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Open-source LIMS in Vietnam: The path toward sustainability and host country ownership

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Abstract

Objective: The objectives of this case report are as follows: to describe the process of establishing a national laboratory information management system (LIMS) program for clinical and public health laboratories in Vietnam; to evaluate the outcomes and lessons learned; and to present a model for sustainability based on the program outcomes that could be applied to diverse laboratory programs.

Methods: This case report comprises a review of program documentation and records, including planning and budgetary records of the donor, monthly reports from the implementer, direct observation, and ad-hoc field reports from technical advisors and governmental agencies. Additional data on program efficacy and user acceptance were collected from routine monitoring of laboratory policies and operational practices.

Results: LIMS software was implemented at 38 hospital, public health and HIV testing laboratories in Vietnam. This LIMS was accepted by users and program managers as a useful

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Author contributions

Kyle Bond, former chief of the CDC-Vietnam laboratory branch, guided the LIMS program for six years and provided significant input into the development of the sustainability plan. Paul Jankauskas served as the CDC-Vietnam LIMS advisor for four years, facilitating the expansion of the LIMS program and working closely with Duong Thanh Tung and Nguyen Thi Hoa on the transition of costs in Ho Chi Minh City. Reshma Kakkar served as the first CDC-Vietnam LIMS Advisor and, with Michelle Meigs, supported this project from its inception with technical assistance and project management, and provided financial analysis data for the national program. Kenneth Landgraf, the current CDC-Vietnam LIMS advisor, conducted the literature review, drafted the manuscript and worked closely with colleagues at VAAC, Phan Thi Thu Huong, Nguyen Viet Nga, Nguyen Duy Thai to implement the sustainability strategies.

Competing interests

Kenneth Landgraf is a personal services contractor assigned to the U.S. Centers for Disease Control and Prevention Vietnam country office. The Association of Public Health Laboratories, Ho Chi Minh City AIDS Committee, and the VAAC-US.CDC Project are recipients of grants from CDC through the United States PEPFAR program.

tool to support laboratory processes. Implementation cost per laboratory and average duration of deployment decreased over time, and project stakeholders initiated transition of financing (from the donor to local institutions) and of system maintenance functions (from the implementer to governmental and site-level staff). Collaboration between the implementer in Vietnam and the global LIMS user community was strongly established, and knowledge was successfully transferred to staff within Vietnam.

Conclusion: Implementing open-sourced LIMS with local development and support was a feasible approach towards establishing a sustainable laboratory informatics program that met the needs of health laboratories in Vietnam. Further effort to institutionalize IT support capacity within key government agencies is ongoing.

Keywords

Laboratory; Information systems; Open source; OSS; FLOSS; Sustainability; Health; Resource-constrained; Medical informatics; Development; LIMS; LIS; PEPFAR

1. Introduction

The United States President's Emergency Plan for AIDS Relief program (PEPFAR) enabled a rapid scale-up of HIV testing and treatment in Vietnam. To effectively manage the increased volume of testing and accompanying data needs, health laboratories in Vietnam required support to strengthen data management. Laboratories services in Vietnam, and particularly testing for HIV care and treatment, are provided in a wide range of facilities (i.e. high and low throughput, automated and manual testing methods, urban and rural settings). The Government of Vietnam desired a laboratory information management system (LIMS) that was both flexible and scalable. The US Government required all PEPFAR-funded programs to have a focus on sustainability, which meant that ownership and financing of these programs would be transferred to the country government over time.

Therefore, in 2006, the U.S. Centers for Disease Control and Prevention (CDC) and the Government of Vietnam (GVN), "the stakeholders", set out to create a sustainable national open source LIMS program in Vietnam in clinical and public health laboratories.

2. Background

Health services in Vietnam fall into two parallel, tiered systems: preventive medicine—managed by the General Department of Preventive Medicine (GDPM) – and medical services – managed by the Vietnam Administration for Medical Services (VAMS). Specialized (e.g. disease-targeted) programs, often with substantial donor funding, operate alongside these systems with separate leadership and program management structures. The medical services system includes 1100 hospitals from the national, provincial/municipal and district level, with over 100 additional private hospitals. The preventive system is comprised of national research institutes, provincial or municipal preventive medicine centers, district health centers and commune health stations. The majority of laboratory services are offered at the district level or higher, with commune health stations providing simple screening tests or collecting and transporting samples for further testing [1].

Published data on the medical informatics landscape in Vietnam is limited. In 2004, two years before the start of the LIMS program, a survey showed that hospital information systems were present in many national and provincial hospitals. District hospitals, while not yet implementing HIS, often had computers and internet access. This survey did not look at systems for laboratory data management [2]. A study conducted in 2008 similarly showed that paper records remained the norm for patient records with only 5% of public hospitals using computerized systems for patient management [3]. A 2008 case study found that the biggest factors limiting adoption of health information systems were lack of qualified IT staff in the health field and lack of financial investment [4]. By 2012, computers had become widespread at district health centers, and in 2016, the Government of Vietnam set the goal that 99% of health facilities would have broadband internet access by 2020 [1,5]. A number of eHealth projects have been implemented in Vietnam, often through donor financing, to support patient management and case reporting, with varying degrees of success [6–8].

Globally, LIMS have helped laboratories meet quality standards, decrease transcription errors, reduce turnaround time from specimen receipt to reporting of results, and improve patient outcomes [9]. Although interest in establishing a LIMS program in Vietnam was motivated by a desire to support testing for HIV care and treatment, the selected LIMS application needed to support broader clinical and public health testing services and, therefore, have an appropriately scalable data model. Indeed, implementers of eHealth projects in developing settings have noted the necessity to design data models with future data needs in mind [10]. Open-source LIMS have been implemented around the world, including resource-constrained settings [11,12]. The Government of Vietnam favored the use of open source applications to reduce software procurement costs and to build information technology capacity within Vietnam [13,14].

