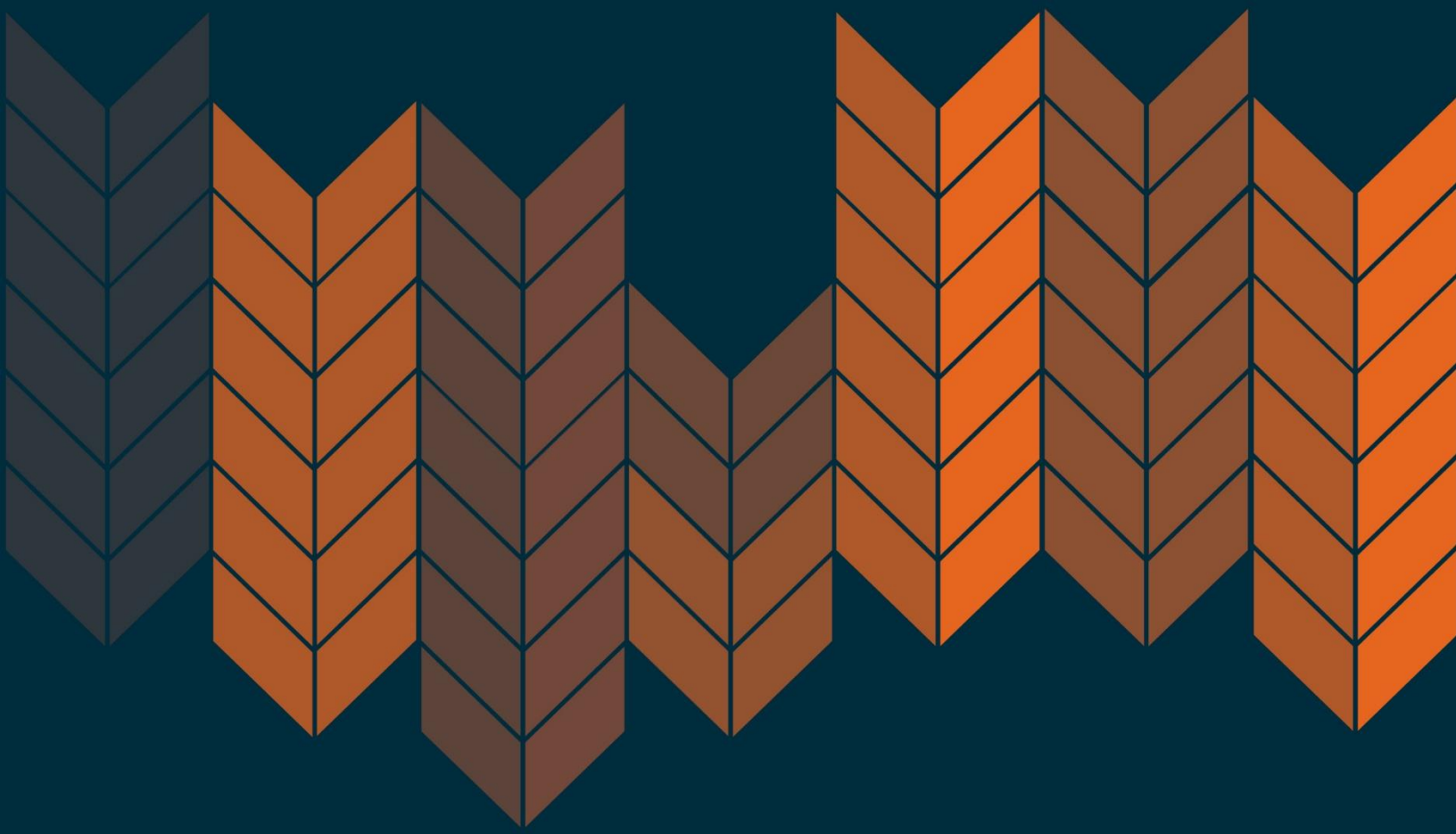

How Electronic Health Records Strengthen the Health Systems of Low- and Middle-Income Countries

Learning from Eswatini and Mexico

September 2018

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MEASURE Evaluation

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September 2018

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CONTENTS

ABBREVIATIONS

CMIS	client management information system
COC	continuity of care
DQA	data quality assurance
EHR	electronic health record
EMR	electronic medical record
HIS	health information system
HISSM	health information system strengthening model
HITECH	Health Information Technology for Economic and Clinical Health
HMIS	health management information system
ID	identification
IP	implementing partner
IT	information technology
M&E	monitoring and evaluation
SAECCOL	Sistema Administrativo del Expediente Clinico de Colima (Management of the Electronic Health Record in Colima)
SOP	standard operating procedure
UCD	user-centered design
UNAIDS	Joint United Nations Programme on HIV/AIDS
WAN	wide area network
WHO	World Health Organization

INTRODUCTION

Managing patient records is a challenge in any country and for all diseases, especially those that require continuity of care (COC). COC helps HIV-positive people stay in treatment, contributing to the 90-90-90 goals described by the Joint United Nations Programme on HIV/AIDS (UNAIDS),[1] and other health areas, such as maternal care and childhood immunizations. One key intervention for COC is electronic health records (EHRs), which have been implemented worldwide to improve patient management and reporting.[2] The EHR (a term used henceforth both for a single record and the system of health records) is a tool for improving the quality, safety, and efficiency of health services. It also provides data and information for assessing health system performance and the health status of the population. According to the 2015 global survey on eHealth of the World Health Organization (WHO), 57 of 125 countries (46%) reported having some sort of national EHR system ((World Health Organization, 2016). But these interventions are part of the much larger health information system (HIS). There is also great variation in the scope and scale of EHR systems used.

EHRs in Colima, Mexico

System: Management of the Electronic Health Record in Colima (SAECCOL in Spanish), developed in Colima

Scope of implementation: One regional state of Mexico with 119 health clinics (primary level care; 21 urban and 98 rural), four hospitals, and several specialized health outpatient clinics (secondary level care).

