Practical Toolkit for Health Information System Evaluation

A systematic, comprehensive, structured, and practical knowledge base for conducting HIS evaluations in global, resource-limited settings

Working Draft: November 30, 2017

I-TECH
International
Training & Education
Center for Health

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Section 1:
Introduction

Why HIS Evaluation?

Over the past decade, low and middle-income countries have made significant investments in digitization of national health information systems (HIS). The World Health Organization (WHO) recognizes HIS as a foundational building block of health systems. The goal of investments in digital HIS, also known as eHealth systems, is to have timely, complete, easy-to-use, and relevant information for understanding needs and gaps and guiding health programs.

The success of digital HIS investments is not guaranteed. There are many reasons that HIS can fail to achieve their intended purpose either alone or in combination, such as poor design, inappropriate fit between technology solutions and available infrastructure, gaps in human capacity to use and maintain HIS, lack of standards for interoperability of systems, and many other reasons. On the other hand, there have been many promising innovations and small-scale successes, even in settings with very constrained resources. However, there are few examples of HIS interventions in resource-limited settings that have demonstrated enduring success

> **KEY TERMS DEFINITION**
>
> According to the International Standards Organization (ISO) a health information system (HIS) is a "system that combines vital and health statistical data from multiple sources to derive information and make decisions about the health needs, health resources, costs, uses, and outcomes of healthcare." (ISO/TR 14639-1:2012).
>
> A national HIS refers to the full set of information tools used to manage health data at all levels, including systems such as:
> - health management information systems (HMIS) used for monitoring and evaluation (M&E),
> - electronic medical records (EMRs)
> - laboratory information systems (LIS)
> - mHealth tools used by health workers and clients,
> - human resources information systems (HRIS) for tracking data on health workers
>
> A national HIS also includes infrastructure and policies that regulate system interoperability, data standardization, and data use.
>
> HIS can include paper-based as well as computerized systems. Many recent efforts to strengthen HIS have involved transitioning to computerized or digital tools. In using the term 'HIS,' we focus on digital health, including both eHealth and mHealth innovations.

when used at large-scale. And interoperability remains a goal that has not been widely met. Moving from a stage of early promise of HIS to a stage of stable, enduring success at a national scale is a true challenge.

Along the pathway to scale-up, careful monitoring and evaluation is essential in order to understand what is working and what is not working as expected. There are multiple reasons to carry out evaluation (see box). In resource-limited settings, where it is so critical to avoid wasting resources on ineffective strategies, HIS evaluation is of particular importance. Evaluation results can be used to guide course corrections and decisions about what to do next.

Reasons for HIS evaluation

- Inadequate assessment of needs and requirements before developing, customizing, or implementing digital health systems and tools can result in a suboptimal fit between stakeholder needs and tool/system design.

- Interventions moved to scale without adequate evidence of success at a demonstration scale can lead to expensive failures.

- Organizations are more willing to adopt potentially useful technology when there is strong evidence about its implementation and effectiveness.

- End-users can be reassured when there is evidence that systems support patient safety and health.

- Funders can become fatigued when investing in HIS in the absence of evidence about the results of these investments.

- HIS evaluation can demonstrate compliance with legal requirements.

Sources: Clarke, 1994; Cresswell, 2016

Despite the potential value of thoughtfully-conducted HIS evaluation, it has often not accompanied investments in HIS in low-resource settings. Indeed, in 2011 a group of HIS evaluation experts from around the globe, convened by the World Health Organization (WHO) and the Rockefeller Foundation, issued a "call to action" for increased attention to eHealth evaluation in global settings (Bellagio eHealth Evaluation Group, 2011). Noting the significant investments in eHealth projects, and the potential of these investments to catalyze performance of health systems toward reaching health and development goals, the group put forward nine principles to guide eHealth evaluations (see box below). These principles emphasize the importance of using evidence from systematic, rigorous evaluations to guide investments.

Bellagio eHealth Evaluation Principles

- Core principles underlie the structure, content, and delivery of an eHealth system independent of the rapidly changing technology used.

- High quality data collection, communication and use are central to the benefits of eHealth systems.

- Evaluating eHealth both demonstrates its impact and fosters a culture that values evidence and uses it to inform improvements in eHealth deployments.

- To ensure the greatest benefit from eHealth and enhance sustainability and scale, eHealth evaluations should recognize and address the needs of all key constituencies.

- Evidence is needed to demonstrate costs and benefits of eHealth implementations, and maximize eHealth's beneficial impact on health system performance and population health.

- The value of a complete evaluation program is enhanced through research that is attuned to the differing requirements throughout the life-course of the project, whether at needs assessment, pilot-, facility level-, regional and national scale-up stages.

- Independent and objective outcome-focused evaluation represents the ideal of impact evaluation.

- Country alignment and commitment to a clear eHealth vision, plan, and evaluation strategy is essential.

- Improving the eHealth evidence base requires more than increased numbers of studies but also improved quality of eHealth research studies.

Source: *Call to Action on Global eHealth Evaluation: Consensus Statement of the WHO Global eHealth Evaluation Meeting, Bellagio, September 2011* (p. 3).

Why an HIS Evaluation Toolkit for Low-Resource Settings?

It could be easy to consider rigorous evaluation of HIS as a "luxury" since it is one more thing that requires specific technical expertise and investment of financial resources. The purpose of this HIS Evaluation Toolkit is to provide Ministries of Health and their partners in low-resource settings practical resources designed to ease the planning, design, conduct and use of sound HIS evaluations, even in the context of limited resources.

There are many challenges in conducting timely, relevant, credible, and useful evaluations across the stages of HIS strengthening projects. They include:

- Lack of awareness of a range of evaluation designs.

- Limited explicit consensus on best practices in designing and carrying out HIS evaluations, including rigorous qualitative and mixed-method evaluations.

- Methodological challenges in designing valid evaluations for interventions that a cross-cutting and complex.

- An absence of standardized, validated measures and tools for HIS evaluation.

We designed this toolkit to address these challenges by providing practical resources for HIS evaluation such as best practices, case scenarios, and templates that Ministries of Health and their partners can adapt for specific HIS evaluation goals.

Context for HIS Evaluation Toolkit Development

HIS and the 90-90-90 Cascade for HIV Epidemic Control

As of 2017, the global HIV/AIDS epidemic has caused more than 35 million deaths, and HIV/AIDS remains among the top causes of preventable deaths in many low-resource countries, particularly in Africa. The US President's Emergency Plan for AIDS Relief (PEPFAR) is supporting the goal of HIV epidemic control by 2030. As a part of reaching this goal, PEPFAR has embraced the so-called "90-90-90" targets that:

- 90% of people living with HIV are diagnosed and know their status;
- 90% of those who are diagnosed initiate treatment; and
- 90% of those on treatment achieve HIV virologic suppression.

Many resource-limited countries have made impressive progress in extending HIV prevention and treatment; however, there is still a long way to go to achieve the 90-90-90 targets.

A robust and efficient national HIS is a critical enabler of progress toward 90-90-90 targets. When successful, HIS provide real-time, localized evidence about progress and gaps along the HIV care cascade. The systems can help pinpoint hotspots in HIV disease burden, where skilled health workers are deployed, and which patients, sites, and regions are facing challenges in meeting the targets along the HIV care cascade. Well-functioning HIS can reduce data errors, improve turnaround times for laboratory results reaching clinicians, shorten patient wait times, promote adherence to clinical guidelines, and help identify patients who have missed appointments. These elements can combine to improve quality and accessibility of health care services, therefore leading to improved patient health outcomes.

There are multiple software systems within a national HIS that can contribute to the HIV care continuum and the 90-90-90 targets, as shown in Figure 1. When these systems are in place, it becomes possible to manage the complex and multi-faceted types of data which are essential to population level services for HIV prevention, screening, care and treatment, including longitudinal person-level data, aggregated service performance data, data on supplies and commodities, data on health sector personnel, and other types of data in both community and health facility settings.

Figure 1: Systems of National HIS Contributing to PEPFAR 90-90-90 Targets

Generalizing HIV-Related HIS within the Broader Health System

This toolkit focuses on evaluating HIS software systems that serve the HIV care cascade and 90-90-90 targets. Although many recent investments in HIS in low and middle-income countries have been motivated by the specific needs of HIV programs, the same HIS designed for HIV programs can be leveraged and generalized to serve the national health system more broadly, beyond HIV-specific programs and services. Table 1 lists HIV-related HIS and similar systems in other areas of health with parallel scope or purpose.

The practical resources contained in this Toolkit can be leveraged and adapted to HIS interventions which serve other health programs. For example, while the examples and cases are drawn from HIV, we give explanation about their relevance to other health program areas.

Table 1: Relationship of HIV-Related HIS to HIS for Other Health Program Areas

HIS system type	Relationship to 90-90-90	Related systems outside of HIV
HIV testing data system	Supports HIV case detection, screening (first 90%)	Primary care data systems with data on health screening Data system for cardio-vascular disease screening
Electronic medical records (including clinical decision support tools and computerized provider order entry systems)	Supports HIV patient diagnosis, clinical management (first, second, and third 90%)	Can be generalized to all primary care programs (beyond HIV)
Pharmacy information system	Supports management of HIV therapies, tracking of ART adherence, forecasting of drug inventory needs based on clinical case data (second and third 90%)	Can be generalized to pharmacy stock management for all programs (beyond HIV)
Laboratory information system	Supports diagnosis, monitoring for ART treatment effectiveness and side effects (first, second, and third 90%)	Can be generalized to laboratory orders and results management for all programs (beyond HIV)
Radiology information system	Supports screening and diagnosis of TB and other conditions affecting PLWHA (second and third 90%)	Can be generalized to imaging services for all programs (beyond HIV)

Patient-facing mHealth tools	Health promotion outreach and patient engagement (first, second, and third 90%)	Health and wellness apps Any patient-facing tool to promote referral, linkage to care, adherence, and retention
Provider-facing mHealth tools	Patient panel management, workload management (first, second, and third 90%)	Messaging systems for transmitting orders and samples between clinical and reference laboratories
HIV case registry	Tracks cases for longitudinal follow-up, supports cascade analysis (first, second, and third 90%)	Immunization registry Cancer registry Chronic disease registry for management of heart disease, diabetes, etc. Any other registry used to manage and track referral, linkage to care, adherence, and retention
HIV case surveillance system	Tracks minimum core dataset for national analysis of disease burden, met and unmet need (first, second, and third 90%)	Infectious disease surveillance reporting systems Chronic disease surveillance systems
Health management information system (HMIS) or district health information system (DHIS)	Supports program reporting (first, second, and third 90%)	Can be generalized to all primary care programs (beyond HIV)
Logistics management information system	Supports rational stock management for HIV test kits and other lab supplies, pharmacy supplies, and other consumables (first, second, and third 90%)	Can be generalized to all primary care programs (beyond HIV)
Unique person identification system and master person index	Foundational system for linking patient records and ensuring continuity of care (first, second, and third 90%)	Can be generalized to all primary care programs (beyond HIV)
Master health facility list	Foundational system for consistently identifying service delivery points (first, second, and third 90%)	Can be generalized to all primary care programs (beyond HIV)

An example demonstrating how HIV-related HIS infrastructure can be leveraged toward broader health system needs comes from the Ebola epidemic in West Africa in 2014-2016. During the outbreak, HIS were leveraged to support disease surveillance and case finding, clinical care of patients with active Ebola infection, and overall monitoring of healthcare activities. While government health systems and partner organizations deployed a number of HIS during the crisis, only a handful proved effective due to the very short timeline and the

lack of staff and infrastructure. The effective HIS included three open-source systems developed initially with funding from PEPFAR and other funders to support the scale up of HIV care in Africa:

- **District Health Information System (DHIS2)**—this system provides a range of well tested tools to manage aggregate data typically from health facilities. During the Ebola crisis, Liberia used it for case surveillance.

- **OpenMRS**—a modular electronic health records system used for managing patient data worldwide. During the Ebola outbreak, Sierra Leone leveraged a modified version to support clinical care.

- **Commcare**—an mHealth tool initially designed to support community health workers collecting data on and tracking patients. During the Ebola epidemic, Nigeria used it for case management initially and then Guinea and Sierra Leone deployed it for contact tracing.

HIS Evaluation Framework

A framework is a useful, structured way of organizing ideas about how an intervention reaches its goals (WHO guide, 2017). There are multiple useful frameworks for HIS evaluation in low-resource settings (Khodja, 2013; Eslami Andargoli, 2017). Our framework recognizes three inter-related aspects of HIS interventions: system type, maturity level, and domains. Being able to describe each of these aspects with regard to a particular HIS intervention can help to clarify what is most useful to learn through evaluation. Articulating these aspects is part of developing a HIS evaluation design that makes sense.
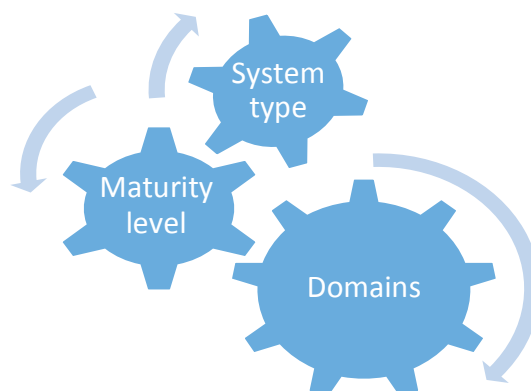
> **System type:** Multiple software application make up a national HIS. Defining the distinct goals and features of the system of interest is one part of the HIS evaluation framework. What value does the system of interest seek to add within the national HIS (also known as "value claims")? Useful HIS evaluation seeks to measure in a valid manner whether and how different HIS systems fulfill their value claims.

> **Maturity:** Maturity of HIS can be described in terms of level of scale within the health system. Does the system exist on a pilot basis in a limited number of health facilities or communities? Or, is it implemented widely across multiple districts or even on a fully national scale? Maturity of HIS can also be described in terms of level of advancement

toward best practices (which can also be thought of a the degree of robustness or quality). To what degree does the system embody standards and best practices? Useful HIS evaluation seeks to measure level of advancement, or quality.

Domains: HIS are socio-technical systems that rely on the complex interplay of humans and technology. It is important for HIS evaluation to examine this complex interplay in order to uncover "what works" and "why". Domains can be thought of as the ingredients or factors that affect the success of HIS. Useful HIS evaluation seeks to examine a range of domains affecting HIS success including health, human, technology, organization and governance, health-sector business process, and economic domains.

"One size fits all" does not apply in HIS evaluation design. Evaluation designs must consider the system type, its maturity level, and the multiple domains that contribute to success. This Toolkit provides resources on evaluation of different system types at different stages of maturity. We recognize that HIS evaluation is strongest when it considers a full range of factors that affect implementation processes and results, so the Toolkit discusses and promotes measurement across a comprehensive set of domains.

Moving from HIS Evaluation Framework to HIS Evaluation Roadmap

In recent years, in conjunction with e-government initiatives, many resource-limited countries have developed national eHealth strategies. These are important aspirational roadmaps. Yet there is often a great distance between the expressed vision and the current reality. In moving across this distance, HIS development does not happen all at once, but rather goes through steps in scale-up and maturation. The HIS Evaluation Framework described above can be useful in defining the evaluation goals, questions and methods for any single HIS evaluation at a particular point in time. However, it is important to take a longitudinal perspective to building evidence about "what works," because a single evaluation at a single point in time cannot answer all important questions.

It is beneficial to plan for evaluation at multiple time point, as countries proceed on the pathway toward a long-term eHealth strategy. A HIS evaluation roadmap can be an important part of a national eHealth strategy. Such a roadmap can clarify the evaluation questions that need to be answered at various stages, such as:

- What improvements need to be made in order for HIS tools to fulfill their purpose?

- Which innovations, solutions, technologies, and HIS projects should be scaled-up?

- What costs need to be covered in order to maintain and sustain systems?

The HIS Evaluation Framework is relevant to conceptualizing a national HIS evaluation roadmap. Different evaluation questions are relevant at different stages across different HIS. An HIS evaluation roadmap helps Ministries of Health and other stakeholders to prioritize what is most important to learn, and when. Because evidence from HIS evaluations can guide national decisions on the pathway toward a long-term eHealth strategy, developing a HIS evaluation roadmap is an important function of HIS governance.