Sustainability is essential to the viability and longevity of health interventions in resource-constrained settings, particularly those funded and implemented by international donors [15]. PEPFAR's Sustainability Agenda includes country ownership, local leadership and appropriate national policies for successful program implementation [16]. Factors linked to the sustainability of open-source projects include presence of developer and user communities, reliable release cycle, governance, modular architecture, software documentation, and professional support services [17]. Open-source projects with sponsorship and reliable financial support have demonstrated improved project success metrics [18]. As with projects in many other fields, the support of executives and the presence of "champions" within an organization have also been shown to improve the outcome of health information system (IS) projects [19]. A model for implementing open-source EMR presented by Ludwick and Doucette recommends the following strategies to mitigate risks: establishing strong leadership, using accepted project management techniques, ensuring adequate staff training, and using a standards-based approach [19]. Implementers of LIMS in resource-constrained settings have identified the importance of building expertise in-country and utilizing local resources in order to maximize impact and ensure financial viability [20].

Informed by this, the stakeholders set out to establish a sustainable, national LIMS program for health laboratories in Vietnam. Routine program monitoring sought to evaluate

the efficacy of the LIMS application and enable implementers to adjust development, deployment and management strategies in an iterative process. This report describes the process of establishing an effective national LIMS program in Vietnam and presents a proposed model for sustainability that could be applied to a wide variety of laboratory programs.

3. Research methods

Qualitative methods are particularly useful in IS research when studying a process as it develops and emerges [21]. Published research on LIMS implementation in developing settings, and the contribution of open-source software to sustainability in this context, are limited. Sources of qualitative data for IS research can include documentation, archival records, interviews, direct observation, and physical artifacts [22,23].

This case report relies primarily on monthly progress reports from the implementer, ad-hoc trip reports from technical advisors and independent consultants, annual reports from Government of Vietnam agencies, and planning records of the donor. These sources were reviewed for information regarding the formation of the national LIMS program as well as descriptive data on program efficacy and the challenges experienced during implementation. Archival budgetary records were used to conduct a longitudinal financial analysis of program expenditures for consumables, personnel, development and contracted maintenance costs. In 2016, a national monitoring tool was implemented in order to continuously improve the program by assessing user adoption, operational processes, the policy framework, the organizational and external environments, and system functionality. This tool was used at six geographically diverse laboratories in Vietnam and uses a structured questionnaire and direct observation to observe laboratory processes and assess laboratory policies and procedures. This LIMS Policy and Adoption Assessment yielded valuable information that could be used for qualitative analysis (Table 1).

The qualitative case report approach in IS research allows investigators to generate theories from practice and explore the complex interactions between numerous variables including environment, processes and the application system [23–25]; indeed, through an iterative process of planning, development, deployment and assessment, the implementers developed a sustainability model and attempted to identify the key factors required for sustainability. These factors, and their effects on development and deployment processes, user acceptance and system functionality, are presented for discussion.

4. Case report

4.1. Establishment and management of the national LIMS program

The U.S. Centers for Disease Control and Prevention (CDC) and the Government of Vietnam (GVN), began planning for a national LIMS program in 2005. An advisory group was convened in 2006 consisting of the Ministry of Health and its affiliated agencies, national and regional institutes, provincial AIDS committees (PACs) and hospitals. Subgroups were created and provided program-specific guidance including standardization of report forms and system requirements. Stakeholders began by reviewing

the “LIS Software Provider Report” and the Association of Public Health Laboratories’ “Requirements of Public Health Laboratory Information Management Systems”, the de facto standard for public health LIMS requirements [26,27]. The “LIS Software Provider Report” did not provide GVN with suitable options for a LIMS and they explored alternatives. GVN was motivated to deploy an open-source LIMS as part of their national strategy. One of the few open-source LIMS applications used in the health sector at the time, OpenELIS, was being implemented by a state public health laboratory (PHL) in the U.S., which would enable a twinning relationship for sharing experiences and provide a network of support. Comparison of OpenELIS functionality with the requirements of PEPFAR-supported laboratories led GVN to conclude that OpenELIS met their needs. Furthermore, OpenELIS used components for which skill sets could be identified in-country, thus allowing for greater ownership.

Stakeholders chose a Vietnam-based IT services contractor (the “implementer”) to customize, localize and support OpenELIS in order to minimize costs and ensure the presence of professional local support. Implementer requirements included: knowledge and experience working with Java, Hibernate, Eclipse, Postgres, Open-Reports and Jasper Reports; experience conducting training for a broad range of users; knowledge of the healthcare domain in Vietnam; and a basic understanding of open-source tools and best practices. A survey confirmed that multiple companies had the required technical skills to implement OpenELIS, though healthcare experience was limited. Members of the global OpenELIS community were able to support the local implementer with advanced projects including data exchange and instrument interfacing and provide guidance on best practices in the health IT field. Hardware and supplies were also procured and supported locally. Following selection of an implementer, two of their staff underwent hands-on training at the Minnesota Public Health Laboratory to develop the skills needed to adapt, deploy and support OpenELIS.

After initial customization and localization, LIMS was launched at two clinical laboratories in Vietnam in 2008. After the initial pilot projects, the LIMS program began expanding to additional HIV testing centers. As the range of facilities expanded into preventive health centers and TB health facilities, the Vietnam advisory group reconvened in order to prevent fragmentation and encourage collaboration across programs and institutions [28]. The project sponsors captured best practices to ensure the scalability of the program and to continuously improve the implementation process. For example, after documenting resistance to process changes in some laboratories (including introduction of central specimen receiving and processing areas, standardized labeling of samples and modification or discontinuation of paper logbooks), an acceptance document was introduced that asked managers to acknowledge the changes that would affect their laboratory workflow. Secondly, while the initial version of OpenELIS was tailored to HIV testing laboratories, the addition of microbiology worksheets allowed microbiology data to be easily captured thus expanding the utility and flexibility of OpenELIS to a wider range of laboratories. Implementers also developed solutions to transfer data between the LIMS and external data sources: laboratory instruments, by capturing test results from analyzers and transferring these to OpenELIS; hospital information systems (HIS), allowing patient demographic data and test orders to be submitted to the LIMS and allowing results to be returned to the HIS; and other health

information systems, like surveillance and reporting systems. To date, data exchange has been established with 100 unique laboratory instruments and 10 HIS, and a demonstration was conducted to link OpenELIS with the HIV voluntary counseling and testing (VCT) system. Of note, the LIMS-VCT exchange was not utilized due to many clinicians' inability to accept HIV confirmatory test results electronically. Finally, in order to facilitate future data exchange and interoperability projects, the OpenELIS test catalog in Vietnam was mapped to the Logical Observation Identifiers Names and Codes (LOINC) standard in 2014. In summary, by monitoring user acceptance and thus modifying the application and the deployment process to meet the needs and concerns of the user, the implementer was able to ensure service quality and a 'good fit' in the laboratory.