Pilot date: 2005

Description: The primary level of care is provided with modules for scheduling, insurance information, vital records, health history, health promotion, laboratory, referral and counter-referral, issuing prescriptions, pharmacy, and management. The management module is only available to the directors of healthcare centers and hospitals; the other modules are available to physicians at the point of care. In addition to those components already described, the secondary level of care (hospital services) has admissions and emergency modules. It is intended for real-time direct data entry by the provider.

Two examples of large-scale EHR rollout that MEASURE Evaluation—funded by the United States Agency for International Development—has studied are the client management information system (CMIS) in Eswatini (previously called Swaziland), in Phase IV of the project, and the Sistema Administrativo del Expediente Clinico de Colima (SAECCOL, or Management of the Electronic Health Record in Colima, Mexico), in Phase III. This report discusses the role of such EHRs as the SAECCOL and the CMIS in overall

[1] These goals are that, by 2020, 90 percent of those who are HIV-positive will have been diagnosed, 90 percent of those diagnosed will be on antiretroviral therapy, and 90 percent of those treated will be virally suppressed (UNAIDS, 2014).

[2] Although EMRs and EHRs are often used interchangeably, they are not the same. An EMR is the digital version of the paper chart in a clinician's office containing a client's medical and treatment history only in that clinician's practice. An EHR collects client information from multiple sources: not only from the health organization that originally collected and compiled the information but also from all other clinicians involved in the client's care, and from other healthcare providers, such as laboratories and specialists. Source: https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/.

health system strengthening. More specifically, it views HIS strengthening through the lens of MEASURE Evaluation's Learning Agenda—the formal approach that the project has been using to document what we are learning about HIS strengthening (https://www.measureevaluation.org/our-work/learning-agenda/learning-agenda?searchterm=learning+agenda). This report also highlights key points to consider when developing an EHR for use on a large scale.

Methods

In Eswatini, MEASURE Evaluation planned to conduct an evaluation of the CMIS implementation as part of our work on the Learning Agenda. We expected to conduct a longitudinal case study with baseline and follow-up data collection. This included health facility assessments with provider and client time-motion studies, client exit interviews, and service readiness. We conducted stakeholder interviews once the implementation began. The evaluation was cancelled after the baseline. In addition, MEASURE Evaluation provided technical assistance to the implementers of the CMIS.

In Colima, MEASURE Evaluation, in partnership with the Mexican National Public Health Institute, conducted a case study of the SAECCOL's implementation. It was a mixed-methods study that framed the socioeconomic and epidemiological profile of the state. To learn about stakeholders' perceptions of implementation and benefits, we conducted a qualitative analysis using in-depth interviews and focus groups of SAECCOL's managers, technicians, operators, and users at the local and federal level.

THE PROBLEMS THAT ELECTRONIC HEALTH RECORDS ATTEMPT TO SOLVE

EHRs are "longitudinal electronic records of patient health information generated by one or more encounters in any care delivery setting" (Healthcare Information and Management Systems Society (HIMSS), 2018). Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports (Healthcare Information and Management Systems Society (HIMSS), 2018). EHRs can be designed to provide clinical support to providers.

EHRs are beneficial in managing patient care and reporting national-level indicators. In the United States, the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act supports the "meaningful use" of EHRs (HITECH Act, 2009). "Meaningful Use: is defined by the use of certified EHR technology in a meaningful manner (for example electronic prescribing); ensuring that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and that in using certified EHR technology the provider must submit to the Secretary of Health & Human Services (HHS) information on quality of care and other measures" ([CDC], 2017

)Therefore, an EHR must not only be able to house a client's health record but also help the provider to perform better, improve the quality of care, allow information exchange across service points and levels of the health system, and report data to the regional and national levels. In sub-Saharan Africa, there has been great interest in implementing EHRs. For example, the Ministry of Health in Zambia, in collaboration with the United States Centers for Disease Control and Prevention, has been using SmartCare, a fully integrated EHR system, since 2005. SmartCare helps ensure continuity of care and provides a clinical management information system at the facility and district levels. It is deployed in more than 700 facilities in every district of the country (Zambia Ministry of Health, 2017). In Kenya, the International Training and Education for Health (I-TECH) supported the Ministry of Health to deploy KenyaEMR, an HIV and AIDS care and treatment EMR developed using the OpenMRS platform, at over 300 healthcare facilities since 2012 (Muthee et al., 2018). Open-source electronic health records are popular because customized systems may be cost-prohibitive for medical organizations. Open-source systems are also thought to be more flexible, because they can be

EHRs in Eswatini

System: CMIS developed in Eswatini

Scope of implementation: National, with 282 health facilities; half are private/NGO and half are government. Government facilities include hospitals, public health units attached to hospitals, clinics, and health centers. There are 231 clinics without maternity, 15 clinics with maternity, 5 health centers, 11 hospitals, and 9 public health units.

Pilot date: 2014

Description: The CMIS has modules for the outpatient department (OPD) service points for the main health programs: family planning, antiretroviral treatment (ART) for HIV-positive patients, antenatal care and prevention of mother-to-child-transmission (ANC/PMTCT) of HIV, tuberculosis, child welfare, and outpatient curative services. It is also using registration, laboratory, and pharmacy modules. It is intended for real-time direct data entry by the provider.

https://www.measureevaluation.org/resources/publications/tr-17-226

modified and redistributed (Alsaffar, Yellowlees, Odor, & Hogarth, 2017). One example is OpenEMR, which is now being used in multiple settings (see https://www.open-emr.org/wiki/index.php/OpenEMR_Success_Stories). The CMIS and SAECCOL systems are not open-source and were developed in-country.

