implementation strategies would further strengthen the evidence base for HIS implementation.

Strengths and Limitations

A strength of this study is the use of a mixed methods design that triangulated quantitative sustainment data with qualitative interview data, allowing for deeper understanding of implementation determinants.

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.

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.

5. 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 LIS beyond pilot phases, identifying determinants for successful implementation, and illustrating factors that distinguish high- from low-sustainment sites. These findings underscore the importance of creating appropriate implementation strategies for further supporting implementation facilitators and overcoming implementation barriers.

Abbreviations

CDC

Centers for Disease Control and Prevention

CFIR

Consolidated Framework for Implementation Research

CNESVS

Comité National d'Ethique des Sciences de la Vie et de la Santé

HIS

Health information system

HIV

Human immunodeficiency virus

ICT

Information and communication technology

IDI

In-depth interview

IQR

Interquartile range

ISO

International Organization for Standardization

I-TECH

International Training and Education Center for Health

LIS

Laboratory information system

LMICs

Low- and middle-income countries

MOH

Ministry of Health, Public Hygiene, and Universal Health Coverage

OpenELIS
Open Enterprise Laboratory Information System
PEPFAR
United States President's Emergency Plan for AIDS Relief
PRISM
Performance of Routine Information System Management
WHO
World Health Organization

Declarations

7.1 Ethics approval and consent to participate

This study was conducted in line with the international principles for medical research as defined by the Declaration of Helsinki. The study was approved by the US CDC and was conducted consistent with applicable Ivorian and US federal law, and CDC policy. This research was determined to be non-human subjects research by the US CDC and University of Washington Institutional Review Board, 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). All participants provided written informed consent prior to participation.

7.2 Consent for publication

All authors consent to this publication.

7.4 Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author Contribution

YH, NPK, SG, NGH, BHW, and LAP conceived of the presented idea. YH, YRK, PHA, and NPK collected and curated the data and managed the project. YH analyzed the quantitative data; YH and RA coded and analyzed the qualitative data. YH and LAP wrote the main drafts of the manuscript. CAT, KJBA, NK, AP and NA, JF, CIH provided technical support for OpenELIS and data collection. All authors reviewed the manuscript, validated the results and discussion, and contributed to the final draft.

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Data Availability

The data that support the findings of this study are not openly available due to protection of privacy and confidentiality and are available from the corresponding author upon reasonable request.

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Figures



Figure 1

Health regions in Côte d'Ivoire included in the evaluation of OpenELIS implementation, 2021.