As the number of laboratories using OpenELIS, and the number of support requests increased, a tiered maintenance and support model was implemented in 2010 to improve service quality (Fig. 1). Every laboratory designates a LIMS supervisor with enhanced software access rights who administers the system, configures master lists and ensures that data are routinely entered in the LIMS. If the LIMS supervisor is unable to resolve an issue, it is escalated to Level 2, the site IT staff. Site IT staff receive specialized training by the OpenELIS implementer and are provided with a list of commonly encountered software and hardware issues. When they receive a request beyond their expertise, they elevate the request to the OpenELIS implementer or the hardware vendor. The GVN LIMS program officer liaises between GVN and the implementation sites and helps prioritize requests for support. The implementer has begun progressively transitioning more challenging tasks to lower levels as staff gain experience.

In 2012, site monitoring at 10 laboratories found that 43.9% (29/66) of workstations were experiencing slow performance due to adware or viruses. This occurred despite receiving antivirus software and training. In response, the training on data security was modified to include a stronger focus on data security, and laboratories were encouraged to limit internet access on workstations connected to the LIMS network. This challenge, however, highlights the need for strong policies, at the laboratory and national levels, related to health information data security.

The implementers were responsible for all end-user training during the deployment phase; however, the need for retraining was quickly identified through support requests and site monitoring visits. In order to promote continuous knowledge transfer, project stakeholders created an online repository of all training resources, processes, monitoring tools, and documentation [29]. Working with members of the OpenELIS Community, the implementer and technical partners developed a tiered certification training program in 2014. This tiered approach enabled knowledge transfer to occur at multiple levels, with targeted training for site-level IT staff and national-level IT experts. Skilled IT staff within GVN agencies and laboratories are being trained and certified so that they may support and even further deploy OpenELIS. The development of a cadre of site IT staff and GVN IT support personnel to perform deployment, maintenance and support functions is critical to provide timely response and is important in further reducing annual costs per site.

In March of 2016, the Vietnam Agency for HIV/AIDS Control (VAAC) and the Ministry of Health Administration for Health IT (ADIT) convened a national LIMS policy and planning workshop. This was motivated by a desire to further establish the LIMS program within GVN structures and ensure its sustainable development and expansion. At this meeting, LIMS users and national stakeholders agreed on the value of LIMS to laboratory operations and national health strategies, discussed challenges, and developed plans to strengthen the national program. At the conclusion, a time-line was developed to fully transition funding and management from the donor. Furthermore, several policy areas were identified that were in need of strengthening, including health interoperability standards and data security policies.

As of May 2016, OpenELIS has been deployed at 38 sites across several administrative and geographic divisions (Figs. 2 and 3). Thirty-six sites are currently operational, with two laboratories merging locations and one laboratory closing. The current geographic distribution of sites was influenced by HIV prevalence, because donor resources were targeted at localities with the highest HIV burden. Expansion to additional provinces is expected to continue using alternative donor and local resources.

4.2. Analysis of LIMS development, deployment and operation in Vietnam

Of course, for a LIMS program to be sustainable, the application must first meet the requirements of laboratory staff, management and clients (e.g. physicians, patients, epidemiologists). To evaluate this, we will look at the efficacy of OpenELIS development, deployment and operation by analyzing financial data, program management documentation and indicators of system adoption.

4.2.1. Development process—Reviewing the software development process, and the role of environmental factors on development decisions, it is clear that customization was initially required in order to meet the requirements of Vietnamese laboratories. Developers were constrained by hospital policies regarding data management and laboratory reporting, as well as by the stakeholders' preference for an open-source ecosystem. Development costs were primarily incurred during the first year of the project, totaling $73,825. Further customization, if required, was conducted on-site during deployment, without requiring significant resources for development. The majority of coding was done by IT developers in Vietnam, with only planning and quality review provided by experts outside the country. Due to difference in Java developer salary between Vietnam and the United States, this helped control the cost of development [30]. As the LIMS expanded to more sites, implementers gained valuable experience in configuration allowing them to provide an adaptable and flexible solution. Indeed, the software was increasingly deployed in microbiology laboratory sections and in lower-throughput district health centers with minimal customization.

Throughout the program's expansion, the cost of software support and maintenance tended to decrease. By implementing the tiered support model and enabling remote access for server maintenance, total software costs per-site decreased. Indeed, the per-site

software costs, comprising all contracted IT services (including deployment, support and maintenance) reduced from $18,364 USD per site in 2008 to $750 USD in 2016 (Fig. 4).

4.2.2. Deployment process—While user satisfaction surveys were not conducted, routine monitoring provides useful information regarding LIMS adoption. Of the 38 laboratories that participated in OpenELIS deployment, none have decided to stop using LIMS or switch to an alternate system. There was one laboratory, included in the initial program plan, which opted to use a commercial system instead of OpenELIS. This laboratory was part of a national specialty hospital with unique laboratory requirements. The hospital had already implemented a hospital information system from a commercial vendor, and a lack of open standards or collaboration of the vendor meant that LIS-HIS data exchange could not be established. In the end, hospital leadership decided to use the laboratory module that was built into the HIS application. However, every laboratory that has received OpenELIS has adopted the system and continues to use it, which is a good indicator of the value of the LIMS to laboratory and hospital staff.

While the time it takes to deploy LIMS varies based on the size and complexity of the laboratory – especially if many automated instruments are used – the average time to deploy OpenELIS in Vietnam decreased over time. The average deployment time decreased from 22 weeks in 2008 to 5.5 weeks in 2015 (Fig. 5). While some of this decrease is attributable to the size of the laboratories (LIMS were increasingly deployed in district health centers in 2014 and 2015) decreases can also be seen when comparing laboratories of similar size. Indeed, deployment of OpenELIS at a district hospital in 2008 took 8 months while in 2015, it took just 1.5 months. This improvement in efficiency is primarily the result of process improvement and good project management by the implementer.