Figure 2 is a schematic of the possible pathway of progress for any type of HIS system. Figure 2A expresses the idea that a system matures over time, and that a system's maturity includes both its scale of implementation and its level of advancement toward best practices. Figure 2B demonstrates the idea of an HIS evaluation roadmap which includes both monitoring for continuous quality improvement over time, as well as periodic systematic evaluations that can inform whether a system is suited to be scaled up, among other questions. The concept of a system's maturity, and how it plays into the design of monitoring and evaluation of HIS, is discussed further in Section 2. An HIS evaluation roadmap can support the planning for the resources and expertise necessary to conduct evaluation at various time points in HIS development and implementation.
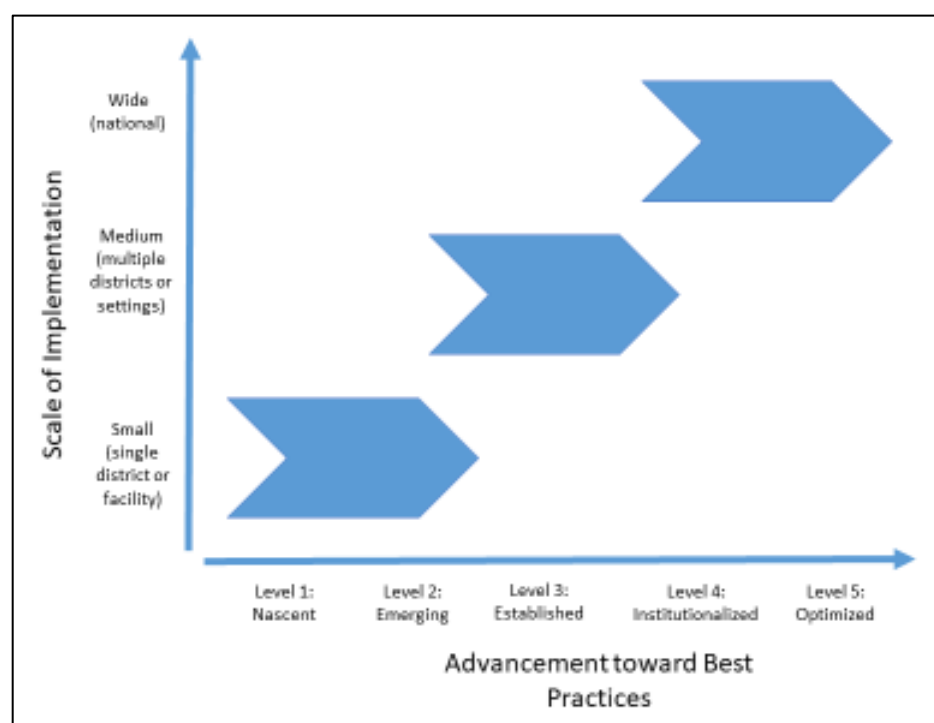
Figure 2A. HIS Maturity
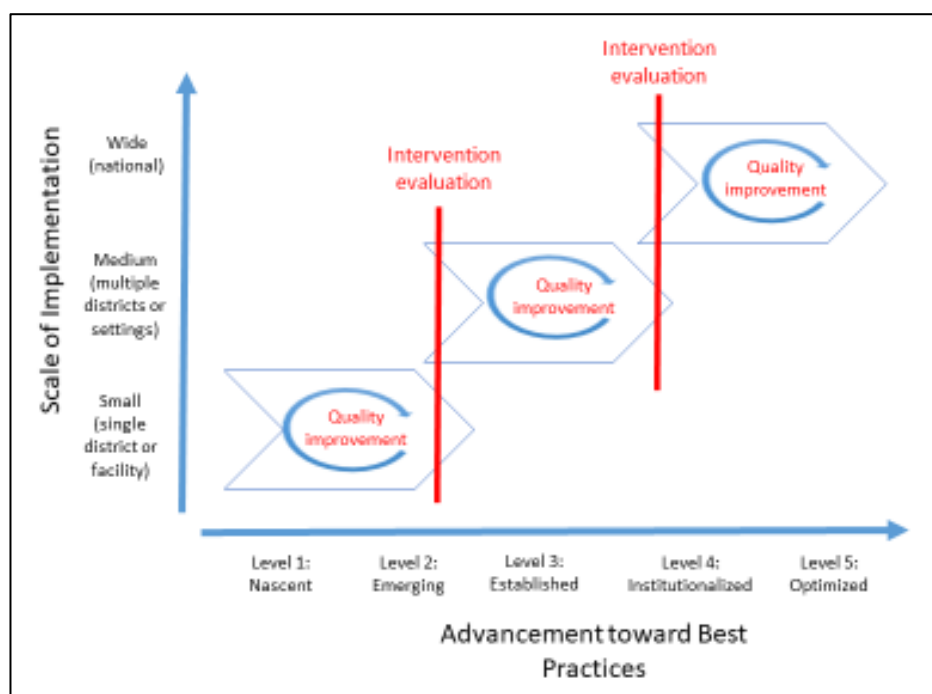
Figure 2B: HIS Maturity Framework and Overlaid Evaluation Roadmap

What Does the Toolkit Include?

This Toolkit provides a set of practical resources for planning a HIS evaluation roadmap, or for designing and conducting a specific HIS evaluation. These resources include:

Planning Guide for HIS Evaluation. This brief guide follows the steps of carrying out a HIS evaluation, and synthesizes best practice guidance from the US Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and academic thought leaders.

HIS Evaluation Case Scenarios. These teaching cases outline how to design HIS evaluations for different types of systems, at different stages of maturity, and with an emphasis on different domains. Each case scenario offers two evaluation study designs: 1) an operational evaluation design seeking rapid, on-going evidence to guide system quality improvement; and 2) a research-oriented evaluation design seeking to carefully and scientifically answer process and outcome evaluation questions.

HIS Evaluation Domain Map. This domain map is grounded in theories of HIS success, reflecting the mechanisms that produce the results of a HIS. The map includes a listing of sub-domains, which are conceptually-distinct factors or processes within the broad umbrella of

each main domain. Each sub-domain reflects a construct or concept which could be distinctly measured within a HIS evaluation.

Supplemental Practical Tools and Resources. The Toolkit includes additional resources that can be customized for developing a setting-specific HIS evaluation protocol or terms of reference document for engagement of an evaluator or evaluation firm. The supplemental practical tools and resources include a generic HIS evaluation protocol template, and tips and considerations for scientific and ethical review of each case scenario.

Compendium of Measures and Instruments. This compendium lists, classifies, describes, and provides links to specific measurement instruments and tools which could be used in an HIS evaluation. The description includes prior uses and type of validation performed.

Literature Reviews and Annotated Bibliographies. In recent years, the body of guidance and evidence on HIS evaluation has increased tremendously. There are three distinct annotated bibliographies: 1) bibliography of major HIS theories and frameworks; 2) bibliography of best practices in HIS evaluation; and 3) bibliography of exemplary HIS studies. The theory bibliography provides generalized concepts about how and why HIS work; theories can be used to guide and select evaluation questions. The best practices bibliography provides references for more in-depth discussion of considerations when planning and carrying out HIS evaluation. The exemplary studies bibliography provides model studies that could be replicated in whole or part in other settings.

Who Is the Audience for This Toolkit?

The primary audience for this toolkit is Ministry of Health units responsible for HIS in resource-limited countries that are interested in evaluating eHealth and mHealth interventions across various stages of maturity. We use the lens of implementing HIS projects in PEPFAR-supported countries throughout this document to illustrate guidance, evaluation concepts, and case scenarios. Secondary audiences include other eHealth and mHealth technical implementers, funders of HIS-strengthening projects, program evaluators, and academics and students working in resource-limited countries.

Often those engaging in HIS evaluation come with deep expertise in either health informatics or research and evaluation methodologies (deep expertise in both realms is rare). This toolkit is intended to demonstrate best practices in research and evaluation methods to those who come from the health IT world, and the unique context and concerns of health IT projects to those who come from the research and evaluation world.

Section 2:

Practical Guide for HIS Evaluation

Overview of the HIS Evaluation Process

Evaluating your HIS deployment is an important undertaking that will have a lasting effect on the direction that your health system takes in implementing digital health systems and technology. HIS evaluation is a multi-step process that involves a deep understanding of the project's purpose, stakeholders, HIS attributes, evaluation questions, and available resources. Below is a preview of the overall HIS evaluation process described in this toolkit through Actions 1-11:

Action 1: Describe project goals and stakeholders

Emphasizes the importance of identifying project goals and key stakeholders whose engagement throughout the evaluation lifecycle is essential for evaluation success.

Action 2: Identify the system type

Describes how clearly understanding the system type of interest helps focus the evaluation design.

Action 3: Identify maturity level of system

Defines HIS maturity, describes various maturity models and discusses the relevance of system maturity for defining the evaluation focus.

Action 4: Identify value claims, develop logic model, and recognize potential risks

Describes how value claims, logic models, and the potential risks from your HIS deployment shape the evaluation questions.

Action 5: Develop a Monitoring and Evaluation (M&E) plan

Discusses the difference between the monitoring and evaluation portions of the M&E plan and how these fit into the overall evaluation roadmap.

Action 6: Identify theories and domains relevant to your evaluation

Reviews the use of HIS evaluation theories and domains and how they can be incorporated into designing an evaluation.

Action 7: Select and refine evaluation questions

Describes how to frame and define evaluation questions based on the purpose of the evaluation.

Action 8: Develop the evaluation study design

Describes the differences between process and outcome evaluations. Reviews the possible types of study designs that can be used for answering evaluation questions, along with potential biases that should be considered when developing a study design.

Action 9: Develop the evaluation protocol

Describes the sections of a protocol and what content should be included along with guidance on completing an ethical review of a protocol.

Action 10: Determine who will carry out M&E activities

Describes a brief summary of how an evaluation team can be established.

Action 11: Defining an M&E implementation plan and reporting the findings

Describes developing of an implementation pan's activities, persons responsible, timelines, budgets, and how to deliver evaluation results.

Action 1:
Describe project goals and stakeholders

HIS evaluations encompass many complexities that need to be well defined prior to the start of any activities. Describing your HIS type, along with articulating the evaluation goals, activities, outputs, and expectations can greatly benefit your evaluation plan by bringing structure to your project and can help prevent implementation challenges and misunderstandings between stakeholders.

Describe the project's health system goals

Prior to developing your evaluation plan, start with creating a broad description of your program, project, intervention, or innovation and its alignment with specific health system goals, for instance the 90-90-90 targets. Health systems' goals typically can be grouped into three main categories:

- improving access to health programs or services within the population;
- improving quality of health services; and
- improving efficiency of health services.

Some HIS interventions may try to address all three categories of goals equally, while others may prioritize one of the goals over others. Contextualizing the health system goals and needs

of your project is important for communicating with others surrounding the evaluation efforts as well as engaging with stakeholders.

The health system goals may be modified during the course of the evaluation planning as new information is introduced and goals redefined. Continue to engage with stakeholders during this process. Once you feel comfortable with the project's goals, attempt to make them as specific as possible, as this will help to better guide your value claims, evaluation questions, and study design.

Engage Stakeholders

Stakeholders should be engaged prior to the design and implementation of any HIS evaluation. These entities bring various perspectives about the goals and objectives they are most interested in seeing as part of the evaluation. Consider stakeholder competencies to ensure there is an equal representation of expertise to provide input and develop a comprehensive evaluation.

Mapping Stakeholders

As early as possible, it is helpful to identify those stakeholders who may have a vested interest in any or all stages of the HIS lifecycle. There are three major groups that stakeholders fall into:

- Staff involved with program operations
- Clients of the health system affected by the HIS intervention
- Users of the evaluation findings

Steps for Mapping Stakeholders:

1. Develop a list of key stakeholders associated with the project or intervention; refer to this list during each phase of the intervention, as stakeholders may change. Consider including actors at different levels of the digital health system, such as providers, patients, health service managers, software developers, and Ministry of Health staff.

2. Use a tool, such as a Stakeholder Matrix (Figure 3), to map out all possible stakeholders. Making this matrix helps prioritize them and determine when they should be involved in the evaluation process. For your own stakeholder mapping, use the template in Appendix 3A.

3. Identify the best communication channel(s) for each stakeholder, to ensure they remain active in the project, and can easily communicate any concerns or suggestions.

4. Continuously engage with stakeholders as the evaluation progresses; ensure they are included in key decision-making steps.

Stakeholder Name and Brief Description	Level of Knowledge of the Issue	Interests in the HIS Intervention	Available Resources	Potential Roles in the Evaluation Process	Engagement Activities
	What is their specific expertise?	*What are the stakes from their perspective?*	*What are material or technical resources do they bring to bear?*	*Sponsorship, planning, adapter, implementer, analysis, communication*	*What specific activities should they be involved in?*

Figure 3. Sample stakeholder matrix

Ongoing Stakeholder Engagement

Once stakeholders are identified, interactions with them occur throughout the evaluation.

Stakeholder Engagement before the Evaluation is Designed

Initially, prior to the design of an evaluation, it is imperative that all stakeholders can agree on one description of the program or intervention. By having a common understanding, decisions concerning the direction of the evaluation can be made more efficiently. When undertaking the activities that describe the HIS you wish to evaluate (detailed in Actions 2-4 below), you may find it helpful to implement the following steps with your stakeholders:

1. Create process-flow diagrams to indicate how data, communications, or personnel flow within the system.

2. Refer to the diagram throughout the evaluation design process and its implementation to ensure that all stakeholders understand which HIS aspects the evaluation will cover.

3. Update the diagram as needed.

Stakeholder Engagement after the Evaluation Starts

Once the evaluation has been launched and data collection initiated, continue communicating with your stakeholders. Share any updates to the evaluation design, preliminary results, and general progress of the planned activities. Allow stakeholders to provide comments during the evaluation as best fits with the timeline of evaluation activities. The following steps may help you be effective in keeping stakeholders involved:

1. Designate which evaluation activities each stakeholder will be responsible for completing, if any; accommodate their needs as much as possible.

2. Update stakeholders if any major adjustments are made to the evaluation plan, or if there are any unexpected events or complications.

Action 2: Identify the system type

Being clear about the type of system that your evaluation will focus on is important to complete early in the evaluation process. Your system type will help define value claims and evaluation questions. (Labrique et al (2013) developed a framework for classifying and describing mHealth and ICT interventions. They justly note that "The absence of a shared language and approach to describe mHealth interventions will continue to hinder efforts to identify, catalog, and synthesize evidence across this complex landscape. The lack of a common framework also makes it hard to explain mHealth innovations to mainstream health-sector stakeholders." They propose a classification centered around health system goals which includes the types of systems summarized in Figure 4. Table 2 links these classifications to the 90-90-90 care cascade.

Figure 4. HIS Types Classified by Health System Business Processes *(Source: Labrique, 2013)*

Table 2. System Types Serving the 90-90-90 Care Cascade

HIS system type (90-90-90 care cascade)	Standard system type (Labrique, 2013)
HIV testing data system	Type 3: Registries / vital events tracking
Electronic medical record (including clinical decision support tools, and computerized provider order entry systems)	Type 5: Electronic health record Type 6: Electronic decision support Type 8: Provider workplanning & scheduling
Pharmacy information system	Type 5: Electronic health record Type 6: Electronic decision support Type 8: Provider workplanning & scheduling Type 11: Supply chain management
Laboratory information system	Type 5: Electronic health record Type 6: Electronic decision support Type 8: Provider workplanning & scheduling Type 11: Supply chain management
Radiology information system	Type 5: Electronic health record Type 6: Electronic decision support Type 8: Provider workplanning & scheduling
Patient-facing mHealth tools	Type 1: Client education & behavior change communication (BCC)
Provider-facing mHealth tools	Type 7: Provider – provider communication Type 8: Provider workplanning & scheduling
HIV case registry	Type 3: Registries / vital events tracking
HIV case surveillance system	Type 3: Registries / vital events tracking Type 4: Data collection and reporting
Health management information system (HMIS) or district health information system (DHIS)	Type 4: Data collection and reporting
Logistics management information system	Type 11: Supply chain management
Unique person identification system and master person index	Not described
Master health facility list	Not described

Further work is underway to develop a standard taxonomy for classifying eHealth and mHealth systems. This classification will be a welcome addition to the field, as it will help HIS evaluators align HIS evaluation resources (e.g., standard study designs) to HIS system types.

After articulating your intervention's health system goals, identify your system type and whether it falls into multiple categories. Be sure to describe your system type in detail, including any novel or unusual attributes that would be important to capture in the evaluation. When working with multiple stakeholders in particular, it is common for specific attributes or functions of a system to be unknown or overlooked. For this reason, a detailed description of the system will ensure all stakeholders share a common understanding.

Action 3: Identify maturity level of system

Maturity Level

Evaluation is beneficial at multiple stages along the pathway of HIS development. However, the evaluation focus will vary depending on the maturity of the system. The questions one naturally asks when piloting a new HIS solution are different than the questions one asks when implementing a system at wide scale. This difference is because the type and level of evidence one seeks varies depending on the maturity level.