In Eswatini, the need for the CMIS emerged from a 2012 assessment of the country's health management information system (HMIS) that comprehensively reviewed the system's structures and processes operating throughout Eswatini's health sector. The assessment identified three main factors that led to the creation of the CMIS: (1) existence of parallel information systems, (2) lack of continuity of care, and (3) statistical inaccuracies owing to the inability to identify people who received services. Data collection methods also made it difficult to follow up with patients and ensure continuity of care: Patients held color-coded cards designating their morbidity (e.g., a red card for HIV), which were easily lost, making it nearly impossible to know what services they had previously received, or where they were in the sequence of a treatment or immunization schedule.

- Electronic health records (EHRs) have the potential to improve continuity of care and reporting, but such an intervention must be considered in the larger context of the health system.
- EHRs are expensive to implement and maintain, and the cost is not one-time, so a clear plan for financial support is necessary.
- Expectations of the EHR's capabilities should be managed
- Stakeholder coordination is crucial for the successful implementation and use of an EHR system, and often involves a large and diverse group of people and organizations.
- EHRs must meet the needs of clinicians, who must be satisfied with the systems to use them correctly. Thus, user-centered design is critical.

Health data were also case-based, not patient-based. For example, people could be tested for HIV multiple times throughout their lives, but the system only counted the total number of tests, which made it difficult to estimate the percentage of the population that had been tested. The same problem existed with immunizations, because officials could not calculate the percentage of people who had been fully or partially immunized (i.e., the proportion who had received more than one dose of a multidose vaccine).

In Colima, Mexico, the SAECCOL system was implemented to improve clinical efficiencies, and to satisfy the information needs of the System for Social Protection in Health (SSPH) or *Seguro Popular*, a health insurance program for poor and vulnerable people, that has become one of the main funding agencies for the health system in Mexico (Hernandez-Avila et al., 2013). The *Seguro Popular* requires information on health intervention costs, medication supplies, and other indicators to support decision making. The EHR is also used to monitor provider performance and the performance of individual health facilities.

IMPLEMENTING ELECTRONIC HEALTH RECORDS IN LOW-RESOURCE SETTINGS

The challenges of adopting EHR systems in the United States and other developed countries are fairly well documented, especially since the HITECH Act actively promoted the adoption of EHRs. The USG developed guidance to help address some of these challenges, such as websites to help providers transition to electronic systems (e.g., https://www.healthit.gov/playbook/electronic-health-records/). The literature on implementing EHR systems in low-resource settings is growing as researchers try to identify challenges that are specific to these settings (Figure 1).