Deployment of LIMS generally replaces most or all of the paper records used in laboratories. However, investigators found that some laboratories continued to use paper records and logbooks, representing a “partial adoption” of the system. The LIMS Policy and Adoption Assessment found that the primary reasons for maintaining paper records included: habit (i.e. resistance to change), requirement of hospital management outside the laboratory, or lack of corresponding functionality in the LIMS (e.g. temperature logs, QC charts, HR files). The laboratories which maintained the most unnecessary paper records (i.e. those records with corresponding functionality available in OpenELIS) tended to be the laboratories deployed earliest in the program. This could indicate that the ongoing modifications to the deployment process, like standardizing the training curricula and improving documentation and guidance for laboratory leadership, led to improved outcomes for the laboratories deployed later during the course of the LIMS program.

4.2.3. Laboratory operations—Deployment of LIMS greatly affected laboratory operational processes requiring changes to every stage of the testing cycle, from pre-analytical to analytical to post-analytical phases of laboratory workflow. Despite the drastic changes to the laboratorians’ daily routine, users largely accepted the system. Semi-annual site monitoring found that over the course of the program, only four laboratories had temporarily ceased using the LIMS. The reasons for these disruptions included hardware

malfunction or a perceived burden on laboratory workflow. With additional training, support and oversight, the system was fully adopted at these sites.

Routine site-monitoring also found that personnel downsizing was made possible at two laboratories due to the reduction in clerical work following LIMS implementation. Laboratorians also reported that greater efficiency enabled them to spend more time on professional development activities, which contributes to quality improvement and accreditation efforts.

Vietnamese-language sources including journals and conference proceedings have presented additional data on the operational efficacy of OpenELIS in Vietnam. A multi-site cross-sectional analysis in 2014 led by the Vietnam Administration for HIV/AIDS Control found that laboratory turnaround times improved at all laboratories with a range of 20–25% following LIMS implementation [31]. The rate of transcription errors also decreased, with one laboratory measuring a reduction from 3–5% to 0% following LIMS deployment [32].

5. Discussion

5.1. Key factors contributing to sustainability

In the context of information systems, sustainability has been defined as the characteristics of a system that ensure its ability to continue operating without significant interruptions [33]. As the implementer and stakeholders reviewed the LIMS program during its expansion, several factors were identified that contributed to sustainability of this program in Vietnam. These factors were formalized into a sustainability model, which has guided stakeholder decisions as the program has matured: (1) selection of appropriate technology; (2) capacity-building and knowledge transfer; (3) financial viability; (4) leadership and management; and (5) alignment with national health strategies (Fig. 6).

5.1.1. Technology selection—The decision to utilize an open-source application was motivated by GVN policies encouraging adoption of open-source software when possible [13,14]. OpenELIS had an active international support community including academic, state, and non-governmental organizations, and was freely available for adaptation by contracted local IT developers. The presence of active and skilled user and developer communities meant that continued development and support of OpenELIS could be expected. Additional benefits of open-source can include smooth migration, greater reliability and security, and continuous improvement through peer review [34]. Importantly, OpenELIS met the requirements of laboratories in Vietnam with limited need for customization. OpenELIS has proven to be a good fit for health laboratories in Vietnam. Software development has continued steadily, with a new software release forthcoming. Furthermore, the OpenELIS Foundation has provided governance and planning, spearheading the development of a technology roadmap in 2015.

The selection of an open-source application provides flexibility in the selection of IT support because decision makers are not tied to a single vendor. The absence of licensing fees can compel open-source providers to focus on service quality to maintain business [15]. With OpenELIS, the lack of vendor lock-in meant that a local IT services contractor could be

used in Vietnam, which ensured that localization, deployment and support of the LIMS were cost-effective.

Open-source implementers often use open standards to ensure compatibility and interoperability within the health system [15,35]. Indeed, the LOINC standard and an open-source interfacing engine, Mirth Connect, were used in Vietnam to promote these efforts. By leveraging the global OpenELIS community knowledge-base and utilizing open-source tools, data integration was enabled, which increased the value of the LIMS to laboratorians, clinicians and other stakeholders. Wider adoption of standards in medical informatics, in both commercial and open-source applications, has created an environment that is conducive to the development of open-source solutions [36]. Given the lack of well-defined interoperability standards in Vietnam, however, exchanging data between health information systems remains a challenge and relies on the cooperation of individual software providers.

OpenELIS was a flexible LIMS, enabling deployment and adoption in a range of health facilities, in both urban and rural settings, with diverse workflows and needs, without significant customization from one laboratory to another. OpenELIS could be installed on a variety of hardware, using open-source (e.g. Debian) and proprietary (e.g. MS Windows) operating systems, as required by laboratory or hospital IT staff. The flexibility and configurability of OpenELIS has also enabled implementers to respond quickly to users' demands. Many of the change requests received from users could be easily configured as a system administrator. Therefore, enhanced training programs were initiated that provided guidance for some of these most common issues.

5.1.2. Capacity-building & knowledge transfer—The development of human resource capacity within GVN and health facilities for deployment, maintenance, program management and especially IT support was essential to build sustainability and country-ownership. One of the primary challenges from the outset was that the implementer was responsible for resolving all technical issues. Due to funding constraints, they were not always able to respond rapidly. Stakeholders were concerned that support costs would increase, or service quality would decrease, as additional laboratories were added. Program expansion would have been impossible without the tiered maintenance and support model. Looking forward, GVN and the donor are now making plans to further transition responsibility for support from the contracted IT services company to IT staff within MOH.

Since the beginning of the program, knowledge transfer has been a priority. Training materials were developed and made freely available in Vietnamese and English, and laboratory feedback was regularly sought to identify future training needs. Collaboration between Vietnam and international experts from the OpenELIS user and developer communities has been firmly established, thus promoting best practices and information sharing at no cost.