What is HIS maturity? Various HIS experts have put forward slightly different, but related, ideas about how HIS maturity can be described. The WHO digital health evaluation guide describes early, middle, and advanced stages of maturity, with the distinction between the stages largely based on scale and number of system users (WHO, 2017). Khoja et al (2013) define four maturity categories—development, implementation, integration, and sustained operation—which follow a project lifecycle perspective. Fraser (2017) identifies five categories of maturity also based on project lifecycle: requirements gathering, design and development, initial deployment, scale up, and long-term use.

Figure 5 demonstrates our concept of HIS maturity, which includes a dimension of scale and a dimension of advancement. Scale refers to the breadth of implementation across settings and geographic units, from small or pilot scale to national scale. Advancement refers to the level of robustness of the HIS. Describing the level of advancement of a system is complicated, because many "ingredients" combine to contribute to a system's maturity. A system may be more advanced or developed in some ingredients and less advanced in others. Our purpose here is not to comprehensively and exhaustively describe levels of maturity, but rather to present a loose profile of the progression of HIS maturity.

Nascent systems continue to rely heavily on paper-based and manual processes for data collection and aggregation, lack standards, policies, and procedures, and have limited capacity to integrate data between programs, organizational units, and levels of the health system.

Emerging systems are more thoroughly digitized, partially integrate standards, include limited automated data exchange between the system and other HIS, rely on a modest ICT infrastructure, and embrace an ad hoc approach to workforce capacity development.

Established systems are fully digitized, embody accepted national and international standards, have stable automated data exchange between core HIS systems, embrace stable structures for ongoing workforce capacity development.

Institutionalized systems are fully digitized, have stable data exchange with both core- and non-core HIS systems, have strong procedures for data security and confidentiality, routinized data quality audits, stable integration of data across health programs, and workforce capacity to ensure system maintenance.

Optimized systems are part of a fully digital national enterprise architecture, embody international standards and best practices, participate in a fully-developed interoperability service layer, have strong compliance mechanisms, and engage strategic and financial planning for long-term relevance and sustainability.

Over time, a system can grow in scale without advancing toward optimization. Alternatively, a system or can move toward optimization without growing in scale. Our model recognizes that it is best for systems to move on the diagonal, toward both optimization and wide scale (Figure 5).
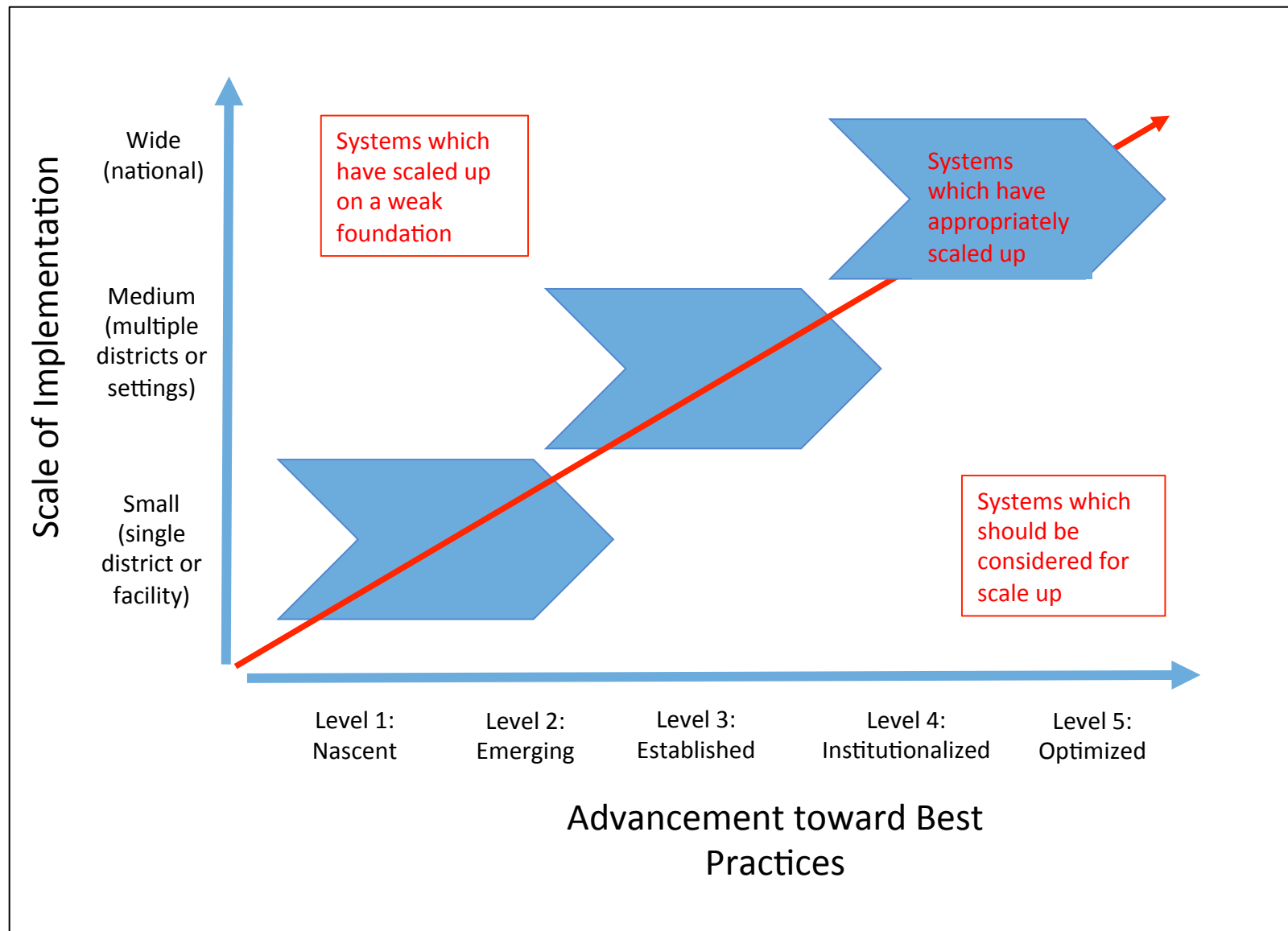
Figure 5. Advancement in Maturity: Towards Wide Scale and Best Practices

An example of a system that has scaled up on the diagonal is the OpenMRS electronic medical record system (EMR) in Kenya. The Kenya Ministry of Health developed national standards for EMRs in Kenya and evaluated candidate systems against the standards in order to recommend specific systems for scale up (Kanga et al, 2016). The OpenMRS-based KenyaEMR system was then implemented at more than 300 health facilities after a structured process of readiness assessment, remediation of IT infrastructure limitations, and training of health care managers and end users (Kanga et al, 2016; Muthee et al, 2017).

Hypothetical and real-world examples of systems falling at different points on the two dimensions of HIS maturity are shown in Figure 6.

- System A: An example is Excel-based registers implemented with manual transmission between facilities, to enable program-specific data aggregation and reporting across multiple districts.

- System B: An example is an EMR with standard taxonomies and data dictionaries, but no standards-based interfaces, implemented in several health facilities.

- System C: An example is an electronic pharmacovigilance surveillance tool that was scaled up nationally (Agoro, 2017). Potentially modifiable challenges included the system's dependence on Internet access that was inconsistently available in real-world settings, a lack of a culture of pharmacovigilance reporting or management support to handle reporting through the electronic tool, and difficulties downloading the mobile device (or 'app') versions of the system.

- System D: An example is a biometric identification system integrated within the HIS ecosystem in pilot regions, in a manner compliant with national policy and international standards.

- System E: An example is a standards-based, national-level integration of EMR, LIS, and SMS messaging for transmission of viral load orders and results, including patient-facing alerts and reminders
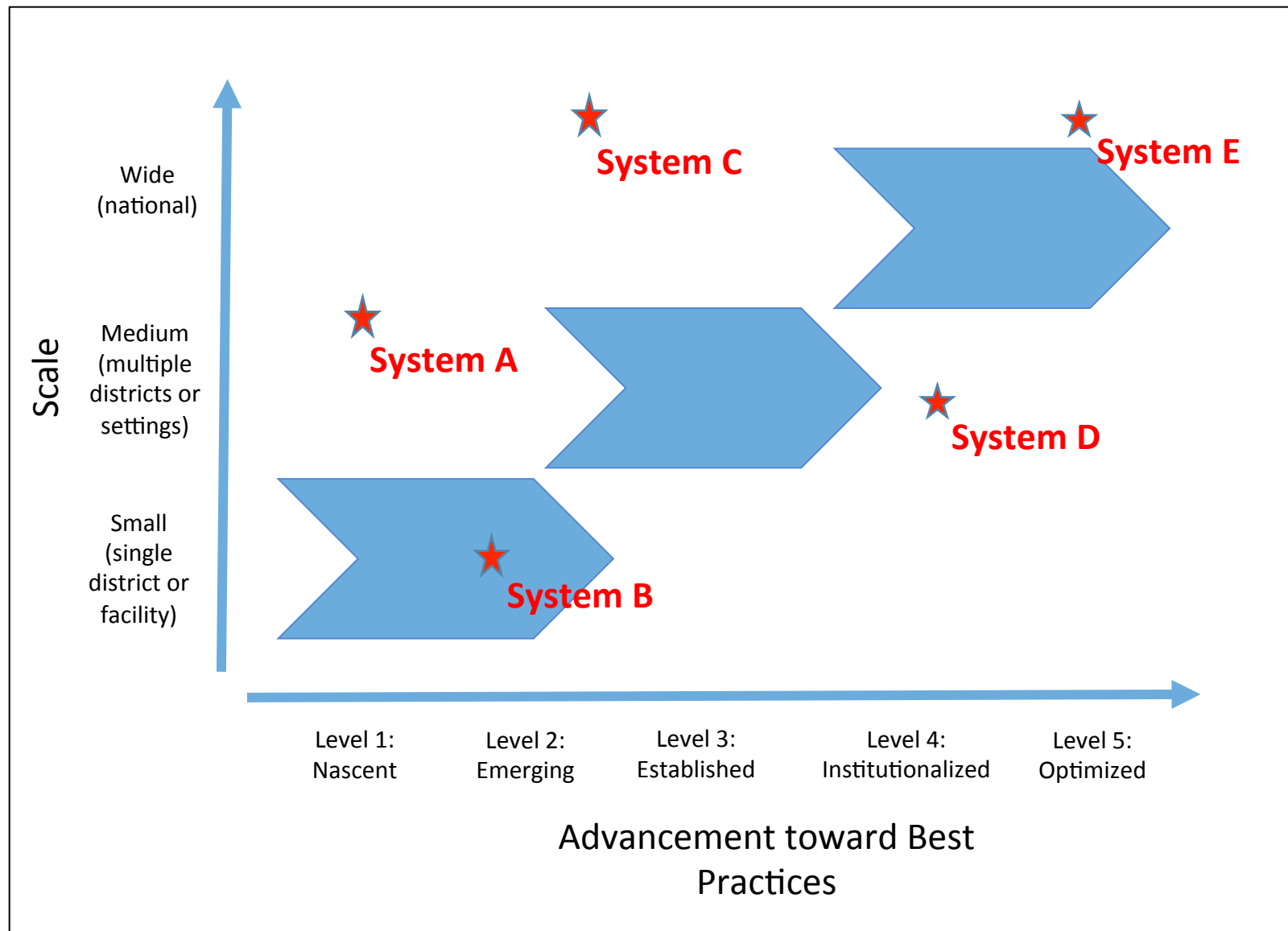
Figure 6. Examples of HIS systems at different levels of maturity

There are two existing HIS maturity models that go beyond our loose categorization of HIS maturity to comprehensively describe and classify the "ingredients" that make up HIS maturity. First, the Digital Health Collaborative Interoperability Working Group and MEASURE Evaluation have developed a Maturity Model which describes five stages toward a fully interoperable enterprise HIS: nascent, emerging, established, institutionalized, and optimized. These stages focus on the leadership and governance, workforce, and technology infrastructure that must be in place to support interoperable digital health systems within a stable and sustainable HIS enterprise architecture (Wambugu, personal communication). Second, the Centers for Disease Control and Prevention has developed an HIS Maturity Model covering strategic planning and governance, standards and interoperability, services and applications, human resources, and technology infrastructure. The CDC model describes six levels of maturity: non-existent, initial, repeatable, defined, managed, and optimized (Kariyuki, personal communication).

The concept of HIS maturity can be used in several ways as part of HIS evaluation:

1. Maturity Models with well-described rating scales, like the two comprehensive models mentioned above, can be used in rapid assessment exercises, either in a self-assessment or expert-led format. The goal is to identify areas of strength and weakness in system development, and to prioritize areas for attention in order to progress toward best practices.

2. Based upon self- or expert-led rapid assessment or based upon stakeholder knowledge of strengths and weaknesses, you can identify areas for in-depth evaluation. The purpose is to gather more evidence about results, strengths, and challenges than is possible through rapid assessment. HIS evaluations may take a more operational form, focused on quality improvement, or a more research-oriented form, focused on generalized knowledge about "what works".

3. An awareness of the present level of maturity of the HIS system can help guide the selection of relevant evaluation questions to seek to answer. Different evaluation questions make sense at different levels of maturity. For example, when evaluating a stand-alone HIS system used at pilot scale, it may make sense to investigate feasibility of integration within the health system workflow. Alternatively, when evaluating an interoperable HIS used at larger scale, it may make sense to evaluate the effects of improved availability of data on clinical care processes and patient health outcomes. Appendix 3C contains sample evaluation questions that are most relevant at various levels of maturity, for different case scenarios.

HIS maturity is a process. Along the way, it is very helpful to plan for evaluation. Doing so will identify strengths and gaps in your current system's maturity level--information that will help

ensure your system is suitable and ready to make the next leap in scale or advancement in best practices. Since careful decision-making is needed when determining what system to scale up and what ingredients to invest in, the concept of HIS maturity can be used to plan an HIS evaluation roadmap. This plan will describe how investments in evaluation will gather evidence for decision-making, from both on-going and periodic assessments.

Action 4: Identify value claims, develop logic model, and recognize potential risks

Value Claims

Applying a clear definition of system type can help make it clear to those interested in your evaluation results what the system is intended to do (see Action 2, above). Of course, understanding a system's functionality is central to defining the results the system is intended to achieve, or its **value claims**. Value claims should drive the focus of the HIS evaluation questions you select.

Different system types imply different evaluation questions. Table 3 gives examples of system types and their value claims, for some of the systems critical to the 90-90-90 HIV care cascade.

Table 3: Value Claims of System Types Used in the 90-90-90 HIV Care Cascade

System type	Value claims
Client/patient identity management system	• Ensures linkage of person-specific information across testing, care and treatment services for greater continuity of care • Ensures de-duplicated counts of clients receiving services, for improved program planning and accountability
HIV case surveillance system	• Facilitates data analysis of rate, trend, progression of disease for epidemiologic profiling • Facilitates measurement of need for and outcomes of public health programs
Electronic medical record system	• Improves accessibility of complete clinical information for appropriate clinical management • Reinforces compliance with treatment guidelines
Laboratory information system	• Reduces transcription errors in recording laboratory results • Reduces turn-around times for lab results • Supports quality management in laboratories through standardized information
Supply chain management information system	• Improves efficiency of managing supplies • Reduces stock outs and wastage of medicines, laboratory supplies and other key commodities

Develop a Logic Model

Logic models are summaries or graphical depictions that show the logic by which a program or intervention achieves its desired results. It shows what is expected to occur, and demonstrates the logical relationships between what goes into an intervention and what comes out of an intervention. By doing this, a logic model makes clear the expected "if-then" relationships that are required for an intervention to move from inputs to outcomes. The typical categories of a logic model are **Inputs**, **Activities**, **Outputs**, **Outcomes**, and **Impact**, though there can be variation in the names of these categories as well as how many are used.

Logic models are very useful in planning evaluations. By showing what we expect to happen at each step in the chain of logic of an intervention, a logic model also makes clear which things we should investigate and understand along this chain. We can ask about the level at which each of the identified inputs, activities, outputs, outcomes, and impact has occurred and why.

Figure 7 shows a very basic logic model of a digital health intervention. Each of the categories is described briefly and the model uses four categories, not five. The case scenarios in the toolkit include logic model examples that are tailored for specific HIS interventions.