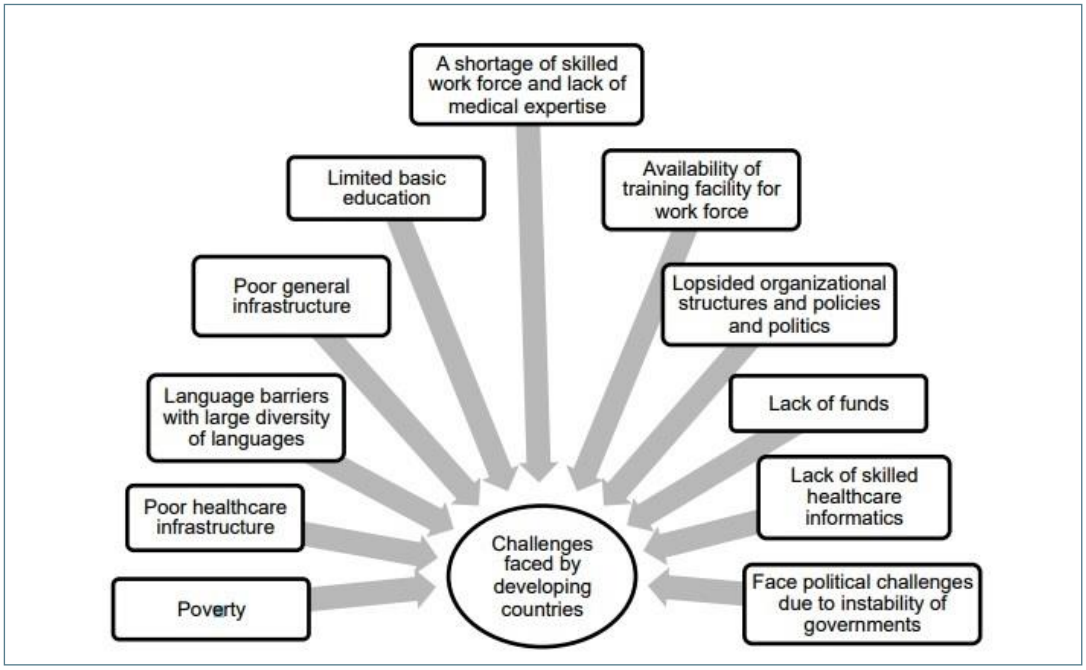


Figure 1. Challenges faced in low-resource settings

Source: Sikhondze & Erasmus, 2016

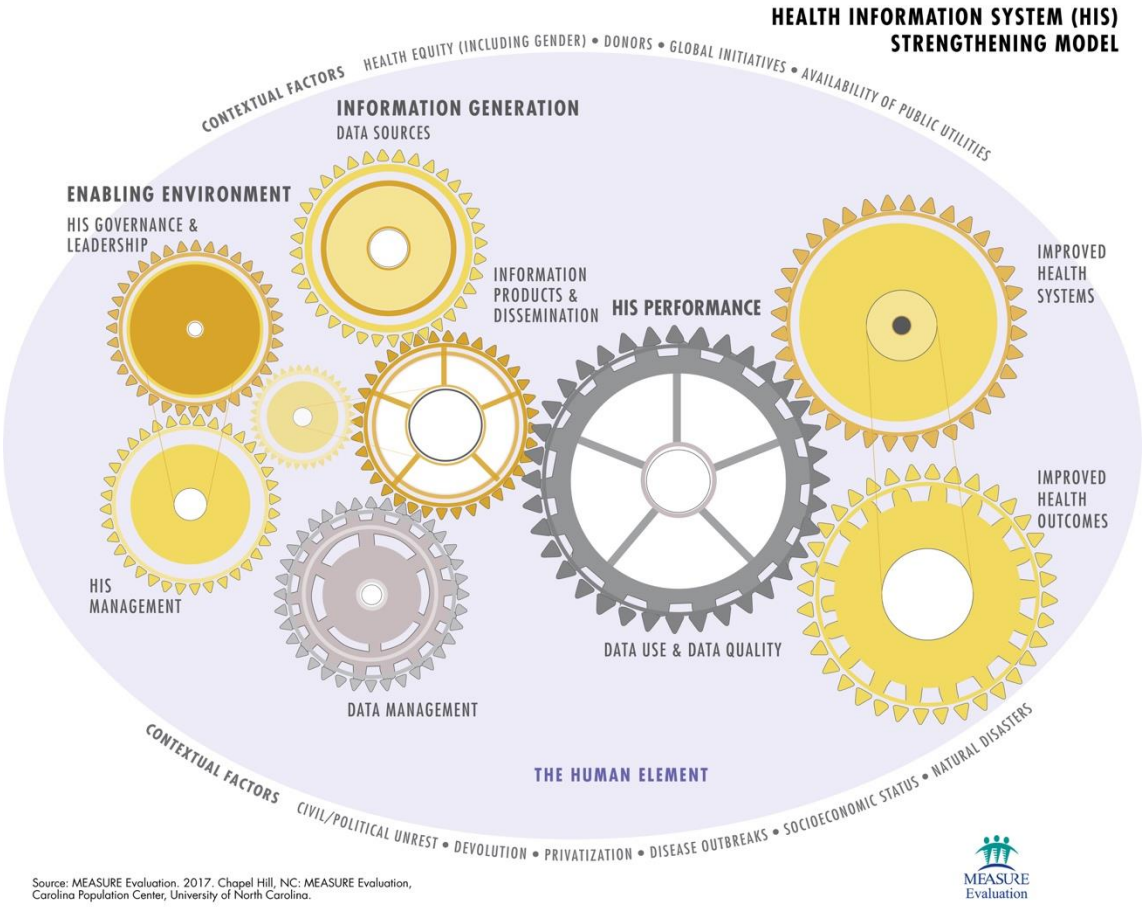
Other limitations for health information technology (IT) interventions include a lack of health IT agendas and failure to use interoperability standards (Luna, Almerares, Mayan, Gonzalez Bernaldo de Quiros, & Otero, 2014).

A lack of skilled workers in health informatics is also an impediment, and in some settings even basic computer knowledge is limited. Surveys in sub-Saharan Africa that focused on providers' computer knowledge prior to implementing an eHealth intervention reported great variation. One study of 554 health professionals working in 7 hospitals, 19 primary health centers, and 10 private clinics in Ethiopia found that only 18 percent had good computer skills, which was assessed with 20 different questions (Alwan, Awoke, & Tilahun, 2015). Another study assessing computer knowledge among providers in rural Tanzania and Ghana found that only 40 percent had ever used a computer prior to implementation of the eHealth intervention (Sukums et al., 2014). Two studies found that length of practice and providers' ages negatively affected attitudes about using computers in healthcare, but this association is not always present (Brumini, Kovic, Zombori, Lulic, & Petrovecki, 2005; Kivuti-Bitok, 2009).

One systematic review of EMR systems' ability to improve the quality of HIV care found only 12 studies that met the inclusion criteria and found some improvements in quality of care (e.g., in one study, clinical compliance with CD4 count testing guidelines improved from 42% to 63%) (Oluoch et al., 2012). The review highlights the need for more evaluations of these systems. Another review of EMR implementation projects in low-resource settings focused on their reported success criteria, and found that about half of the systems reviewed served a specific disease area, and most were HIV-specific (Fritz, Tilahun, & Dugas, 2015). The success criteria from most- to least-identified were functionality and organizational, technical, training, political, ethical, and financial factors. Another finding from these two systematic reviews is that many of the electronic systems did not involve real-time data entry by providers. Instead, encounters are still paper-based, and clerks later enter the information into the computer. Both SAECCOL and CMIS were designed for real-time data entry by providers.

HEALTH INFORMATION SYSTEM STRENGTHENING

Figure 2. MEASURE Evaluation's HIS strengthening model



Source: MEASURE Evaluation. 2017. Chapel Hill, NC: MEASURE Evaluation, Carolina Population Center, University of North Carolina.

"HIS strengthening" means implementing one or more interventions that target one or more components of an HIS to improve data quality and use for decision making at all levels of the health system. HIS strengthening consists of a range of technical, behavioral, and organizational interventions (Salentine & Silvestre, 2017). The output of a strengthened HIS is the increased availability of high-quality data that are continually used for decision making at all levels of the health system.

Part of MEASURE Evaluation's HIS Learning Agenda is developing a health information system strengthening model (HISSM). The model illustrates the logical progression of the effects of HIS strengthening activities on data management, data quality, and data use to improve health systems and health outcomes (Figure 2). This model is divided into several areas: the human element and contextual factors (both of which affect everything), the enabling environment (HIS leadership and governance and HIS management), information generation (data sources, data management, and information products and dissemination), and HIS performance (data quality and use). It is a starting point for framing how an HIS works, what is known about contributions to improved outcomes, and where opportunities exist in the framework to learn more about strengthening the HIS.