5.1.3. Financial viability—Open-source solutions do not have licensing costs, which can be a source of long-term savings. However, an open-source solution must follow a licensing format to support development, distribution and use of software code. OpenELIS

is distributed under the General Public License (GPL); any group selected to implement and configure OpenELIS must meet the terms of this license [15]. Implementers who abide by these requirements can take advantage of code developed by other groups, thus reducing costs and duplication of effort while expanding LIMS functionality. Open-source solutions can also provide implementers with flexibility when choosing components. GVN opted to utilize several open-source components in order to minimize costs (Table 2). Shared financial commitment between the donor and the sites was required to demonstrate buy-in and ensure that local investment would be sustained after donor funding ceased. During the first phase of the project, the donor provided laboratories with funding for consumables and personnel. This practice has ceased for new deployments, and those already receiving support have seen their donor financing diminish, requiring local resources take their place. In Ho Chi Minh City, annual donor expenditures on supplies have decreased from $1500/site in 2011 to $933/site in 2014. Personnel funding has also reduced from an average of $7131/site in 2011 to $1617/site in 2014 (Fig. 7). In 2014, LIS was implemented at two sites without donor financing for consumables or personnel, and two hospitals procured their own hardware as well. Laboratories are provided with budget projections so that LIMS may be incorporated into their institutional financial plans. This transition of funding is an indication that LIMS is becoming institutionalized at the laboratories where it has been adopted.

It is important to consider the value and sustainability of information systems investments, particularly in a resource-constrained setting. Implementing LIMS does not always result in increased revenue; however, LIMS greatly impact operational efficiency and allow more tests to be conducted in less time. An open-source LIMS can be tailored based on preferred platforms, organizational policies, user requirements and specialized workflows, thus improving efficiency and potentiating cost savings [34]. Information systems can be expensive to deploy and maintain, and governments must make financial decisions that will have the greatest impact on patient care and public health. An analysis of information system projects in developing settings found that one of the two most valuable and cost-effective benefits of health information system projects was the ability to return laboratory results to remote areas in a timely manner [10]. OpenELIS in Vietnam has enabled quicker return of laboratory results, and a pilot is currently underway to implement electronic reporting from referral laboratories to provincial medical centers.

5.1.4. Leadership & management—At the national level, a technical working group (TWG) is recommended to provide strategic direction and coordination to a LIMS program [38]. Administrative structures and donor funding for specific diseases have a tendency to produce vertically managed, “siloed”, programs where standalone information systems are implemented [39]. In developing settings, information systems are often implemented with the primary goal of facilitating reporting to government or donors with limited concern for system interoperability or user requirements [40]. As LIMS were being deployed in diverse laboratories in Vietnam – falling under several different jurisdictions and administrations – the national LIMS working group provided a forum for sharing best practices and developing comprehensive system requirements. Presence of a LIMS program officer helped ensure that activities and priorities were locally managed and not driven by the donor.

At the site level, hospital and laboratory management's commitment to LIMS implementation was a key requirement for success; therefore, it was critical to engage with laboratory and hospital leadership early in the implementation process. A common barrier to LIMS adoption and sustainability is the perception that software is external to laboratory processes. This mindset can lead laboratory staff to assign LIMS tasks to non-laboratory personnel, thus preventing the system from being integrated into laboratory workflows [34]. Through the assignment of LIMS supervisors at each site, OpenELIS was introduced to staff as a tool integral to the laboratory's business processes.

Previous research has shown that LIMS affect both laboratory processes and products, and that user acceptance is partially determined by how a user sees their primary role in the laboratory: process-oriented (i.e. bench work) or product-oriented (i.e. producing lab reports) [41]. Product-oriented staff tend to accept LIMS readily due to the ease with which reports can be generated; however, process-oriented staff can see LIMS adoption as increased work. The acceptance documents prepared laboratory staff for the brief disruption and alteration to workflow caused by the LIMS implementation and communicated the operational benefits that could be realized from adopting the system. Microbiology worksheets and development of a tool for importing results directly from laboratory analyzers introduced operational efficiencies that would appeal to the process-oriented laboratorians and support user acceptance.

Effective program management, especially project monitoring and control, was recognized as a critical requirement for program viability and effectiveness. Planning and coordination are performed by the LIMS program officer, who is able to communicate achievements to the wider laboratory community in-country. In addition, the donor assigned a LIMS advisor who provided mentorship and support to strengthen management capacity and served as a liaison between the donor and GVN. Implementation of project management documentation, establishment of change management procedures, and strengthening of position descriptions and project roles all contributed to an effectively managed program, capable of expanding rapidly and transitioning smoothly to local government ownership. The LIMS advisor also served as a resource for global best practices, and provided strategic guidance to stakeholders and implementers. Finally, continuous quality improvement by the LIMS implementer was critical. As they gained experience deploying OpenELIS, they were able to improve their processes and strategies, contributing to faster deployments and improved adoption.

5.1.5. Alignment with national health strategies—GVN is committed to building laboratory capacity in Vietnam, specifically focusing on laboratory automation and quality assurance. The government's long-term goal, as described in the National Laboratory System Strategic Plan to 2020, is to pursue laboratory accreditation and to follow international best practices in quality management. LIMS were identified as an important tool for achieving these goals [42]. GVN also demonstrated an eagerness to develop open-source software. This was motivated by a desire to reduce software piracy, protect copyright and reduce software procurement costs [13].

The recent LIMS policy and adoption analysis identified several way to strengthen LIMS policy and ensure alignment with national laws and strategies, namely developing standards for national health interoperability, providing guidance on the use of electronic signatures in medical records and developing legal policy on privacy and security of patient information. However, as demonstrated by routine site monitoring, policies are only useful when there is clear guidance to implement them in the laboratory, and consistent monitoring to enforce them. This requires coordination across administrative divisions, and the development of use cases and implementation guidance documents.

Thus, through planning, review of existing policies, and collaboration, this project was closely aligned with the national health strategies of Vietnam. As the economy in Vietnam grows and donor funding diminishes, this alignment contributes to the project's sustainability.

5.2. Recommendations for further analysis

While this case report relies primarily on qualitative sources, the investigators recommend additional quantitative analysis to help fill the gap in the literature on LIMS sustainability. Further study is recommended to evaluate the effects of development and deployment processes, environmental factors and the application itself on sustainability, laboratory quality and patient care. Specifically, researchers should evaluate the roll of national and site-level LIMS policies on system adoption, and develop metrics to assess the impact of LIMS on medical and public health outcomes. In Vietnam, further study is required to understand the use of health information systems in the private sector. Quantitative analysis should be conducted using the total-cost-of-ownership approach to analyze the economic impact of the LIMS program and enable a comparison with proprietary LIMS projects [37].