Inputs	Activities	Outputs	Impact

1. Hardware
2. Software
3. Operations
  • Trainers
  • Personnel
  • Utilities
  • Maintenance contract
	1. Hardware installation
	2. Software testing
	3. Personnel training
	4. Quality control
	5. Pilot testing
		1. More complete patient records
		2. Better adherence to clinical guidelines
		3. Better quality care
			1. Improved patient-level health outcomes
			  • Life expectancy
			  • Quality of life
			2. Increased efficiency of health service delivery
			  • Cost-effectiveness
			  • Affordability

Figure 7. Sample Logic Model for an HIS Intervention

Stakeholders should be included in the logic model development process and should review drafts of the logic model before it is finalized. When engaging stakeholders to reach agreement on planned evaluation activities, use the logic model as a tool for clearly laying out your approach and expectations for the evaluation.

Consider Potential Risks

In addition to considering value claims and the positive goals of the HIS intervention or innovation, you should also think of what failure might look like. In evaluation, we need evidence of not only the degree of success, but also the degree to which adverse events were

observed. Therefore, it is important to envision some of the possible unintended consequences of your system deployment ahead of time.

For example, your new HIS system may actually introduce more complexity without generating a payoff in efficiency or information quality may ironically worsen rather than improve. More importantly, the introduction of a digital health innovation may compromise patient safety or patient privacy—issues that are essential to understand and address before expanding your intervention beyond the pilot stage.

Evaluation questions can be framed based upon potential risks or failures, in addition to how resources are allocated to particular evaluation activities.

Action 5: Develop a monitoring and evaluation (M&E) plan

As mentioned in Section 1, having a concept of the HIS's maturity and plans for scaling are important for development of a HIS evaluation roadmap. A monitoring and evaluation (M&E) plan makes this evaluation roadmap concrete. The monitoring portion of the M&E plan generates information rapidly on needed program and system improvements needed. Monitoring data also identify on-going quality improvement activities. As this toolkit focuses on evaluation rather than monitoring activities, we recommend you look at WHO's digital health M&E guide for additional information on how monitoring activities can be incorporated into an HIS M&E plan (WHO, 2016).

The evaluation portion of the M&E plan has a different focus and involves stepping back to carefully ask and answer a set of specific questions about necessary ingredients, implementation process, effects, or value of the HIS intervention. Compared with monitoring activities, evaluations tend to be more rigorous methodologically and the findings offer stakeholders more comprehensive or in-depth answers to specific questions of interest. Results of evaluations can be used for assessing progress made on the HIS evaluation roadmap.

Each case scenario in this toolkit describes evaluation designs and methodologies for one operational evaluation and one rigorous, research-oriented evaluation. Operational evaluations focus on ongoing quality improvement. As such, these evaluations may draw heavily from data that are routinely collected as part of program monitoring, as defined in the monitoring portion of an M&E plan. Research-oriented evaluations, on the other hand, pose questions that can only be answered through carefully-designed protocols involving novel,

non-routine data collection and analysis. Both operational and research-oriented evaluations may be described in the evaluation portion of an M&E plan.

Both portions of the M&E plan will define the indicators assessed during monitoring and evaluation. Indicators should be designed to be specific, measurable, achievable, realistic, and timely (SMART). Data collected for these indicators will help answer the questions that you seek to understand during M&E. The case scenarios provide specific examples of these indicators for different types of evaluation designs.

Action 6: Identify relevant theories and domains

Health information systems are cross-cutting systems which WHO identifies as a building-block within the health system (WHO, 2007). As such, HIS reflect the complex interactions among the people, processes, and structures of the health system. Since health systems have many moving parts, a health information system must fit with all these moving parts. When we make changes to reinforce or strengthen HIS, it can be difficult to assess the results of these changes, because the systems are intertwined with the many other moving parts.

Why Are Theories Useful?

Theories can help us make sense of the complexity of an HIS intervention. A theory is "a set of hypotheses related by logical or mathematical arguments to explain and predict a wide variety of connected phenomena in general terms" (Collins dictionary as quoted in Brender McNair, 2016). In short, theory explains "the way things work." In abstract, general terms, they tell us why we observe the conditions and realities that we do. For example, a theory of HIS success can describe and show the ingredients, steps, or processes that are necessary to produce success from that system implementation. Similarly, the same theory can explain the outcome of HIS failure, based upon the absence of necessary ingredients, steps, or processes.

In an ideal world, theory can inform both the design of HIS-strengthening interventions themselves *and* the design of evaluations about those interventions. Theories tell us how and why the intervention is supposed to work. Through evaluation, we can then measure whether or not things worked out like we thought they would—i.e., as predicted by the theory. However, even when an HIS-related intervention is designed without specific reference to theory, it can still be useful to use theory when planning an evaluation. By being explicit and clear about why and how an intervention is intended to work (the mechanism of action), theories can help guide us on what to measure during evaluation.

There are multiple HIS theories described in the literature. Some arise from organizational psychology, informatics management, and other disciplines. Broadly speaking, most theories reflect a socio-technical perspective that acknowledges the central interaction between technology, the humans who use it, and the settings or environments where it is used (Cresswell, 2016). Appendix 5B contains an annotated bibliography with descriptions of theories about routine health information systems—or, more broadly, theories about information technology integration and adoption of innovation in service industries (such as health care). It is common to draw upon multiple theories in designing an HIS evaluation. Each theory provides a lens for viewing why a system might work or not work as intended when implemented in the real world.
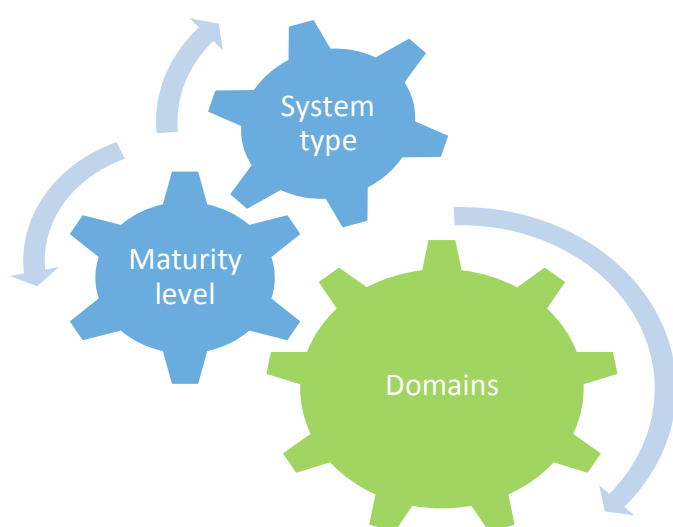
Domains

A synthesis of HIS theories and expert judgment suggests several principal domains, or factors, that affect the success of HIS projects across each stage of maturity or lifecycle of a digital health project. We focus on the following six domains: health, economic, technology, human, business process, and organization and governance (Figure 8). Appendix 5B further summarizes the relationship between several HIS theories and the domains that they invoke.
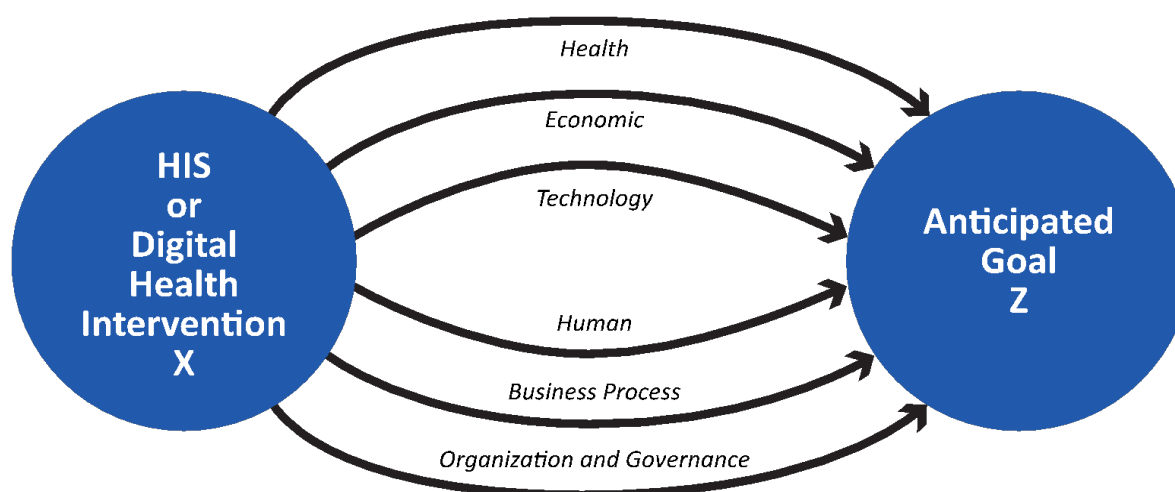
Figure 8: HIS Evaluation Domains

Health: This domain encompasses measurement of proximal indicators of health, such as quality of data used in health care delivery, quality of care, or accessibility and coverage of health services. It also encompasses distal indicators that can be more difficult to measure, such as quality of life, functional status, morbidity, and mortality.

Technology: This domain encompasses measurement of system usability, technology infrastructure, technology performance, application of technical standards, data integrity, degree of integration across technology platforms and tools, data security outcomes, and other aspects of a system's technical quality.

Human: This domain encompasses measurement of knowledge, attitudes, beliefs, skills, motivation, self-efficacy, and satisfaction of system users. It also covers outcomes of training and human capacity development.

Business Process: This domain encompasses the fit between HIS functionality and business processes, and between the HIS and the business workflow; linkage and flow of information between business units or actors; unintended consequences to business process; and data quality arising from system use in the business setting.

Organization and Governance: This domain encompasses organizational readiness for change, change management, inner setting of the organization culture and structure, outer context of implementation (including incentives and competitive pressure), policy development and policy practice, governance of ethics and security, mechanisms for engagement with standards, and enterprise or sector-level business planning.

Economic: This domain encompasses measurement of the resources required to deploy and use the HIS, the system's impact on time use of patients and health care providers, and other efficiencies and opportunity costs. This domain seeks to quantify total cost of ownership, return on investment (ROI), and cost effectiveness of HIS investments.

All of these domains come into play on the pathway between a digital health intervention and its goal (Khoja et al, 2013, Fritz et al 2015). Each of these domains represents an area of possible inquiry and measurement in HIS evaluation. Khoja, et al. (2013) argue that strong evaluations should include assessment across as many of the domains as possible.

Each domain encompasses an array of sub-domains, or distinct concepts. Sub-domains are useful for breaking down broad areas into separate concepts that can be distinctly assessed, measured, and evaluated. There is presently no comprehensive and definitive "map" of HIS domains and sub-domains. Creating such a "map" is tricky because certain concepts relate to more than one domain. For example, the concept of IT usability relates to both the Technology and Human domains. Other concepts can be closely related or overlapping, so they are difficult to categorize. We undertook a review of HIS theories and exemplary HIS studies from resource-limited settings to identify an array of sub-domains related to each

domain. We grouped the terms used by different authors and identified the set of terms that appeared to be most comprehensive and non-overlapping.

The list of sub-domains is included in Appendix 1B. We used this list to label the compendium of tools and instruments we identified in the published and grey literature. This effort to define sub-domains and the tools for measuring them represents only preliminary work. More work is needed to define and validate sub-domains and measurement tools using well-established validation and psychometric methods.

Action 7: Select and refine evaluation questions

As part of Actions 1-4, we considered the system type and its value claims, the interests of stakeholders, the theories and domains that come into play to influence the system's success, and the system's maturity level. These considerations generated many possible evaluation questions. During this action, the focus of the evaluation is narrowed to a limited set of evaluation questions.

The evaluation questions will shape the structure and scope of the evaluation. Questions should be specific and closely tied to the evaluation purpose. Moreover, the type of questions addressed will depend on whether the evaluation is process- or outcome-oriented. See Action 8 for additional details about process vs outcome related evaluations. Figure 9 below describes what to consider when creating questions for these two types of evaluations.
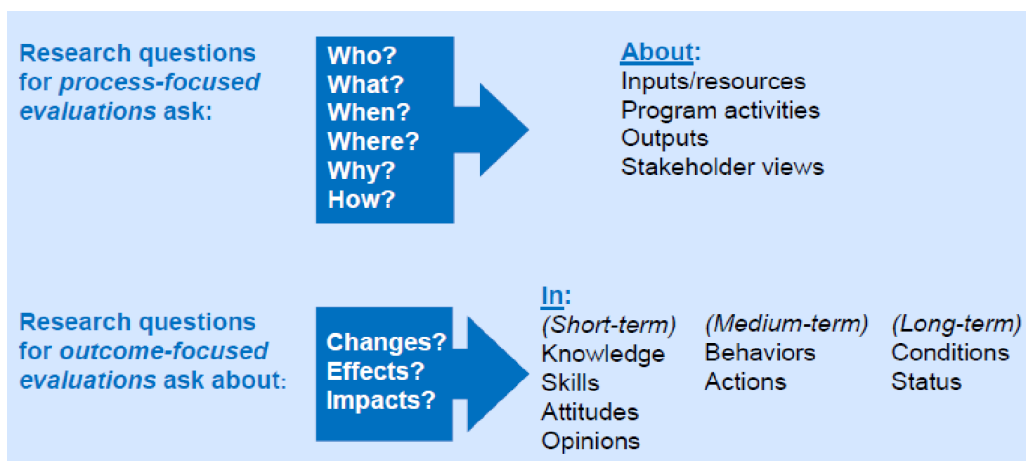
Figure 9. Evaluation Question Content in Process vs. Outcome Evaluations

(Source: https://www.nationalservice.gov/sites/default/files/resource/Asking_the_Right_Research_Questions.pdf)

To specify the questions you need for your study, we recommend that you list out the value claims of your system type first and then brainstorm a list of potential questions that « test »

the validity of the value claims. Table 4 provides some examples of questions that may address certain system types and their value claims.

Table 4: Potential Evaluation Questions for Certain System Types and Value Claims

System type	Value claims	Possible evaluation questions
Client/patient identity management system	● Ensures linkage of person-specific information across testing, care and treatment services for greater continuity of care ● Ensures de-duplicated counts of clients receiving services, for improved program planning and accountability	● What are client attitudes toward the identity management system? ● What is the sensitivity and specificity of the identifier system, with respect to a gold standard identifier? ● What proportion of ART patients are "silent transfers" between care sites?
HIV case surveillance system	● Facilitates data analysis of rate, trend, progression of disease for epidemiologic profiling ● Facilitates measurement of need for and outcomes of public health programs	● What is the technical performance of automated data transmission to the case surveillance system? ● What is the completeness of core data for HIV case surveillance? ● How are system data used for health-sector decision-making?
Electronic medical record system	● Improves accessibility of complete clinical information for appropriate clinical management ● Reinforces compliance with treatment guidelines	● What is the completeness and accuracy of EMR data? ● What are clinician attitudes toward clinical decision support features? ● How does use of EMR affect clinician compliance with national treatment guidelines?
Laboratory information system	● Reduces transcription errors in recording laboratory results ● Reduces turn-around times for lab results ● Supports quality management in laboratories through standardized information	● What data management tasks are handled through the LIS vs. standard paper-based processes following LIS implementation? ● What is the average turn-around time for commonly-used tests before vs. after LIS implementation? ● How are LIS data used in laboratory quality management?
Supply chain management information system	● Improves efficiency of managing supplies ● Reduces stock outs and wastage of medicines, laboratory supplies, and other key commodities	● How is the electronic system used in actual practice? ● Are there aspects of supply chain management that the system does not cover? ● What is the frequency of stock outs and how does this change as a result of system implementation?

The next step after crafting the evaluation questions is to gather credible evidence to support the evaluation purpose and activities. This process involves reviewing what has already been published that is related to the evaluation of interest. Published materials include: journal articles, research briefs, country reports, or conference presentations. The evaluation should be comparable to other studies assessing similar outcomes. Novel approaches to evaluation can be appropriate when implemented properly and in line with the evaluation objectives. Previously conducted evaluations can provide justification for a particular approach to an evaluation.

Action 8: Develop the evaluation study design

Types of Evaluations: Process and Outcome

Outcome evaluation measures *whether* an intervention works, while **process evaluation** measures *how* it works. Both are important, especially when our interventions are complex.

PROCESS EVALUATION

Process evaluation measures how extensively or well the HIS intervention is implemented. We ask questions about the Inputs, Activities, and Outputs of an intervention's logic model. It often focuses upon:

- **Implementation process**. Process evaluation can measure whether the intervention is being used or applied as expected (*fidelity*), how frequently or intensively the intervention is being used (*dose*), whether any adjustments or work-arounds are applied (*adaptations*), and how extensively the intervention is taken up (*reach*).

- **Context**. Process evaluation can measure conditions that are external to the intervention but affect implementation. Examples of context include the availability of staffing or budget resources, the presence of other change initiatives or competing priorities, and the overall policy environment.