MAPPING ELECTRONIC HEALTH RECORDS TO THE BROADER HEALTH SYSTEM AND HEALTH INFORMATION SYSTEM

EHRs are part of the larger HIS, and the HIS is one core function of the health system. The others are service delivery, health finance, health governance, medical products, vaccines, and technologies, and human resources for health (USAID, 2016). WHO states that health systems do not consist of their components alone; multiple relationships and interactions convert the individual components into a system (World Health Organization, 2009

). Therefore, a "systems-thinking approach" is appropriate to improve specific components of a system, such as the HIS (WHO, 2009). Systems-thinking is an approach to problem-solving that views the issue at hand as part of a larger and dynamic system, in this case, the health system. It requires understanding the linkages, interactions, relationships, and behaviors of the entire system. This means a health system must be understood before any part of it can be strengthened. Understanding a system involves assessing how its components affect the specific HIS intervention to be implemented and the consequences of these interactions on the system's other core functions. Thus, to improve an HIS, we must understand how each core function of the health system affects the HIS and how the HIS (a strong, average, or weak system) affects other core functions of the health system. The HIS can be only as strong as the overall health system. The effects of and on the other core functions can be positive, negative, or both, and there may be multiple consequences for any core function.

Table 1 provides some illustrative examples of how a national EHR—an HIS intervention—would be affected by or affect other core functions of a health system. Placing an EHR in the larger context of a health system can highlight the components required for it to be successful at a large scale and reveal the potential effects of the intervention on other core functions.

Table 1. Health system core functions and how they can interact with an EHR intervention

Core function	Affected by	Affects
Health information	Indicators for health programs available	Quality of reporting
Service delivery	Rotation of nurses within health facility	Changes provider/patient interaction
Health finance	Resources allocated for equipment, training, and support	Financing of specific health services based on data
Health governance	eHealth policy	Coalition building around a health problem
Medical products, vaccines, and technologies	Availability of appropriate technology to implement the system	Distribution of commodities
Human resources for health	Capacity of staff to use and maintain the system	Job satisfaction

Health Information

An EHR is a health information intervention that can be affected by other health information functions in a given country. If the intent is to use data collected for national-level reporting, there must be nationally agreed-upon health indicators to collect. If one health program does not have harmonized indicators that are collected uniformly across the country and aligned with national or international standards, then it will not be possible for an EHR to collect data that meet the information needs of all health programs.

An EHR may also affect data quality. There are seven dimensions of data quality[3] and an EHR can be programmed to minimize some common data entry errors. High-quality data are those that are available in a timely manner, and EHRs can facilitate making data available in real time at facilities or at higher levels. Reporting can also be faster if another electronic system is used for the HMIS or the routine health information system (data collected at regular intervals at public, private, and community-level health facilities and institutions [MEASURE Evaluation, n.d.]). Data quality may initially decline as providers begin using an EHR, and if there are infrastructure problems, such as frequent power outages, data may be incomplete. In both Colima, Mexico, and Eswatini, users reported experiencing network or power issues that affected their ability to use the EHR. Patients were still attended to during these outages, and it was not always clear if data were entered in the EHR after the restoration of network services or electricity.

Service Delivery

An EHR is a tool for improving service delivery, but other characteristics of the service delivery mechanism will affect how well it functions. For example, in Eswatini, all nurses rotate departments every three or six months so they can fill in whenever there is a staff absence. This is one strategy to ensure continuous service at the facility, but it also means that nurses may not develop specialized knowledge of any given department, such as the antenatal clinic or HIV treatment. These nursing rotations can affect data quality and the quality of care that patients receive when nurses switch departments and must become reacquainted with procedures. The modules in an EHR are customized to specific programs (i.e., the child well-check collects information on growth and immunizations and a TB module collects different information for patient care) and nurses may make mistakes using a particular module in a new department.

Switching to an EHR also alters the provider-patient interaction. Providers spend time looking at the screen, typing, and scrolling, which may reduce their direct communication with patients. Less time spent talking with a patient has been associated with lower patient satisfaction with the quality of services received (Farber et al., 2015). Direct communication is most affected when providers start to use a new system, and should improve as they get better using it. Finally, while the SAECCOL and CMIS developers touted saving time as a potential benefit of their systems, providers in Colima, Mexico, and Eswatini noted that their consultations were now longer—not because they were interacting with their patients, but because they were keying information into their computers.

[3] These are accuracy, completeness, reliability, timeliness, confidentiality, precision, and integrity. Source: MEASURE Evaluation. (2017). Data quality audit tool. Chapel Hill, NC, USA: MEASURE Evaluation, University of North Carolina. Retrieved from https://www.measureevaluation.org/resources/publications/ms-17-117

Health Finance

Health financing greatly influences the development, implementation, and sustainability of a national-level EHR. Even when there is substantial donor support for the information system, there are direct and indirect costs for hardware, software, routine maintenance, and any necessary security enhancements. For example, in Eswatini, rooms that housed computers had to be secured from theft, so security bars were attached to the windows. The server room had to be temperature-controlled, so air-conditioning units were installed. There were also costs to network the health facilities internally and externally. Human resources costs also apply to the development and maintenance of the EHR, including training costs (which are continuous owing to staff turnover and the need for refresher trainings); change management; and logistics, such as transport and fuel costs. In Colima, some computers were obsolete or broken, or were not functioning optimally. There were no long-term technical support plans, supervision of users (to make sure they were using the EHR correctly) was not permanent, and training was temporarily interrupted when support from the state was halted. Additional costs arise in settings that use EMRs and convert to EHRs, because different systems must be integrated and made interoperable to capture a patient's health service consumption across facilities.

A well-functioning EHR can provide data that may be used to make decisions about national resource disbursement. One state-level director in Colima described how he used information from the EHR to determine the number of units needed when reordering medications. When asked how much medicine he needed, he replied, "'I'll have it in an hour.' We searched the system and it showed that two hundred thousand patients had been seen, how many drugs were dispensed, and thus we knew what we needed to buy."

Health Governance

Health governance are instrumental in laying the groundwork for HIS interventions. Specifically, for electronic and digital interventions, the American Health Information Management Organizations defines governance as: "…the process to ensure the availability, usability, integrity, and security of the data held by an organization" (Geetter & Van Demark, 2017).