6. Conclusion

Laboratories providing clinical testing services in resource-constrained settings often struggle to ensure healthcare providers receive quality laboratory results within acceptable timeframes. Recent national and international quality improvement initiatives are encouraging laboratories to pursue accreditation [43]. While data management and record keeping are an important part of the accreditation roadmap, it can be intimidating to consider implementing a LIMS in addition to routine laboratory duties. Even when a LIMS is in place, continued investment of human and financial resources is required to ensure its viability [44].

The approach described in this paper provides a strategic model for implementing a sustainable country-owned LIMS program. These strategies enabled the deployment and support of an affordable, scalable, and localized LIMS in 38 health laboratories in Vietnam. Further expansion of the program is anticipated using local financing. The authors believe that many of the approaches from this model are applicable to a variety of settings with diverse LIMS platforms, both open-source and proprietary. Effort is needed to institutionalize the capacity for LIMS governance, IT support and management within key government agencies and to develop a stronger policy framework to promote interoperability.

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Summary points

What was known:

- LIMS can greatly improve the quality and efficiency of clinical laboratory testing
- Sustaining donor-funded health information systems in developing countries can be challenging

What this research has added:

- Open-source LIMS can be sustainably developed, implemented and maintained in Vietnam
- Flexibility of the LIMS application, and effective management of the deployment and training process, contributed to the adoption and expansion of OpenELIS in Vietnam.
- Financial transition from the donor was successfully initiated by reducing maintenance costs, encouraging cost-sharing, and developing local capacity for IT support.

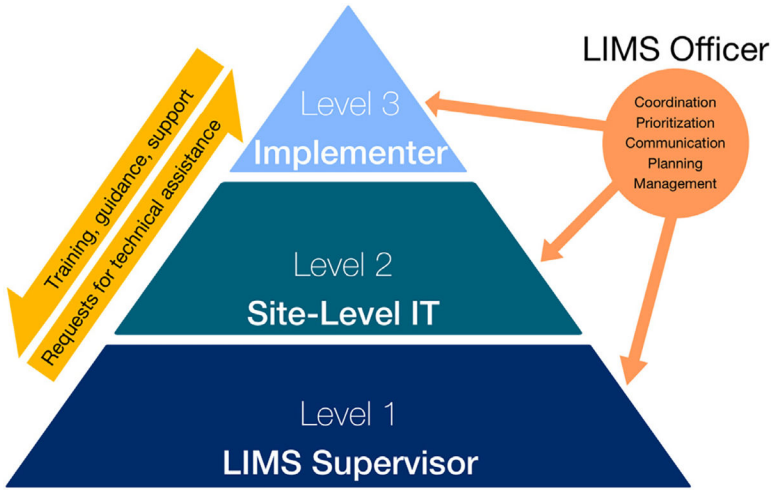

Fig. 1.
Tiered Maintenance and Support Model.

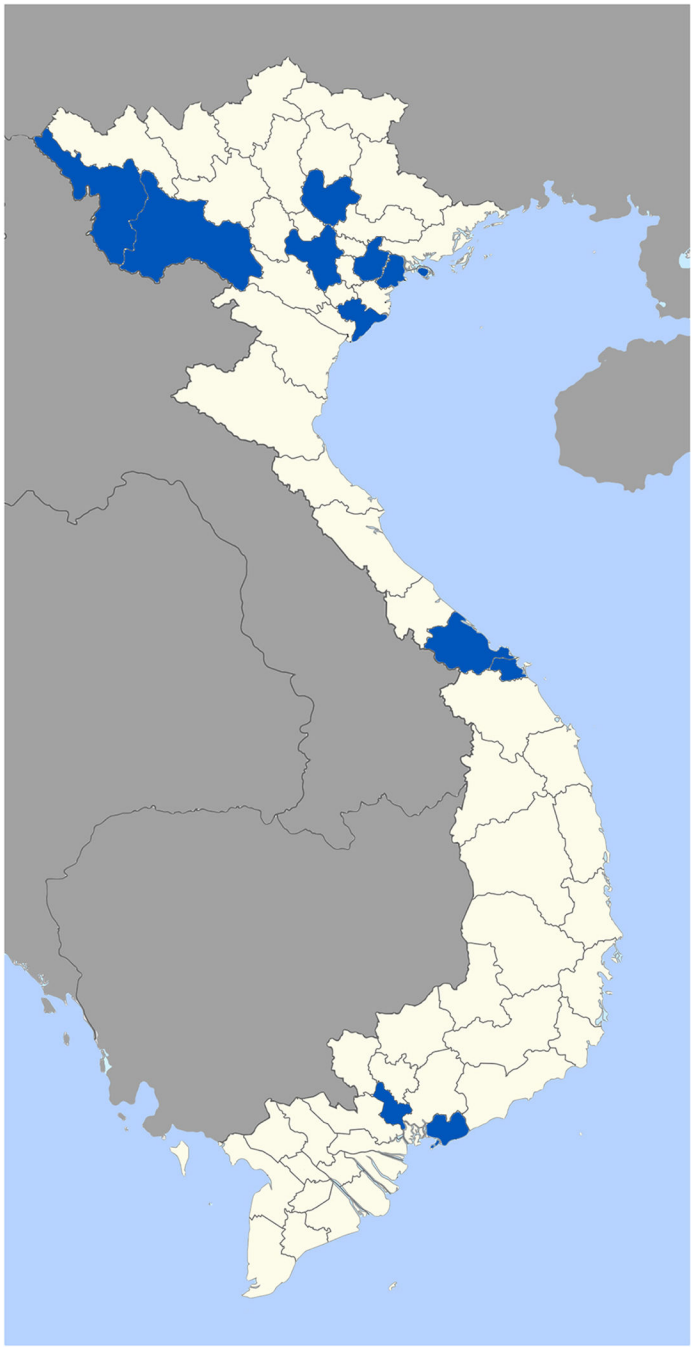

Fig. 2.
Provinces with active OpenELIS implementation sites in Vietnam, 2015.