- **Mechanisms**. Process evaluation can measure participant responses to the intervention, whether the intervention plays out differently in different settings or with different types of users, and any unanticipated consequences of the intervention.

OUTCOME EVALUATION

Outcome evaluation for HIS projects typically focuses on measuring the level of intended results achieved. We ask questions about the Outcomes and Impacts phases of a logic model. It often focuses on:

- **Data quality outcomes**. Outcome evaluation can measure completeness, timeliness, and accuracy, and other attributes of data quality based upon changes in the HIS.

- **Data use outcomes**. Outcome evaluation can measure whether data are used in decision-making, leading to evidence-informed decisions. Data use can be measured at the level of managing the care and treatment of individual patients or clients, the level of planning and management of health programs, or the level of making health policy at regional, national, or international levels.

- **Quality of care or program quality outcomes**. Outcome evaluation can measure HIS support compliance with care guidelines or quality management guidelines. HIS interventions often include alerts and reminders to signal deviations from quality standards.

- **Person and population health outcomes**. Outcome evaluations can measure retention in care, adherence to treatment, quality of life, functional status, morbidity, and mortality outcomes. Health outcome measures are the ultimate assessment of our intervention's success. However, measuring health outcomes can be very challenging. Health outcomes of interest can be rare, or take a long time to observe.

Engaging Stakeholders during Evaluation Design

Stakeholders help define the evaluation's objectives and methods. They may have particular preferences on the most effective methods for collecting data. Expectations about the purpose and potential findings stemming from the evaluation should be clarified *before* the evaluation design is finalized.

Do the following steps to involve stakeholders in the design process:

1. **Define stakeholder expectations** by asking key questions
   - "What are the top three priorities for your organization?"
   - "What are your key expectations of this project?"
   - "How can this project add value to your organization's mission?"
   - "What is the main outcome you expect this digital health intervention to achieve?"

2. **Identify the relevant claims of the HIS or intervention made by stakeholders** that are being addressed by the evaluation. Doing so will ensure appropriate indicators can be included in the evaluation design. Stakeholder's evidence priorities and reporting needs should be specified upfront to make sure the evaluation design reflects these.

3. **Upon completion of the evaluation design, make sure that all objectives align with stakeholder expectations** (WHO, 2016; WHO, 2015).

Study Designs

EXPERIMENTAL STUDY DESIGNS

Standard Randomized Controlled Study

A **randomized control study** can be used within a facility to evaluate the impact of particular HIS features that can be turned on or off in a predetermined random fashion. This study modality can also be used when patients or providers can be randomly assigned to use an HIS innovation without risking contamination, such as when providers always see the same set of patients, and there is no patient crossover among providers. It is also possible to randomly assign health facilities to use an HIS innovation. In each case random assignment allows us to compare results with versus without the HIS innovation, to determine its effects.

Stepped Wedge Cluster Randomized Study

Where the intention is to eventually have a new program or intervention implementation at multiple sites, and the evaluation team is able to work closely with implementation teams to determine the order and timing of implementation, a **stepped wedge cluster randomized approach** can be used. When pre-intervention measurements are taken for every site, this approach has the advantage, of each site (or cluster) serving as its own control. It also has the advantage of being able to better control for background historical trends than is possible with a simple before-and-after design. However, this study type adds complexity to the statistical methods and models required to analyze the data.

QUASI-EXPERIMENTAL STUDY DESIGNS

Non-randomized Comparison Group Study

This design compares performance of selected metrics or indicators between groups, sites, or locations with vs. without implementation of the HIS intervention under study. Like a randomized controlled study, there is a treatment group and a control group. However, in a non-randomized study, these groups are purposefully rather than randomly allocated. This type of design is useful when it is not possible to randomly select population groups or sites for an intervention. It is important to use matching criteria so that the comparison groups or sites are as similar as possible to the intervention groups or sites.

Before-After Study

The primary goal of this design, also known as "pre-post study", is to compare performance of selected metrics or indicators before and after implementation of the program or intervention, where historical data are available. Ideally, the pre-implementation period should involve a period when no aspect of the program or intervention has been initiated. The post-implementation period should involve a time beyond the initial phase of the implementation. Evaluation teams should ensure that any training associated with the introduction of the

intervention also be conducted during the pre-implementation period—this will help prevent attributing any improvements observed with the intervention that may actually be associated with training on guidelines.

Difference in Differences Study

This design uses a statistical technique that attempts to mimic an experimental research design using observational study data, by studying the differential effect of an intervention on a 'treatment group' versus a 'control group' in a natural experiment. It compares the average change over time in the outcome variable for the treatment group, compared to the average change over time for the control group. This design is useful in HIS evaluation because it is possible to use the data captured in routine HIS, such as a national HMIS like DHIS2, when comparing results between sites participating in the natural experiment. Therefore, routine data documented at the sites exposed to a digital health innovation can be compared with the data from the control sites using non-digital tools or processes.

Interrupted Time Series Study

Time series designs use observations from routinely-collected data at regular time points at regular intervals, such as monthly. An interrupted time series can be used when an intervention is implemented universally, and therefore, there is no comparison group available. This study type involves a special type of time series analysis in which the intervention occurred at a specific point and the series is broken up by the introduction of the intervention. If the treatment has a causal impact, the post-intervention series will have a different level or slope than the pre-intervention series. As in difference in difference study designs, this method can take advantage of data already captured within routine HIS, such as a national HMIS, electronic medical record systems, or surveillance systems.

Data Quality Assessment

Data quality assessment can be done through two methods: 1) comparison to a "gold standard" or "source of truth"; or 2) comparison to an absolute standard or maximal accepted error rate. As an example of the first type of data quality assessment, an HIS might be used in parallel with a standard paper-based system for capturing data, such as a paper-based register used in an outpatient HIV clinic. In this case, the paper-based register may be considered as the "gold-standard" data source. Data quality assessment can compare the electronic data to the "gold-standard" data to measure concordance of information. This study design does not require before-after measurement, and can be assessed at a single point in time. Or, the assessment can be repeated serially to investigate data quality changes over time—again, compared to the "gold-standard" source. As an example of the second type of assessment, the dimensions of completeness and consistency of data quality can be assessed by interrogating the data that exist within a system at a single point in time. This study design

works well when there is an absolute standard that a system is being judged against—for example, having < 1% missing data for patient age.

Consistency of data can be examined when:

- The same information, especially information that should not change over time, is collected several times in the system—e.g. during multiple clinical encounters. For example, some systems could capture a person's date of birth multiple times.

- Different pieces of information should lead to the same conclusion. For example, coded data stating a patient's HIV status should be comparable to that patient's HIV test results.

- Various pieces of information can be used to derive an answer, and accuracy of this answer can be verified. For example, one can look for gender and pregnancy status; the combination of these two can flag 'pregnant males,' which would indicate a data quality problem.

HIS systems can be designed to automatically evaluate for internal consistency of data over time, or relevant queries can be run on the data to determine this consistency. Note that this approach only flags data with quality issues; it does not necessarily identify what the gold-standard, or correct information, is. As such, a second layer of validation may be required. This validation can be performed either manually, or by having the user enter the data for which the discrepancy exists for a third time, and taking the third time as the gold standard. This presumes, obviously, that the third entry will match one of the first two.

QUALITATIVE ASSESSMENTS

Qualitative assessments are very useful for understanding reasons for non-compliance, or explaining some of the observed outcomes of HIS systems. Qualitative research uses analytical categories to describe and explain social phenomena (Pope et al 2000). These categories may be derived inductively from the data or deductively using a predetermined categorization schema to frame the data. Inductive analysis is the most common approach in qualitative research (Kuper et al 2008).

The most frequent methods of data collection include: interviews, focus group discussions, and observation.

In-depth interviews

In-depth interviews are most commonly conducted one-on-one with an evaluation staff member and a participant (usually a HIS system user, healthcare provider, or patient). This type of data collection often yields the richest, most in-depth data and is excellent for information that may be considered private or sensitive. Interviews often use an interview guide that is structured, semi-structured, or unstructured to elicit responses from the participant. Interviews are typically audio-recorded, transcribed, and then coded. A frequently

used type of interview is known as a *key informant interview (KII).* Key informants are individuals with in-depth knowledge of the HIS goal, challenge, intervention, etc. Information from KIIs is often used for process evaluations or implementation studies. In general, interviews provide rich information on perspectives, knowledge, and attitudes for enhanced understanding of a particular phenomenon. There are a few challenges with collecting data via interviews. Interviews can be time consuming to analyze, yield small sample sizes, and hinge on the ability of a few individuals to articulate key perceptions.

Focus group discussions

Focus group discussions are conducted with a group of participants. The amount and type of information gathered from a focus group depends on the group dynamic. Focus groups can help identify consensus or a lack of consensus about a particular topic. Focus groups work best when the group members feel comfortable sharing their views in front of the other members. Good discussion facilitators are also critical for obtaining information from all participants and maintaining an appropriate group dynamic. Like interviews, focus groups are typically audio-recorded, transcribed, and then coded. Challenges with focus groups include: dominant speakers so other member views are lost, individual perspectives may not be captured, and transcription can be difficult with large group sizes.

Observations

Observation involves observing participants engaged in an activity important to the evaluation. In HIS evaluation, observation is often used as part of studying usability of HIS tools (Boland et al, 2014). Time and motion studies are one type of observation frequently used in HIS evaluation; these studies can include both quantitative and qualitative observations. Observations are conducted by an evaluation team member or group of members and allow for behaviors and actions to be captured in real-time. Detailed information can be gathered in a setting that is more "natural" to the participants. Evaluators may take detailed notes during an observation and/or use an observation checklist to capture activities and behaviors that occur during the observation period. Evaluators have less control over the data with this method than the previous two methods described, however. In addition, there is the potential for observed bias to influence the data gathered from observation evaluation activities.

MIXED-METHODS STUDIES

The **mixed-methods** approach is generally beneficial when evaluating HIS projects, as both technical and socio-technical factors are important. Quantitative methods are mainly deductive. They are ideal for assessing patterns in data and for assisting with the development of inferences of causality. Qualitative methods are mainly inductive and help provide explanations of why and how phenomena occur (Creswell et al 2011). Mixed methods research

can address some research questions more comprehensively than either quantitative or qualitative methods alone (Tariq & Woodman 2013).

In some studies, the qualitative component is carried out first, to aid in understanding the activities of, and challenges to, an HIS intervention. The quantitative component is then designed on the basis of the activities and problems uncovered. This is sometimes referred to as an *exploratory sequential* design. An alternative approach is to carry out a quantitative study to define the performance of the system on key metrics, followed by a qualitative evaluation to explain the findings and help determine how generalizable the study is. This approach is sometimes referred to as *explanatory sequential* design. Finally, both types of studies may also be conducted simultaneously, known as a *convergent* design. Most commonly in convergent designs, qualitative and quantitative data collection occur within the same timeframe and the two forms of data are analyzed separately and then merged (Fetters 2013).

ECONOMIC EVALUATION (COST) STUDIES

The following designs incorporate the costs of a HIS, both financial and otherwise, into an evaluation. As resources for HIS may be limited, it is essential to partner financial considerations with other health process or outcome indicators. We describe several methods of incorporating cost into an evaluation or analysis below:

Cost-Effectiveness Analysis (CEA)

Cost-effectiveness analysis (CEA) measures outcomes in "natural units," and allows comparison of interventions in a given indication, or for a particular setting. In a clinical intervention setting, CEA may estimate outcomes for an indication such as management of hypertension, in which the outcome is the percentage of reduction in mm Hg as a result of a given intervention.

In an EMR system setting, system-level outcomes, such as reductions in the total time spent per patient in the clinic, or reductions in the percentage of patients not reminded of the dates of their next visits, may be assessed.

For this particular case, in which analysts were interested in measuring the impact of an EMR system on completeness of records, adherence to guidelines, or quality of care, a cost-effectiveness analysis would be the most appropriate method.

Other outcomes of interest for a CEA include occurrence and timeliness of testing for a disease, if there is a clear reference pathway. So, in the case of HIV, timeliness of initiation of antiretroviral therapy, timeliness of detection of treatment failure, appropriateness of regimen, detection of drug-drug interactions, and detection of adverse events and allergies can all be

studied through with a CEA design. In addition linkage to care is another relevant outcome of interest, if the EMR is connected to testing data.

Cost-Utility Analysis (CUA)

Cost-utility analysis (CUA) estimates outcomes as a combination of length of life and quality-of-life, either as quality-adjusted life-years (QALYs) or disability-adjusted life-years (DALYs). QALYs and DALYs allow comparison of the value of interventions for, or the burden of diseases with, predominantly morbidity consequences, such as anxiety; and the value of interventions for, or the burden of diseases with, predominantly mortality consequences, such as suicide. As mentioned above, it is often difficult to ascribe health outcomes to system-level interventions. However, model-based analyses may be able to leverage intermediate outcomes that result from EMR systems to health outcomes, making CUAs potentially useful as an analytic tool in applications where the ultimate impact of the EMR system is of interest to analysts

Cost Consequences Analysis (CCA)

Cost consequences analysis (CCA) presents a multidimensional listing of outcomes; it places the onus of deciding whether interventions are desirable on the consumers of the analysis. Different health and system-level outcomes may be presented alongside costs of the interventions without aggregation of the costs or outcomes. This kind of analysis may be particularly suited for the evaluation of EMR systems, given the wide range of possible outcomes that can be considered to be a result of implementing HIS interventions.

Cost-Benefit Analysis (CBA)

Cost-benefit analysis (CBA) estimates outcomes in monetary units. For clinical interventions, CBAs involve the monetization of health outcomes using a variety of methods, such as discrete choice experiments, contingent valuation, and value-of-a-statistical-life. Policy makers and other stakeholders often do not encourage or readily accept the explicit monetization of health benefits; this makes CBAs relatively rare in the economic evaluation of health care programs literature. CBAs of HIS interventions have been reported in the literature, with such monetized benefits as reductions in paper chart storage areas, and reductions in medical transcriptionists' wages.[5] Another study reported monetized benefits in terms of reduced need to create medical records, decreased labor costs, and reduced drug adverse events and dosage errors.[6]

Return-on-Investment (ROI) Analysis

Return-on-investment (ROI) analysis estimates the financial return of investment in an intervention over a given period of time.[2] ROI analysis compares the timing and quantity of financial returns to the timing and quantity of costs, and is therefore dependent on time horizon. ROI analysis is not recommended for economic evaluations of health care programs,

because health effects are not considered.[2] For an EMR system however, ROI analysis may have a role, given the difficulty of ascribing health effects to a system-level or provider intervention. For example, Driessen, et al. modeled the potential ROI in a hospital-wide EMR system.[4] Although they considered a limited set of savings—length of hospital stay, transcription time, and laboratory time—Driessen estimated a net financial gain in the third year of operation of the EMR system, and a financial return of over $600,000 over five years.[4]

Budget-Impact Analysis (BIA)

Budget-impact analysis (BIA) estimates the expected change in the expenditures of a health system after the adoption of a new intervention; it can be used for budget or resource planning.[3] In a BIA, the costs of health care in the new (post-intervention) environment are compared with the costs under the old (pre-intervention) environment. The difference in costs is the **budget impact**. A BIA can be conducted to assess affordability of the new HIS system for planning purposes. The estimate of the expected change in costs between the pre- and the post-HIS periods can be used to determine cash flow from revenues or government disbursements. In the context of planning, the BIA can be the main input into whether the HIS is implemented.

Potential Bias in Evaluation Research

Bias occurs when systematic error results in an outcome or answer that differs from the "truth". In research, we want to identify the truth, but in reality, we strive to give our "best guess". Depending on the type and amount of bias present, our best guess may differ greatly from the truth. Bias can occur for any type of study and at any phase of a study process, including study design or data collection and analysis.

It is useful to understand the common types of biases that can occur in research in order avoid or mitigate the effects of these biases. Three major categories of bias are described in the following paragraphs.

Selection Bias

Selection bias occurs when the population or entity being studied is not representative of the target population or entity of interest. For example, results from a voluntary survey regarding a new HIS's usability may suffer from selection bias in that those who volunteer to complete the survey may be different from the general population of HIS users. Those who volunteered to take the survey may be more familiar with system, may have more highly favorable (or negative) experiences that they wish to explain, or a host of other factors that may make the survey takers different from the "average" HIS user. Evaluations should aim for information that is generalizable to the population of interest.

Selection bias can also occur in when choosing where an evaluation takes place. When resources are limited, HIS exhaustive evaluation activities may only occur for a subset of users, clinics, etc. For example, an intensive audit of data quality may only be possible at a few of the many MOH clinics in a country. If evaluators choose to assess data quality from only the clinics in the capital, the quality of the data from these sites may be different from those in more rural communities and may not be representative of data quality at the national level.