Specific interventions should be linked to the overall health strategy for the country and clear policies are needed:

> *Experience shows that harnessing ICT for health requires strategic and integrated action at the national level, to make the best use of existing capacity while providing a solid foundation for investment and innovation. Establishing the main directions as well as planning the detailed steps needed is essential to achieving longer-term goals such as health sector efficiency, reform or more fundamental transformation.* (World Health Organization & International Telecommunication Union, 2012)

Therefore, it is important to have HIS and eHealth strategies to guide the development and implementation of an EHR. In Colima, there were no national guidelines for EHR development when the SAECCOL was first developed but international standards were followed. In 2010, a national standard (NOM-024-SSA3-2010) established functional goals that EHR system products should observe to ensure interoperability, processing standards, interpretation of data, confidentiality, security, and use of standards and information catalogs.

The development and implementation of an EHR can also be the catalyst for developing national policies and regulations. For example, specific standard operating procedures (SOPs) were needed when the CMIS began to be implemented in Eswatini. These included an SOP for data privacy, confidentiality, security, and recovery, which outlined the following considerations:

1. Maintaining data confidentiality;
2. Access control functions that limit access to health data to selected individuals, based on defined and documented roles and privileges;
3. Maintenance of a detailed audit trail of all events and activities happening within the CMIS system;
4. How to follow defined standard practices on logins and passwords (Administrative rights and security);
5. How to incorporate technical security functions in line with requirements regarding encryption and data transmission;
6. Ensuring data protection by meeting requirements for data backup, disaster recovery, and documentation of systems.

Medical Products, Vaccines, and Technologies

Ideally. a comprehensive EHR would provide information to managers and clinicians on the availability of medicines. But before this is possible, a country must have a national medical products availability and price monitoring system. Without it, the EHR will not be able to deliver or link to this information.

One function of an EHR is providing information on the use of medicines and other commodities, such as immunizations, to decrease or eliminate stockouts at specific health facilities. Managers in Colima reported that the SAECCOL had helped them feel confident when making management decisions or requesting resources for their facilities. "I am careful to look at what I produce and follow the quality indicators rules, and when I go to the Secretary, I feel my demands are justified," said one hospital director.

Human Resources for Health

The success of any new electronic system depends on human factors. People develop and use these systems, and their level of training and comfort with the system will greatly affect implementation of an EHR system. Providers must be adequately trained and re-trained to use new systems. This includes trainings before the implementation of the EHR and on-site support as the system is being rolled out. People's feedback on their experiences with the system allows the developers to adjust the EHR continuously to be user-centered and to align with the workflow. Users of SAECCOL and CMIS cited a lack of such on-site support. One provider in Eswatini said they were initially told someone would provide on-site monitoring and mentoring. She stated, "We had some [help] for a week or so when it was still new. After that they left. There is no one that is supporting us here."

The use of an EHR system can affect providers' job satisfaction. Many studies have found that when an EHR is working well and providers are satisfied with it, their overall job satisfaction can improve (Heyworth et al., 2012; Jones et al., 2013). However, this also means that if providers are unhappy with the EHR, overall job satisfaction may decrease. One provider in Colima, Mexico, told us that he would rather retire than use the new EHR system.

EHRs within the HISSM

The various components of national EHR implementation can be mapped out using the HISSM (Table 2). The HISSM provides a framework for understanding how different parts of the system interact.

Table 2. Components for successful EHR implementation

Enabling Environment		Information Generation		
Governance & leadership	**HIS management**	**Data sources**	**Data management**	**Information products and dissemination**
Agree upon data elements	Human resources for HIS	CMIS SAECCOL	SOPs	Facility and district reports
Legislation outlining data privacy, reporting requirements, etc.	Financial management		Institutionalized data quality checks	Data briefs
Partnerships and coalitions to leverage resources	Training and continuous education		Supportive supervision	Dashboards
Policies and guidelines	Infrastructure development		Data quality assurance	Data review meetings
Financial sustainability plan	Interoperability with other systems		User manual for the system	Annual statistical report

Enabling environment: Many of the components under "governance and leadership" and "HIS management" were discussed earlier, but some additional components must be considered. First is the importance of partnerships and coalition building. The successful implementation and meaningful use of EHRs requires support and input from many sectors. For example, in Eswatini, the Ministry of Health had to coordinate with the Ministry of Home Affairs (which managed the personal identification numbers that were used to uniquely identify people in the CMIS), the Ministry of Information, Communications and Technology (which maintains national network infrastructure), and the Ministry of Public Service (which manages human resources). To achieve full coverage and use of the EHR, private facilities and providers must also be incorporated.

Planning for training and continuous education is essential. With staff turnover and upgrades to the system, training cannot be viewed as a one-time event. In Colima, this meant establishing partnerships with medical schools for pre-service training: The University of Colima agreed to train all medical students to use SAECCOL, equipping the doctors with one more skill to provide high-quality service. After finishing school, doctors in Colima perform one year of community service at health centers or state hospitals before receiving their medical degree and continuing with their residency. Some rural health centers can be staffed primarily by these *médicos pasantes* (medical interns).

Another important component is interoperability. For two systems to be interoperable, they must be able to exchange data and subsequently present those data in a format that can be understood by a user (Healthcare

Information and Management Systems Society (HIMSS), 2013). The EHR is just one data source and system developers must ensure that EHR information can be exchanged with other electronic systems. Both Colima and Eswatini, encountered interoperability issues. In Eswatini, the lab information system (LIS) stores HIV viral load results and transmits them back to the ART clinic. CMIS is not currently interoperable with the LIS, so viral load tests do not automatically appear in the CMIS when results are available. Instead, a provider must correctly link a viral load test with a patient and manually enter the results into the patient's CMIS record.