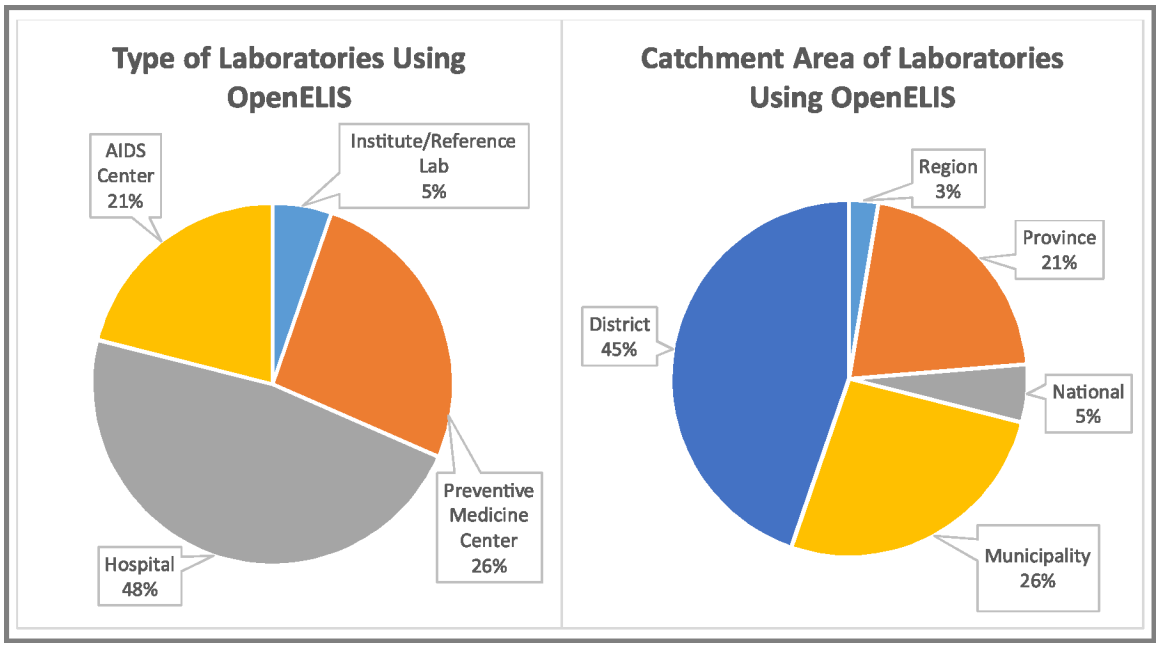

Fig. 3.
Types of laboratories using OpenELIS, by administrative division and catchment area.

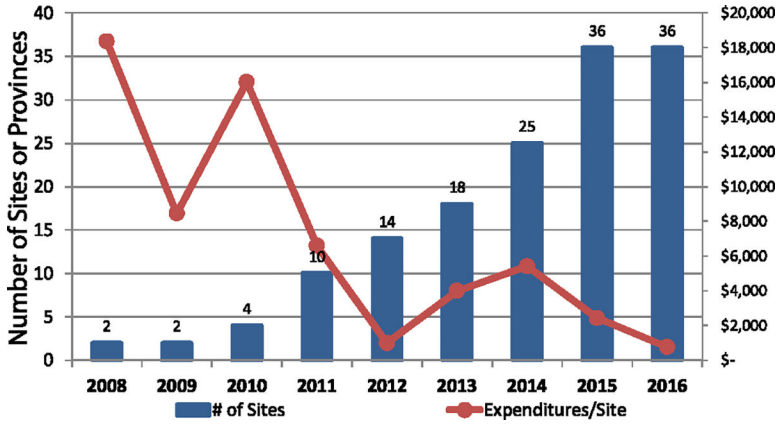

Fig. 4.

Software deployment, support and maintenance costs during program expansion, excluding initial development costs. The number of sites is calculated by the date the site began fully using the LIMS.

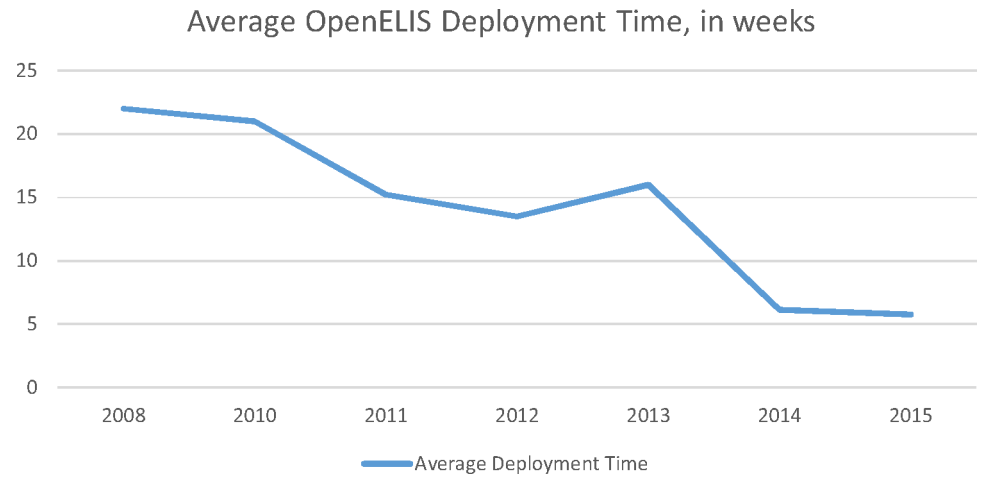

Fig. 5.
Average deployment time of OpenELIS over time, in weeks.