How to address selection bias

To avoid issues regarding selection bias, ensure that the units selected for the evaluation are representative of the target population for which the evaluation is intended to address. This can be achieved by randomly selecting individuals, clinics, etc. to be evaluated within a larger system. Stratifying national clinics by size or location (or another meaningful characteristic), and then randomly selecting clinics within those strata for auditing may help to address selection bias.

Confounding

Confounding occurs when a variable (known as a confounder) that is related to two factors of interest falsely obscures the relationship between those two factors. For example, a HIS begins to include automatic appointment reminders sent to HIV patients via SMS messaging. The outcome of interest is a reduction in hospitalizations due to opportunistic infections. HIV patients who are relatively stable are enrolled in the SMS reminder program, while patients who have more complex health conditions receive visits from a community health worker to check on them and remind them of their upcoming clinic appointments. After 12 months, the SMS messaging appears to decrease hospitalizations. Here, disease severity is a confounder-the severity of one's condition is related to both enrollment in the SMS reminder program AND the likelihood of hospitalization. Those who are less sick are more likely to receive SMS reminders AND those are less sick are also less likely to be hospitalized for an infection.

Confounding is particularly important when evaluating value claims or assessing impact. It is necessary to consider alternative causes of the desired result other than the HIS intervention of interest. Few HIS initiatives happen completely independently of other activities within a healthcare setting and it is critical to consider the way in which these activities may interact to cause an effect.

How to address confounding

Confounding can be addressed in the design phase of an evaluation or later during the analysis phase. In the design stage, techniques to avoid bias due to confounding include: randomization, restriction, and matching. Randomization allocates study units to either the intervention (or innovation) or the comparison condition based on chance, restriction involves

only including certain study units in the evaluation, and matching ensures that the distribution of key characteristics are similar between the intervention and comparison groups.

Information Bias

Information bias (also known as measurement bias) is a distortion in an outcome or impact of interest caused by inaccurate, inappropriate, or inconsistent measurements of key variables. For example, an electronic vaccination registry (EVR) aims to improve recommended, age-appropriate vaccine coverage for children under five. In one district, coverage is calculated as the percentage of children in the *registry* who have received all age appropriate vaccines and, in another district, coverage is calculated as the percentage of children in the *district* who have received all age appropriate vaccines. The EVR will appear to perform better in the first district where the denominator for coverage outcome is smaller, as children who have never been vaccinated will not be captured in the calculation. HIS evaluators will want to ensure that metrics are assessed correctly and consistently across settings.

Another common type of information bias is responder bias. **Responder bias** occurs when a respondent (e.g., survey taker or interviewee) does not answer a question or questions accurately and/or completely. **Recall bias**, a type of responder bias, occurs when information cannot be accurately recalled due to errors in memory. Asking clinicians about a previous point-of-service system from years ago may result in recall bias if clinicians do not remember specifics about that system. **Desirability bias,** another type of responder bias, occurs when respondents give information that is perceived to be more favorable or "desirable", rather than accurate. An HIS user may report no issues with a system upgrade in efforts to protect his or her job security.

How to address information bias
Common strategies to address information bias include: standardized evaluation protocols to be reviewed by several team members with a variety of evaluation strengths, adequate training of data collectors, and pilot studies to identify potential problems with measurement instruments such as surveys.

Action 9: Develop the evaluation protocol

An **evaluation study protocol** defines the study objectives and rationale; identifies exactly how the study will be carried out, and how data will be managed and analyzed; and clarifies how results will be disseminated. Having a clear, written protocol before doing an evaluation study is an important part of making sure the evaluation is well thought through, and will be a good use of time and resources to complete.

Considerations for Protocol Development

There are many factors to consider when developing an evaluation protocol. Key components to address include:

- **Stakeholder engagement**: involvement of stakeholders in both planning and implementing the evaluation.

- **Clearly stated evaluation questions, purpose, and objectives**: framing the evaluation in a manner that is well-articulated and in line with the overall goals of the evaluation.

- **Use of appropriate evaluation design, methods, and analytical techniques**: ensuring the best fit between the evaluation goals and the activities described in the protocol.

- **Ethical considerations**: evaluation need to consider the potential risks those involved in the evaluation.

- **Resources and budget**: matching the evaluation scope and goals to the available resources.

- **Data collection and management plans:** a clear strategy for gathering and utilizing relevant information.

- **Appropriate evaluator qualifications:** evaluation team should have the skills and experience needed to perform the evaluation activities.

See Checklist for Scientific and Ethical Review in Appendices 2A, 2B, and 3B for additional guidance on addressing these factors.

Sections in an Evaluation Protocol

Commonly included sections in an evaluation protocol are briefly described below. A generic sample protocol is included in Appendix 2C.

Investigators and Roles

This section describes who will be conducting the evaluation and what the specific roles these individuals will play. Sponsoring institutions, partners, and any collaborators will be listed and described in this section. It is important to acknowledge the funding organization(s) or source(s) for the evaluation activities.

Background

This section will describe the health concern, challenge, or process that the HIS is designed to address. For example, this section may describe the population level details regarding a country's HIV/AIDS epidemic. This section will also detail the key systems of the HIS or HIS intervention, including its implementation and functional capabilities.

HIS Evaluation Overview

This section will provide justification for the evaluation and the intended use of the findings, as well as their audience. Evaluators will describe the evaluation questions, general approach, and evaluation activities. This section will also outline plans for monitoring evaluation activities and progress. The sponsoring institution may be in charge of the protocol oversight. Finally, this section will include an evaluation timeline, or intended time horizon for all of the evaluation activities.

Define HIS Evaluation Methods

This section will summarize the relevant data collection methods and sampling strategies for each evaluation data collection activity. Data collection methods may include activities such as: secondary data analyses, surveys, key informant interviews, or patient focus groups. Sample size calculations will be included for primary evaluation outcomes. A strategy for data storage, ownership, and sharing will be outlined here. A data analysis plan will detail how the data will be used to address the evaluation questions. Finally, this section includes a plan for dissemination, notification, and reporting of results.

Identify Sample Size

Evaluators will want to consider the sample size necessary to answer the evaluation questions; doing so will require consideration of the number of study units needed for the evaluation. Sample sizes are calculated based on the primary outcomes of interest and will differ depending on the anticipated effect of an intervention. This process sometimes requires involvement of a biostatistician to determine sample size and to assist in the analysis of evaluation results.

Ethical Review

Elements of Ethical Conduct

The following are important **elements of ethical conduct**. When these principles are in place and guide our actions, we can ensure that we are acting ethically and with integrity in our evaluation research.

- **Maintain confidentiality**. Keep information—about program participants, patients, staff, and anyone else who may have provided confidential communication—private.

- **Protect the welfare of human subjects**. Minimize harm and maximize the benefits to all people who participate in our research or program activities.

- **Know the laws, regulations, and oversight requirements** for all program activities in each setting we work in.

- **Be diligent and careful**. Be diligent in maintaining our knowledge of current laws, regulations, and oversight requirements related to program activities.

- **Maintain integrity**. Strive for honesty in all reporting—for grant proposals, on program work, or in publications.

- **Respect intellectual property**. Make sure we have permission to use, analyze, and report data, that we give credit where credit is due, and that we consult and acknowledge any contributors to our program work or ideas

Institutional Review Boards and Ethics Committees

The primary role of **Institutional Review Boards** (IRBs) and **Ethics Committees** is to ensure that human subjects—people—participating in a program or research activity are protected. IRBs and Ethics Committees require the investigator to report any adverse events, increased risk, or harm to study participants.

While IRBs and Ethics Committees monitor risk, it is ultimately up to the investigator or evaluator and evaluations staff/research members to maintain a vigilant eye on risks to participants. They have ultimate responsibility, and are accountable for any risk or harm to study participants as a result of study or data collection activity. This investigator responsibility and accountability remains in place even if no IRB or ethics oversight is required.

> **PEPFAR Standards for Research and Evaluation Ethics**
>
> **ESoP4: ADDRESS ETHICAL CONSIDERATIONS AND ASSURANCES**
> 4a. The evaluation report describes procedures in place to ensure human rights were protected with respect to privacy, confidentiality, and maintenance of the dignity of participants and received IRB approval where applicable or other human-subject review (for non-research evaluation).
>
> 4b. If interviews were conducted, informed consent procedures were described and documented in the evaluation report to ensure that participants were informed of the risks and benefits of their participation, as well as the lack of consequences in their eligibility to receive services regardless of their participation.
>
> *Source: PEPFAR Evaluation Standards of Practice (https://www.pepfar.gov/reports/guidance/c61317.htm)*

Human Subjects

A **human subject** is a living person about whom we collect information during an evaluation or a study. Data are collected through direct intervention or interaction with the person, including obtaining identifiable private information from someone. We typically apply the term human subject to research, but non-research activities may also involve interaction with human

subjects. Human subjects in HIS evaluations could be clinicians or service providers, patients, community members, or government representatives.

In HIS evaluations, information we collect from health workers may touch on such themes as their knowledge, usage, and satisfaction with a digital health tool, their opinions on how the tool has affected their job duties, or their use of data for decision-making. Health workers may have concerns about being judged in their jobs, or may worry about disciplinary consequences based on the data they contribute to an HIS evaluation study. Therefore, we must be very attentive to the need for confidentiality of information we collect about health workers. Information we collect from patients or clients may touch upon similar themes, such as their knowledge, usage, and satisfaction with a digital health tool. They may also have concerns about being judged, or about not being able to continue to receive health care services, based on their response. In addition, we may also seek to use personal health data from patients and clients in an HIS evaluation, such as when we wish to measure how a digital tool affects patient health. When we do this, it can be best to use de-identified or anonymized data so information cannot be traced back to a particular person.

Informed Consent

Informed consent is a process involving direct communication between a person who may participate in the research (a human subject) and an investigator or an evaluator. Informed consent can be obtained verbally (orally) or in writing. Verbal informed consent is appropriate when collecting written consent may actually increase the risk to a participant (since the participant's name must be included as part of a written informed consent form) or when the risk of harm to participants is quite minimal.

Informed consent includes the following:

- Disclosing to potential human subjects the information they need to make an informed decision about participating.

- Confirming that the person understands what they are consenting to.

- Ensuring that participants are informed of the risks and benefits of their participation.

- Ensuring that a person's decision to participate is voluntary.

A sample written informed consent form is included in Appendix 2C: Sample Protocol.

Completing Ethical Review

Each IRB or Ethics Committee may also have their own specific template to follow, and some may have additional forms to complete. Upon review, the investigators or evaluators will receive written comments from the IRB or Ethics Committee. These comments may include requests for clarification, or requests for modification. The investigators must then revise the

protocol, providing a response and justification for each change made in response to the comments. Most committees will request both "track changes" and clean versions of the documents, and with updated version numbers and dates on all portions of the protocol and appendices that are modified.

It may be necessary to have several rounds of modifications based upon committee feedback. Ethical review may take anywhere from several months to up to one year to complete, so it is best to plan for this time within an overall project calendar.

Select Data Collection Methods and Tools

There are a wide variety of options for data collection in HIS evaluations. Common methods include:

- **Abstraction of data from HIS tools.** This process is also referred to as "secondary" data use, since it uses existing data that were originally collected for a primary purpose (e.g., clinical care, laboratory services, etc.) It requires an understanding of the data model and database structure, and the ability to write query scripts for gathering the appropriate data.

- **Survey data collection.** There is a wide array of online data collection tools that can be easily set up to collect questionnaires or surveys. See Appendix 4 for a listing of such tools and features.

Action 10: Determine who will carry out M&E activities

This step outlines the roles and responsibilities of the evaluation team. An agreement among the evaluation team members might involve a legal contract, a memorandum of understanding, or a detailed protocol. Some tips from the Centers for Disease Control and Prevention document, *Introduction to program evaluation for public health programs*, are summarized below.

Establishing an Evaluation Team

The first step in establishing an evaluation team will be to select an evaluator or institution that will be responsible for planning and implementing the evaluation. The lead evaluator is responsible to stakeholders and in charge of coordinating the activities of consultants and other collaborators. Other evaluation team members should clearly define their roles, responsibilities, and expected timeline for their respective tasks. Evaluation team members should reach consensus on the following:

- Purpose of the evaluation

- Potential users of the evaluation findings and plans for dissemination

- Evaluation approach

- Resources available

- Protection for human subjects.

See the following resource for more information: Centers for Disease Control and Prevention. (2006). Introduction to program evaluation for public health programs.

Action 11: Define an M&E implementation plan and report the findings

An implementation plan provides a roadmap of the timeline, resources and activities required for an evaluation protocol and monitoring activities. M&E implementation plans will differ depending on the evaluation but will often include the following elements:

- A structured list of activities and sub-activities that need to be carried out to implement each piece of the M&E framework. Activities may include drafting of manuals or training evaluation personnel.

- Responsible persons assigned to activities to ensure accountability. Details will often be determined when the evaluation team is assembled (*see Action 10*).

- A timeline and target dates when each activity should be carried out and the deadlines for completion of each activity. It is important to be realistic with the timeline and attentive to deadlines that are determined by the all parties involved in the evaluation. Make sure to budget time for unforeseen setbacks and delays. It's better to deliver ahead of schedule than to have to ask for extensions.

- The budget and details of other resources required for each component of each project activity.

> **Report Findings to Stakeholders**
>
> Communication with stakeholders is essential. Do the following upon completion of the evaluation:
>
> 1. **Review how findings meet stakeholder expectations**. Determine whether the evidence you obtained supported the initial claims of the intervention, as dictated by the stakeholders.
>
> 2. **Present findings** to high-priority stakeholders, ensure they understand how their expectations have been addressed, and provide justifications for any unexpected results or deviations from the intended objectives.
>
> 3. **Review lessons learned and potential next steps**.

For more guidance on M&E, see: World Health Organization. (2016). Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment.

The final deliverables from an evaluation are usually in the form of recommendations for future actions or justifications for why an innovation or intervention is superior to the comparison condition. The deliverable is typically drafted as an evaluation report. An evaluation report should be written for a specific audience. An outline for a traditional evaluation report might follow the format shown in the box below.

For research-oriented evaluations, the final deliverables may be drafted as a manuscript to be submitted for publication in a research journal. Articles are peer-reviewed prior to publication to help ensure that the evaluation design and the claims from the findings represent high quality evidence and best practices from the field. Journal articles are often written for academic audiences, though it is becoming increasingly common to publish in implementation journals that tend to have a broader audience. Evaluation teams can also choose to publish in open source journals that are more accessible to other HIS implementers, especially those outside of academic institutions.

> **Standard Outline for an Evaluation Report**
>
> I. **Executive Summary**
> II. **Background and Purpose**
>   a. Program background
>   b. Evaluation rationale
>   c. Stakeholder identification and engagement
>   d. Program description
>   e. Key evaluation questions/focus
> III. **Evaluation Methods**
>   a. Design
>   b. Sampling procedures
>   c. Measures or indicators
>   d. Data collection procedures
>   e. Data processing procedures
>   f. Analysis
>   g. Limitations
> IV. **Results**
> V. **Discussion and Recommendations**
>
> *Source: Centers for Disease Control and Prevention. (2006). Introduction to program evaluation for public health programs.*

The two primary deliverables described above are for both internal and external stakeholders, funders, and other implementers in the HIS field. These deliverables help ensure that the evaluation's central focus is well represented and accurate with respect to the evaluation design and objectives. Evaluation reports and scientific publications encourage findings to be highlighted in decision-making processes. In addition to completing final deliverables, it is important to communicate the findings of the evaluation to all relevant audiences in a timely manner. Full disclosure and impartial reporting is essential. To appropriately communicate evaluation findings, you need participation from the entire evaluation team and group of

stakeholders. It is important to modify the style, tone, and format of information products to the audiences of interest (CDC 2006).

For more guidance on M&E reporting, see: Centers for Disease Control and Prevention. (2006). Introduction to program evaluation for public health programs.