Information Generation

The e CMIS and SAECCOL are data sources that required the development of data management procedures and products This effort included the development of SOPs. Eswatini developed multiple SOPs in addition to the one for data privacy discussed above. These covered the following areas:

- Assigning the unique identification (ID) to clients registered in the system
- Data governance
- Data management
- Data quality assurance (DQA)
- Data recovery

SOPs should also be developed to address power outages, computer problems, or network failures and ensure that data are entered in the EHR once the problems have been resolved. The missing data are problematic both for reporting purposes and quality of care, because providers will not have complete records for their patients.

DQA procedures are critical and must be adapted for systems that have gone 100 percent electronic, because the original DQAs were developed to verify data quality in paper-based systems (comparing the source document against values reported to higher levels). Beyond periodic DQA procedures, methods should be developed for facility managers or districts to assess data quality at the facility level. At the early stages of implementation, it is advisable to keep paper records that can be compared to the EHR and to prevent data loss while providers are still learning to use the electronic system. This does involve duplicate work for the users, and may be interpreted as a lack of confidence in system functionality.

In Colima, some facilities continued to use both paper and electronic records during the time-period of the case study owing to a lack of trust in the EHR, mainly because of blackouts and computer failures, and because the EHR's information may occasionally be inaccessible for lack of printers, ink, or paper since it was still necessary to print out records for some procedures. Eswatini decided not to keep official paper records once the facilities went live, although some facilities were asked to do so when they identified some potential problems with the CMIS. One region reported that it decided to do double-entry, because of a concern that data would be lost once the CMIS was implemented. The nurses objected, and demanded the facility choose one system.

The implementation of an EHR will fundamentally change how data are received, which may affect information products and dissemination. For information to be useful, the EHR should be able to produce customized reports based on the nationally agreed indicators. The CMIS in Eswatini and SAECCOL in Colima, Mexico, can generate reports by facility, which can be used by facility managers as well as supervisors

and decision makers. The electronic capability has made these reports available much faster. Staff members must be trained to read and use these reports, because they may not look exactly like the paper reports. In addition, monitoring and evaluation (M&E) staff members who use data generated from routine sources for quarterly and annual reports or annual planning must also be trained to use the data from an EHR. For example, the CMIS produces individual-based data, while the old system produced encounter-based data, which captured the total number of encounters and not unique encounters. The data sets looked different and the M&E team needed substantial support from the implementing partner to use CMIS data in its reports.

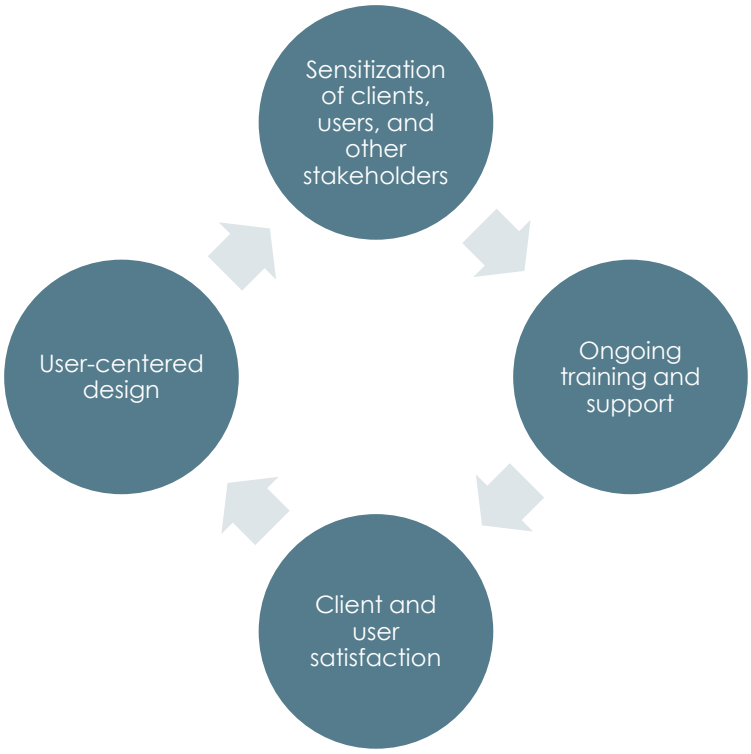
HIS Performance

EHR interventions, like other HIS interventions, need a strong M&E plan to help track the progress of system development and implementation. Monitoring should be in place from the start. This includes monitoring the process and evaluating whether the EHR is achieving its stated goals and objectives. There is a need for more evaluations of EHRs (Fritz et al., 2015).

Human Element

We must remember that the success of these systems relies heavily on the people who interact with them. They include the system developers and implementers, clinical and M&E users, patients, and other stakeholders who may invest in, support, or use data from the system. Figure 3 highlights some key areas of the human element to consider in the design of national EHR systems.

Figure 3. Key areas of the human element in EHR implementation



User-centered design (UCD) is particularly important for EHR systems. It is a process in which the user's needs are considered at each stage of design and development. UCD has four phases (U.S. Department of Health and Human Services, 2018):

- Specify the context of use: Identify the people who will use the product, what they will use it for, and under what conditions they will use it.
- Specify requirements: Identify any business requirements or user goals that must be met for the product to be successful.
- Create design solutions: This part of the process may be done in stages, building from a rough concept to a complete design.
- Evaluate designs: Evaluation—ideally through usability testing with actual users—is as integral as quality testing is to good software development.

Why is UCD important? System usability is associated with provider satisfaction. A survey of clinicians conducted by the American College of Physicians suggests that dissatisfaction with the EHR's ease of use increased from 23 percent in 2010 to 37 percent in 2012 (American College of Physicians, 2013). In 2014, the Office of the National Coordinator of Health Information Technology (ONC) in the United States Department of Health and Human Services added usability process requirements and testing requirements to the Standards and Certification Criteria for EHR certification (Department of Health and Human Services, 2012). In both Colima and Eswatini, providers complained about certain program features and felt that clinicians were not consulted enough during the design of the EHR systems. Usability and user satisfaction are critical, and there are examples of providers who have stopped using EHRs that did not meet their criteria (Tilahun & Fritz, 2015).