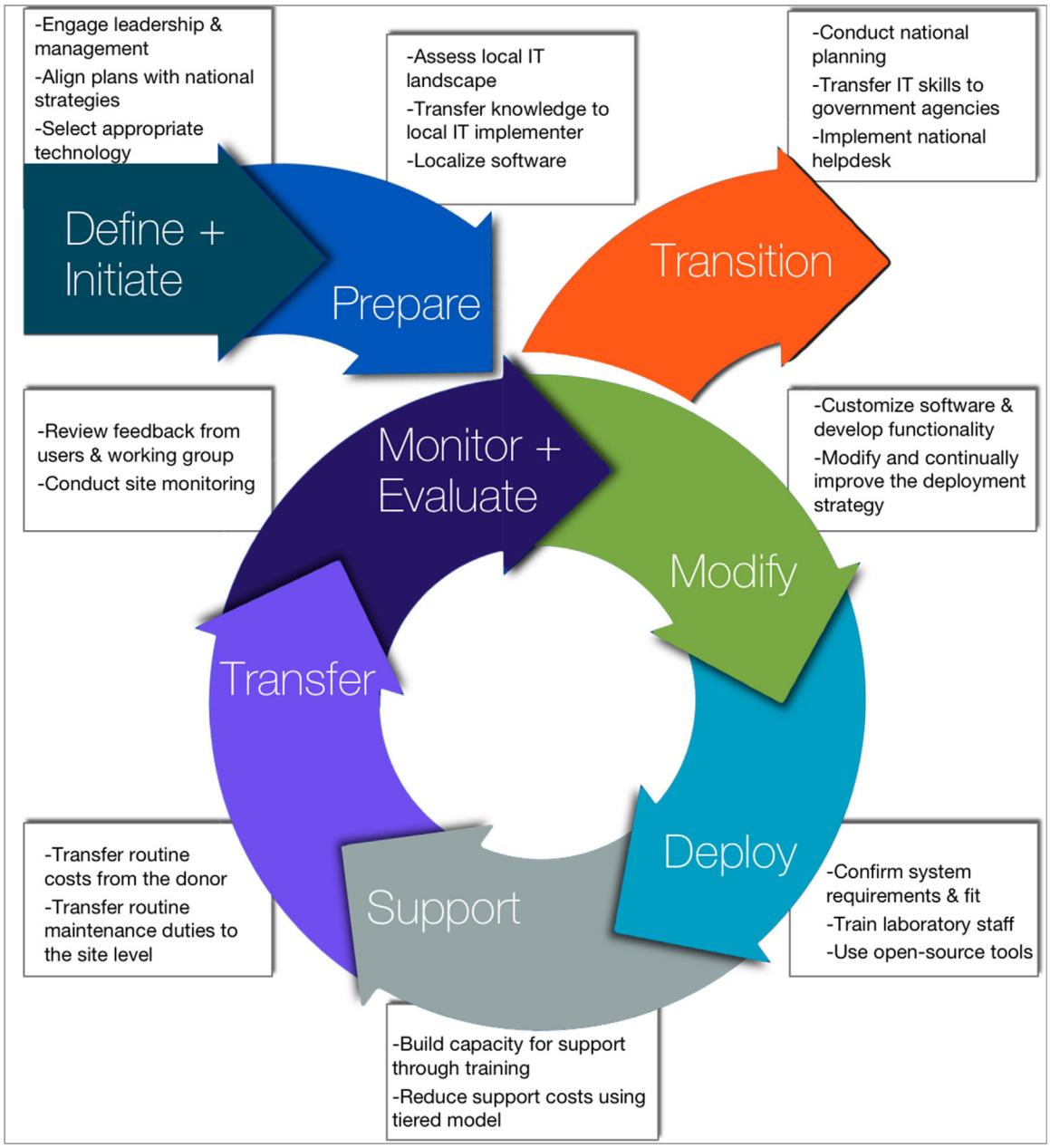

Fig. 6.

Key strategies contributing to sustainability during the program management cycle.

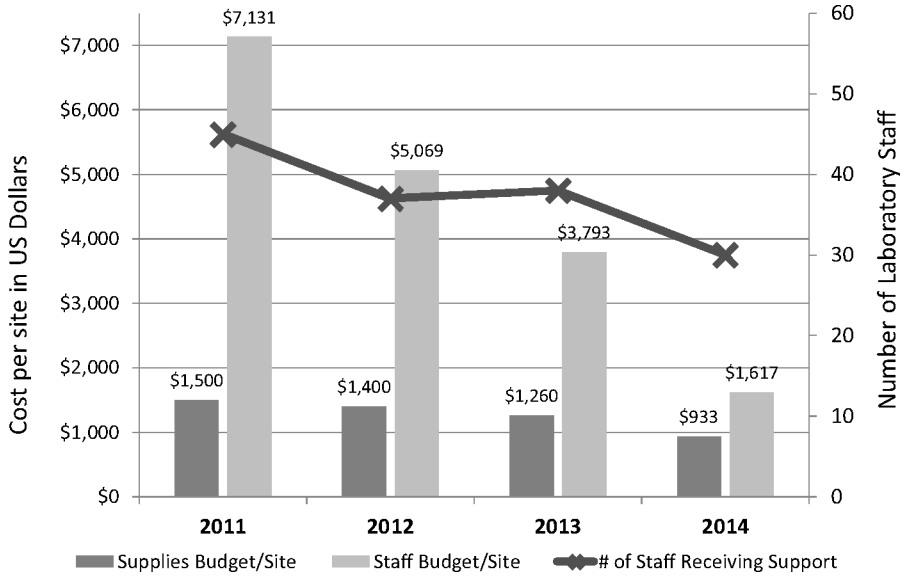

Fig. 7.

Annual donor site-level expenditures for supplies and personnel in Ho Chi Minh City LIMS sites.

Table 1

Data sources.

Name	Source	Analysis
Monthly reports	Contracted Implementer	Qualitative review of deployment and operational metrics
Policy & Adoption Assessment	Technical Partner, 3rd party academic partner, Government of Vietnam	Responses to open-ended survey questions were collected in a standardized way and analyzed qualitatively. Observational assessment data was analyzed quantitatively.
Semi-Annual Site Monitoring Reports	Ho Chi Minh City AIDS Committee	Monitoring reports were reviewed for data regarding operational and technical issues experienced in laboratories
Field Reports	LIMS advisor, technical partners	Trip reports were reviewed for indications of LIMS adoption or function
Budgetary Records	Donor	Longitudinal financial expenditure analysis

Table 2

Open-source components used in Vietnam installation of OpenELIS.

Component	Open-Source Solution
Database	PostgreSQL
Programming Language	Java
Reporting Engine	Jasper Reports/OpenReports
Interoperability/Messaging Engine	Mirth
Web Server	Tomcat
Server	Debian/Linux[a]

[a]Overtime, manysites optedtouse Windows serverto install and runthe application.