Practical Toolkit for Health Information System Evaluation

Section 3: Case Scenarios

Working Draft: November 30, 2017

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Center for Health

Health Information System Evaluation Case Scenario #1

Title

Strengthening case-based surveillance for prevention of mother-to-child HIV transmission (PMTCT): Evaluation of a tablet-based electronic PMTCT registry

Overview of Case Scenario

HIS system type: Electronic PMTCT Registry (eMTCT-R)

Stage of maturity: Level 1- Nascent

Intervention purpose: introduction of a digital prevention of mother-to-child-transmission registry for improving HIV case-based surveillance

Project type: Pilot electronic registry among 10 facilities in 1 district

Domains: Health, Human, Business Process

Study designs:

Operational evaluation- retrospective using mixed methods

- Data quality of eMTCTR- concordance analysis

- Acceptability and fidelity of eMTCT-R post-deployment survey

Research-oriented evaluation- time series analyses

- Change in coverage- interrupted time series analysis

- Timeliness of treatment administration- difference in differences analysis

- User attitudes- post-deployment key informant interviews

Results:

- Will inform future updates of the eMTCT-R technology and improvements in the training and standard operating procedures before the solution is scaled

- Provides evidence for a "proof of concept" for implementation of electronic registries

- Generates more substantive evidence about the effects of the eMTCT-R on intermediate health outcomes

Introduction

Background

Registries in healthcare settings often serve as the sole data source of patient records for a particular service. As defined by the Agency for Healthcare Research and Quality (AHRQ), a registry collects uniform data on a particular disease, condition, or exposure in an organized system to evaluate specified outcomes for a population.[i] Registries can serve many purposes, including measuring quality of care, tracking completion of treatment or an immunization series, or describing the natural history of a disease, among many others.

HIV surveillance among pregnant women attending antenatal care (ANC) provides important information on the burden of HIV among women of child-bearing age. It also identifies women most in need of treatment. HIV prevention and treatment services during the ANC visit offers an opportunity for diagnostic HIV testing, prevention of mother-to-child-transmission of HIV (PMTCT), and the dispensing of antiretroviral therapy (ART).

During these services, individual level data from ANC and PMTCT services are routinely recorded in paper-based registers and aggregated for reporting to the national health management information system (HMIS). Ideally, all pregnant women should be included in the HIV surveillance system and, therefore, in the ANC registry.

The electronic PMTCT registry (eMTCT-R) aims to decrease the burden of collecting, using, and reporting these data. These data are also used to improve testing and treatment adherence among pregnant women and infants as well as enhance perinatal HIV case-based surveillance.

Technology Context for Case Scenario

Before eMTCT-R deployment

Throughout the health districts of a country in a low-resource setting, an HIV disease surveillance program routinely collects data from hundreds of health facilities. Currently, it uses a paper-based data reporting system to manage these data. Healthcare workers (HCWs) record individual level patient information on HIV status, PMTCT, and ART initiation in paper-based registers. HIV surveillance indicator data are tallied and aggregated for reporting purposes; each month these paper reports are sent from the health facilities to the provincial level, where they are electronically uploaded into the national HMIS.

eMTCT-R deployment

To improve perinatal HIV case-based surveillance reporting, the Ministry of Health (MOH) has decided to invest in an eMTCT-R that will capture digitized data directly from clinics and laboratories and reduce reliance on the paper-based system. The MOH deploys eMTCT-R in a pilot district in order to help identify the appropriate technology, design, and implementation on a

national scale. To allow health facilities with poor electricity access to the registry, tablets are used for data collection and reporting.

Functionality of eMTCT-R:
- Captures electronic data directly from multiple health facilities for delivery to sub-national and national levels
- Integrates information from laboratory systems on HIV diagnosis for mothers and infants
- Supports tracking of retention along PMTCT cascade
- Supports epidemiologic analysis of longitudinal patient level data

Figure 1 shows the workflow of the PMTCT care cascade (top) and the information workflow of eMTCT-R, including the electronic registry's various data source inputs (bottom).
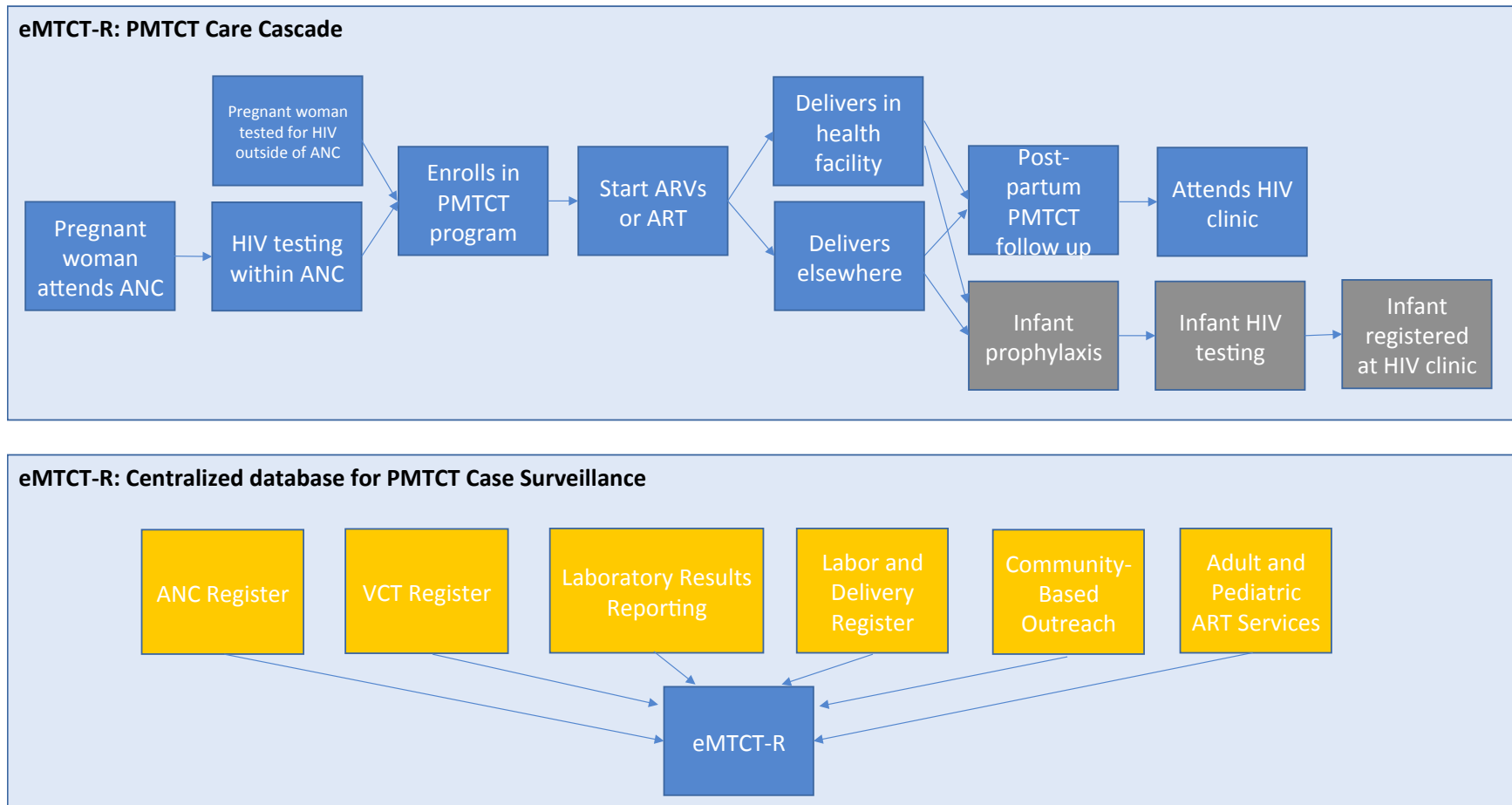
Figure 1. Workflow of the electronic PMTCT Registry (eMTCT-R)[ii]

Value claims of eMTCT-R

Improvements to:
- disease surveillance of HIV among pregnant women, mothers, and infants
- initiation to HIV care and treatment among patients
- the efforts for conducting outreach to patients lost to follow up due to increased data accessibility
- tracking and reporting of key benchmarks and sentinel events of the HIV surveillance cascade
- data quality and accuracy of benchmark estimates at project facilities
- completeness and timeliness of routine monthly reports submitted by HCWs to HMIS
- monitoring of the use and effectiveness of the national PMTCT system

Benefits of Evaluation

Evaluating the new electronic MTCT registry is particularly important for understanding how it may need to be modified. The country's MOH needs to understand if the registry is being used as intended and if it is acceptable to the users: the health care workers at the pilot facilities. Evaluation can also help determine if the registry can be scaled for use in more facilities or other settings.

This case scenario describes two evaluation approach for a pilot project of an electronic MTCT registry (eMTCT-R) in the country. Findings of each option can show how the eMTCT-R delivers the intended benefits to stakeholders and how it improves HIV surveillance among pregnant women, mothers, and infants. Such evidence informs decisions about future investments in the eMTCT-R, made by decision makers in the country's MOH, implementers, and software developers. Ideally, both evaluation approaches will be implemented as they complement each other.

Logic model

The logic model for the eMTCT-R shows how the MOH expects the project to achieve its goals (Figure 2). The MOH ensured this logic model was agreed upon by all stakeholders before the evaluation began.
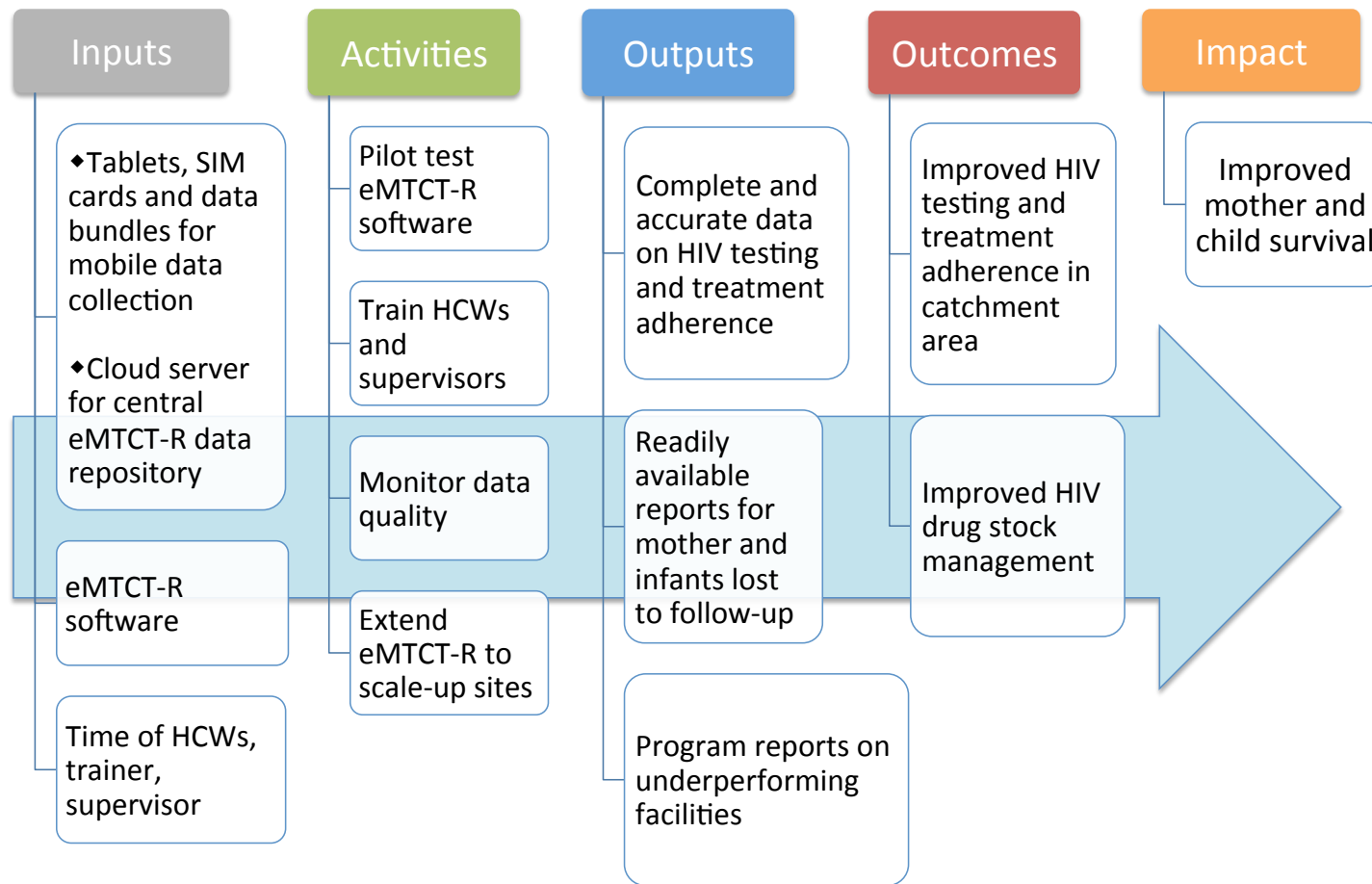
Figure 2. Logic Model for Electronic PMTCT Registry (eMTCT-R)

Deployment of eMTCT-R

As part of the pilot project, a purposeful sample of 10 health facilities was selected, using the following criteria:

- Public health facilities
- HIV testing and treatment are provided daily
- Historically good performance in terms of compliance with program guidelines
- Availability of electricity

Healthcare workers, the users of the eMTCT-R, will be responsible for data collection per their regular duties. As part of the piloting of the eMTCT-R intervention, HCWs at the pilot facilities will need to record the same patient data in both the paper registers as well as the tablets provided for the electronic registry until the eMTCT-R has been proven as a proper replacement for the paper registers.

Stakeholder Roles and Priorities

Different stakeholders have been involved with the project during each phase of the design, development, and deployment of the eMTCT-R. Their roles and priorities differ (Table 1).

Table 1. Stakeholder roles and priorities

Stakeholder	Role	Priorities
National MOH and HIV surveillance managers	Oversee HIV program staff, performance, and supplies	More timely and better quality surveillance data to understand program performance and use data for decision making; will eventually oversee data collection and use
Implementing partners	Oversee development of eMTCT-R and implements eMTCT-R in pilot district	eMTCT-R deployment, training of HCWs, ongoing supervision of system use, and system maintenance
Pilot healthcare workers (HCWs) at facilities	Use eMTCT-R as part of routine activities	Easily accessible information about patient HIV testing and treatment to identify and track patients lost to follow-up and report HIV surveillance benchmarks more efficiently
Sub-district and district managers and supervisors	Oversee performance of HCWs at facility level	More timely and better quality data to improve program performance
Patients (mothers and infants)	Visit facility to receive antenatal care, HIV testing, and treatment	Complete HIV testing and treatment record that can be accessed from any online facility using the registry; ensure HIV-positive infants are identified as soon as possible

Software developers	Design and build eMTCT-R	Creation or adaptation of software to meet technical and functional requirements; complete software updates
Funders	Provide resources and guidance for building, deploying, and evaluating eMTCT-R	Continual and successful project progression
HIV surveillance global community	Provide feedback on how HIV surveillance can be improved across partners and settings	Lessons learned from the project for future registry deployments in other settings and countries

Maturity stage of eMTCT-R

As with most pilot projects, this eMTCT-R is at an early stage of HIS maturity and needs to be evaluated prior to scale-up. By conducting an evaluation at the Level 1: Nascent stage of maturity, implementers can better understand what needs to be adjusted in order to move the eMTCT-R implementation and associated activities to the next maturity level (Level 2: Emerging). At the same time, this evaluation can provide insight into how to further the project in terms of scale: from a pilot study in one district to multiple districts or settings.