Preparing both clients and providers for the adoption of an EHR is important. These systems change the client experience (how they register, make appointments, identify themselves to access their information, and what they experience during consultation) and this must be taken into consideration. System users may be clinical or nonclinical and all need to prepare for changes. Nonclinical users include United States government implementing partners (IPs). In Eswatini, when there was a reduction in key indicators at the start of the CMIS, one IP respondent said:

> … immediately when CMIS rolled out in facilities, you would find that the numbers are drastically falling. Like there would be fewer cases, fewer people seen, and things like that. Of course, we know that previously there were more repetitions…we expect that there would be a drop. However, I think the drop was so huge.

The drop was a major concern for clinical IPs who are responsible for PEPFAR indicators and have targets to achieve. The targets were set based on the previous method of collecting health information, which was not individual-based. It may be necessary to revisit how targets are set based on the individual-level data that the CMIS can collect.

Contextual Factors

Many possible contextual factors can affect the success of an EHR. One is international donor priorities. A study of 16 countries' information and communications technology use to improve health financing and delivery found that almost half of the health IT projects in these countries are donor funded (Lewis,

Synowiec, Lagomarsino, & Schweitzer, 2012). This may be true in the early stages of EHR development and deployment, but financial plans must be developed to ensure that the system lives beyond the donor commitments. Another major contextual factor is the general IT infrastructure of a country. Adequate technology and infrastructure must be available for a country to roll out an EHR at the national level. In many cases, technologies can be imported and adapted in-country, such as the DHIS 2 software platform and the Open Medical Record System (OpenMRS). These are open-source examples. Proprietary technology may have drawbacks if the country never gains ownership of or develops the capacity to modify the system. This was one reason Eswatini decided to develop its own system rather than to adapt an existing system. Many low- and middle-income countries do not possess consistent power supplies, much less a well-developed Internet or wide area network (WAN). Both Colima, Mexico, and Eswatini experienced power outages that interrupted the systems. During the Colima case study, in 2011, not all of the facilities using SAECCOL were connected by WAN, and the Colima state health office was in the process of copying all of the EHR data produced throughout the state from flash drives or computer discs to a central server. Eswatini originally planned to connect all facilities to the WAN, to allow for rapid transmission of information, but the Ministry of Health had no control over which facilities would be connected via the WAN, because this connection was the responsibility of the telecommunications sector. To avoid further delaying the implementation, some health facilities went live without the WAN connection, and must synchronize manually, which occurs weekly, every two weeks, or monthly (answers varied). This means that if a patient registers in facility X, and then tries to get services at facility Y before the scheduled synchronization, facility Y will not find the patient in the system. Implementing CMIS at facilities without a WAN connection increased system coverage in the country, but it meant that the CMIS did not function as it was originally intended.

DISCUSSION AND CONCLUSION

Developing and implementing a national EHR is a complicated process that fundamentally changes how clinical care is delivered and reported within a country. EHRs are becoming a popular HIS intervention, but many factors must be considered before the process begins.

- EHRs have the potential to improve continuity of care and reporting, but the intervention must be considered in the larger context of the health system. This includes understanding how the other core functions of the health system (leadership and governance, human resources for health, health financing, service delivery, medical products, vaccines, and technologies) may affect the successful implementation and use of the EHR and how the EHR will affect the other core functions.

- EHRs are costly to implement and maintain. The legislation in the United States has provided incentive payments, but cost is an ongoing concern. The total cost of an EHR deployment is estimated to be approximately US$120,000 per physician in the first year after implementation, with annual recurring costs of US$30,000 per physician (Fleming, Culler, McCorkle, Becker, & Ballard, 2011). This is not a one-time cost, so a clear plan for financial support is necessary.

- Expectations about the EHR's capabilities should be managed. Promoting the advantages of a new, innovative system over the current paper-based system is natural, but users and stakeholders must understand that there are limitations, so they will not be disappointed when the system does not always work as they had hoped. In many instances, the EHR is another data management tool. It should not be expected to solve problems with data collection or service provision. For example, some respondents in Eswatini cited the potential of the CMIS to help improve retention of HIV-

positive clients on antiretroviral therapy and loss to follow up. While this is reasonable (if the CMIS provides a list of people who missed their appointments), the CMIS will not improve retention all by itself. When asked about existing policy or guidelines for following up with patients who have missed appointments, the respondents could not identify any. A lack of national standards can result in staff across the country using different procedures to follow up with clients who have missed appointments. Before assessing whether the CMIS assists in this process, the strength of the current patient follow-up system must be examined.

- Stakeholder coordination is crucial for successful implementation and use of an EHR, and often involves a large and diverse group of people and organizations, because the health sector in low- and middle-income countries often has many actors: for example, national ministries of health, education, and technology; health facility staff and managers; international donors; United States government implementing partners; local nongovernmental organizations; telecommunications providers; and clients.

- The EHR cannot be viewed as a data source only. Other pieces of the enabling environment are needed, such as strategic plans, SOPs, and other guiding documents that outline the clear purpose of the EHR and how to manage it.

- UCD is essential. Ultimately, EHRs must meet the needs of clinicians, who must be satisfied with the systems to use them correctly.

- Despite the increased popularity of EHRs and EMRs, additional assessments of these systems are needed. Evaluation studies with strong methods and comprehensive reporting should be conducted, to create best practice recommendations for future EMR/EHR implementation projects.

EHRs can be great tools to improve continuity of care and the availability of data for decision making, but significant effort is required to achieve meaningful use. Implementation projects for EHR applications in low- and middle-income settings must be planned carefully and be based, ideally, on best practices, to avoid wasting scarce resources. Implementers and policy and decision makers must address a myriad of factors to achieve success.

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