In terms of the HIS's dimensions of scale and advancement, the eMTCT-R is at a low level of maturity (see location of blue box in Figure 3). Even though this registry is thoroughly digitized and may, therefore, not be considered nascent, it is still considered to be between a nascent and emerging system nonetheless. The eMTCT-R lacks interoperability standards and policies. Importantly, it does not have any capacity to integrate data between applications used by other programs, organizational units, and levels of the health system (e.g., between HIV and vaccine programs). While the eMTCT-R's architecture for data management and use have been planned, these have yet to be observed. Moreover, the eMTCT-R has not yet been incorporated into the program's HIS ICT infrastructure.
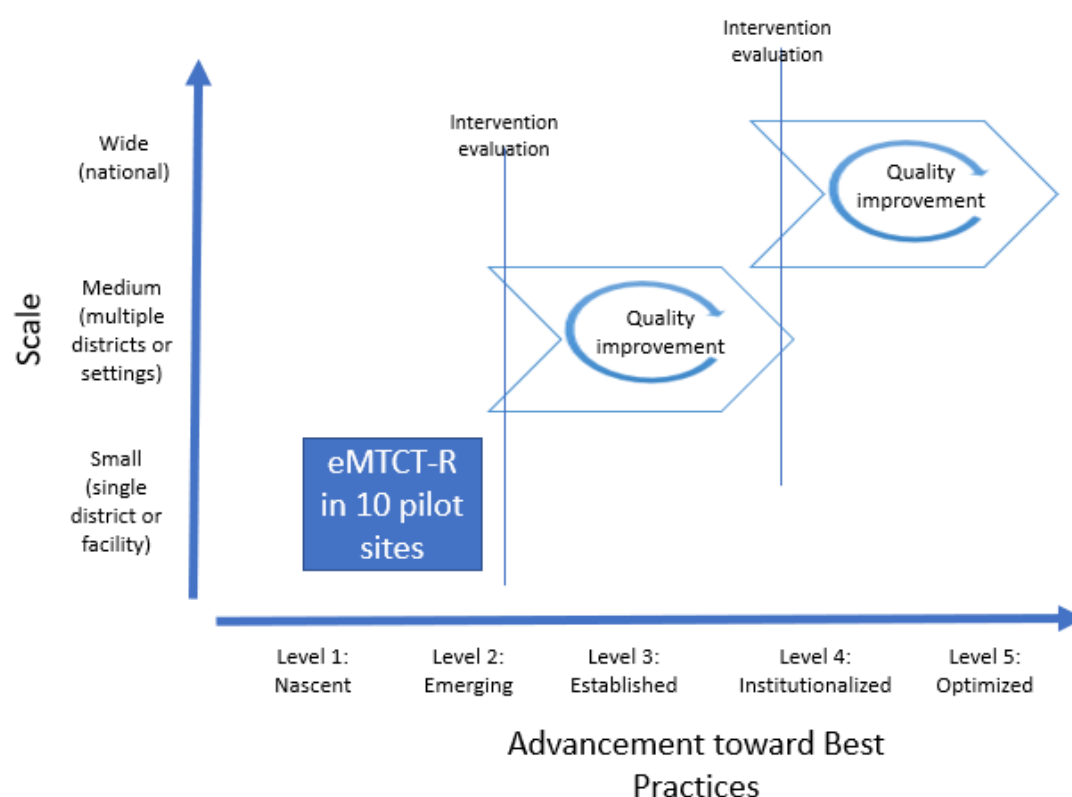
Figure 3. Maturity model for eMTCT-R

Evaluation approaches

The country devises two evaluation approaches to understand if the eMTCT-R has delivered its intended benefits as described in the logic model. Each evaluation approaches serves different purposes and answers different questions. The process evaluation, called the operational evaluation here, aims to understand the factors that may affect the outcomes. It assesses whether the intervention was implemented as intended. The outcome evaluation, called the research-oriented evaluation in this case scenario, measures changes in outcomes following the implementation of the eMTCT-R. Therefore, in this case scenario, the process evaluation will help show how and why the pilot eMTCT-R deployment was successful or not, while the outcome evaluation will help show changes in intermediate health outcomes.

In some situations, a country may choose to do only one approach. For this reason, each is described here as a standalone activity. Table 2 provides a brief overview of the differences between the two.

Table 2: Operational vs. Research-oriented Evaluations

	Operational Evaluation (Process)	**Research-oriented Evaluation (Outcome)**
Primary purpose	Learn about immediate eMTCT-R improvement needs before scale-up	Understand effectiveness of eMTCT-R Contribute to global evidence base on HIS implementation
Logic model phases	Activities; Outputs	Outcomes
Use of findings	Inform updates of eMTCT-R technology Help improve training and standard operating procedures before scale-up Serve as a 'proof of concept' for implementation in a small geographic area	Provide insight into effects of eMTCT-R on intermediate health outcomes Share with regions or countries interested in similar solutions Disseminate results in a peer-reviewed publication
Demand on resources	Can be conducted rapidly with minimal effort	Significant amount of time for data collection and analysis
Staff capacity needed	Standard skills in program management and monitoring	Specialized expertise in statistics

Operational evaluation

The country's MOH and HIV surveillance program managers choose an internal operational evaluation of the eMTCT-R's first six months of deployment. This assessment serves as the process evaluation. Table 3 provides a summary of this evaluation approach. More specific details follow the table.

Table 3. Overview of operational evaluation approach

Evaluation Questions	Domains	Type of Evaluation	Type of Data	Methods
1) Does the eMTCT-R improve the quality of reported HIV surveillance data? *Value claim:* • *Improved data quality and accuracy of benchmark estimates at*	Business process, Health	Process and Output	Quantitative	• Summarize data completeness and timeliness • Concordance analysis comparing number of patients included in registry with those recorded in paper tools

project facilities				

2) What is the acceptability of the eMTCT-R for health facility, district, and national MOH staff?
 	
What factors will assist with introducing and implementing the eMTCT-R?
 	
What factors will hinder it?
 	
Value claims:
• *Improved disease surveillance of HIV among pregnant women, mothers, and infants*;
• *Improved monitoring of the use and effectiveness of the PMTCT system*
	Human, Business Process	Process and Output	Qualitative	• Open-ended survey questions describing how the eMTCT-R is used, focusing on:
				  o acceptability
				  o perceptions of effectiveness
				  o factors encouraging use
				  o barriers to use

3) What is the fidelity of the eMTCT-R?
 	
Is the system being used?
 	
Is it being used as intended?
 	
Value claims:
• *Improved tracking and reporting of key benchmarks and sentinel events of HIV surveillance cascade;*
• *Improved efforts for conducting outreach for patients lost to follow-up due to increased data accessibility*
	Business Process, Human	Process	Qualitative and quantitative	• Standardized survey questions on uses of the registry by each stakeholder group
				• Analysis of process monitoring data:
				  o Workforce data from eMTCT-R on frequency of registry use over time
				  o Number of facilities and HCWs using registry for tracking and reporting on patients lost to follow-up

Domains of measurement

Ideally, all HIS evaluation domains of measurement should be included in any HIS evaluation, though resource constraints often limit the evaluation's scope. This operational evaluation focuses on the following domains:

• **Health**: The intent of the eMTCT-R is to improve the data collected for tracking the PEPFAR 90-90-90 goals and for improving HIV-related health outcomes by identifying patients lost to follow-up. While this evaluation, does not explicitly capture this information, it does assess the impact of the eMTCT-R on intermediate health outcomes of the PMTCT care cascade, namely HIV testing and treatment .

- **Business process**: Within facilities and district MOH offices, processes and workflows will change with the introduction of the eMTCT-R. Therefore, this evaluation should capture how these processes change as well as any factors that will either help or hinder staff in conducting their work. In addition, this evaluation should assess how the increased accessibility to data, leads to the development of new business processes or activities that would require additional assistance or training.

- **Human** The eMTCT-R requires significant buy-in and acceptability to be successful. If the staff find the eMTCT-R difficult to use, they may forgo using it altogether. Therefore, this evaluation documents how stakeholders use the eMTCT-R as well as their level of comfort and perceptions about the solution.

Design: retrospective, cross sectional

This operational evaluation seeks to analyze the eMTCT-R implementation after deployment. Therefore, it uses mixed methods – a retrospective analysis of quantitative data and a cross-sectional qualitative survey – to provide a rich snapshot of how well the eMTCT-R has been implemented in the pilot facilities. The quantitative results will inform stakeholders of any changes in HIV surveillance system outputs and whether the expectations for the eMTCT-R intervention are being met. In addition, quantitative analysis of programmatic monitoring data on technical problems and troubleshooting needs will provide additional information on registry use. To determine any change in data quality from the eMTCT-R intervention, the country's evaluators will compare patient data collected on the paper registers with the same data input into the electronic registry via the tablets. The survey findings will help contextualize the introduction and use of this type of intervention, as well as help identify opportunities for future improvements. This study does not aim to assess causality or impact of the eMTCT-R on HIV testing or treatment.

This study design incorporates elements of a process evaluation that assesses the activities and outputs described in the logic model. Evaluating the activities helps stakeholders learn how the eMTCT-R was deployed, namely if HCWs used it correctly. This understanding helps to understand if any observed outcomes can possibly be attributed to the tool. Conducting a process evaluation on the outputs provides insight into the reach, usability, and acceptance of the eMTCT-R.

Timing and resources

The country decides to use data collected 3-6 months after eMTCT-R deployment. It waits for at least three months because facility staff were still becoming familiar with the new software and troubleshooting technical problems during the first three months. Collecting data from the 3rd month through the 6th month of deployment is enough time to observe true differences in data quality, usability, and outputs after eMTCT-R introduction.

The evaluators will leverage the quantitative information routinely collected by the HMIS for some indicators, but for some of the indicators, data from paper-based records will need to be collected. It is important to remember that it can be time consuming to complete these activities

depending on the quantity of the data needed for the analyses. This can be a burdensome data collection activity, especially at large facilities with lots of paper records. Therefore, we felt the need to limit the amount of time needed for the analysis in order to reduce the additional staff time needed for data collection activities. Additionally, the evaluators will require time from the HCWs for the qualitative survey activity.

Overview of evaluation methods

Table 4 describes the methods and indicators that the country uses to answer each evaluation question.

Table 4. Operational Evaluation: Indicators and methods to address evaluation questions

Evaluation question	Indicators	Methods	Data sources
1) Does the eMTCT-R improve the quality of reported HIV surveillance data?	• Concordance ratio of the number of women with HIV status recorded and infants on PMTCT recorded in the paper-based tally sheets and monthly aggregate reports • Completeness of case information at the individual level based on a comparison of the number of individuals with lab tests ordered with those that have lab results recorded	**Method**: Concordance analysis between data sources **Description**: For the 3-6 months after eMTCT-R deployment, paper-based tally sheets will be compared to the aggregate monthly counts reported from the eMTCT-R and to the HMIS for the number of infants initiating PMTCT recorded. In addition, the test orders and results captured electronically by the laboratory staff will be compared with those input on paper registers. Concordance between the two data sources will be assessed, with concordance defined as 95% matching. Tests of significance will be used to determine if statistically significant changes in concordance scores were observed.	• Paper-based monthly reports • eMTCT-R • HMIS
2) What is the acceptability of the eMTCT-R for health facility, district, and national MOH staff? What are the major strengths and weaknesses of introducing and implementing the	During the first six months post deployment: • % of staff at each level of the health system indicating comfort and understanding of the eMTCT-R • % of staff at each level of the health system indicating particular uses of the eMTCT-R • % of staff at each level of the health system identifying strengths and	**Method**: Post-deployment survey supplemented by process monitoring data **Description**: The semi-structured survey will ask staff about their level of comfort using the eMTCT-R, how they use it, barriers to use, and their intended uses for the registry in the future. Each interviewee will be asked a set of standard questions applicable to all types of health care workers, along with a set of questions specific to their job function and use	• Post-deployment survey • Data bundle bills • Monitoring tools

eMTCT-R?	weaknesses with the eMTCT-R • % of facilities indicating technical problems with the eMTCT-R or additional training needs for properly using the registry	of the registry. The purpose of the survey is to describe differences in registry use and acceptance at each level of the health system. Responses from the surveys will be supplemented by routinely-collected process monitoring data that indicates which facilities had technical problems or needed assistance with the eMTCT-R throughout the project period.	
3) What is the fidelity of the eMTCT-R? How is the system being used and is it being used as intended?	During the first six months post deployment: • % of staff from each level of the health system indicating their uses of the eMTCT-R • Average amount of time per week spent using the eMTCT-R by staff from each level of the health system • % of facilities experiencing technical problems or requiring additional training • % of data bundle used per month by each facility • Number of treatment records input on average per facility per day (indicates workload per day) • Number of calls made by HCWs for troubleshooting	**Method**: Post survey supplemented by process monitoring data **Description**: To assess whether the eMTCT-R is being used as intended, responses from the post-deployment survey on use and acceptability will be paired with monitoring data that show areas of non-use or inappropriate use. These areas may be indicated by the eMTCT-R troubleshooting needs identified at each health facility, the volume of information entered into the registry, and the usage level of each data bundle.	• eMTCT-R • HMIS • Post-deployment survey • Data bundle bills • Monitoring tools

Analysis Plan

Since the value of this evaluation design partly lies in its use of both quantitative and qualitative data, the country's analysis plan needs to consider how both types of data interact in yielding the evaluation results. Findings from the quantitative data should be backed by the qualitative data and vice versa. Therefore, the evaluators should decide the method of synthesizing these findings prior to data analysis.

For analyzing data quality, concordance ratios for each pair of data sources per indicator will be calculated (Figure 4), along with a summary of the number of observations with complete lab testing results. For reporting user acceptability of eMTCT-R, the frequency of responses from the post-deployment survey will be summarized. Moreover, the major technical assistance and capacity building needs will be summarized thematically based on a review of the tools documenting troubleshooting. For assessing fidelity of the eMTCT-R, data bundle bills will be reviewed and assessed to calculate average usage as well as to record total data used per facility per month, noting when facilities use all of their data bundles. Additionally, the number of individuals and the number of HIV indicators recorded in the eMTCT-R each month will be documented. Finally, the troubleshooting logs will be reviewed to understand any inconsistent or surprising findings in the data.
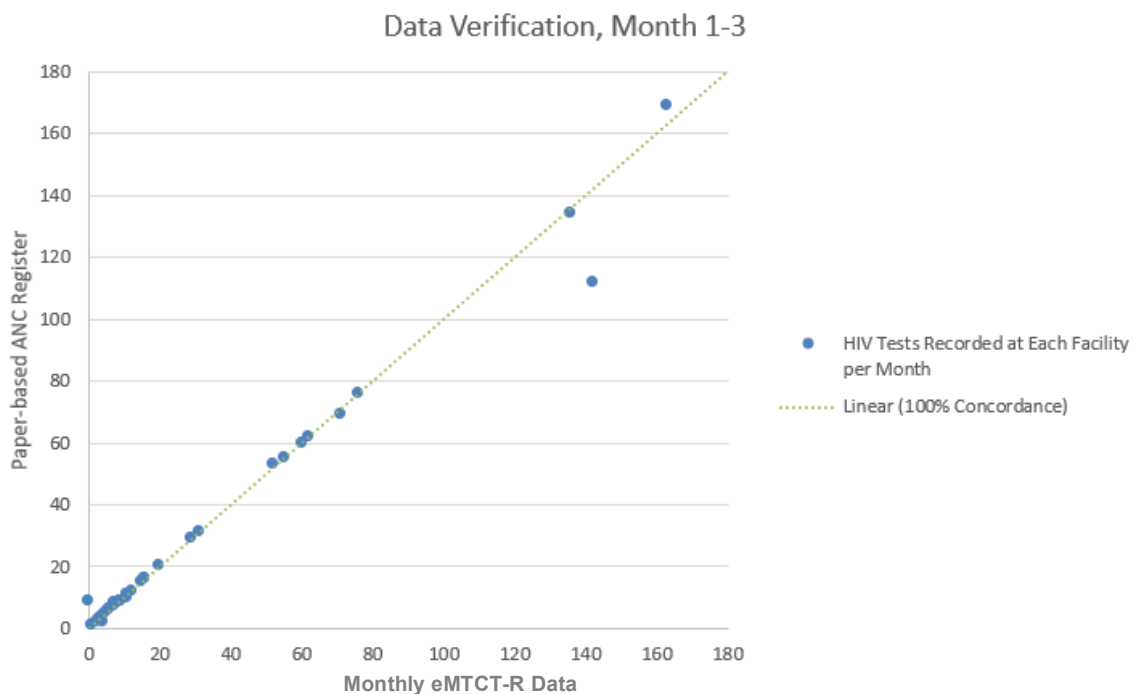
Figure 4. Example of presenting concordance ratios between two data sources

Use of findings

The country will use the operational evaluation findings to:

- Document strengths and challenges of eMTCT-R implementation
- Inform future updates and needs for scale-up in the district and country
- Describe the reach of the eMTCT-R amongst HCWs and patients in catchment area
- Characterize the best use cases, lessons learned, and workflows for this type of innovation for the global community
- Describe changes in data quality before and after eMTCT-R implementation

Research-oriented evaluation

The country's MOH partnered with an academic institution it collaborates with to conduct an outcome evaluation one year after the deployment of the eMTCT-R. It aims to understand if the introduction of this type of system has an effect on health-related outcomes.

To do so, the evaluators utilize a retrospective study design to conduct an interrupted time series analysis[iii] comparing the HIV testing and treatment initiation at facilities included in the project to control facilities before and after the deployment of the eMTCT-R. Additionally, they use a difference in differences analysis[iv] to assess changes in the timeliness of HIV treatment initiation pre versus post deployment of the eMTCT-R. To understand facility staff perceptions of the new electronic registry, the evaluators conduct a qualitative arm of the evaluation. Table 5 provides a summary of the evaluation approach.

> **KEY TERMS DEFINED:**
>
> **Interrupted time series:** A special type of time series analysis in which the series is broken up by the introduction of the intervention that occurred at a specific point. If the intervention has a causal impact, the post-intervention series will have a different level, or slope, than the pre-intervention series**.**
>
> **Difference in differences analysis:** A statistical technique that attempts to mimic an experimental research design using observational study data, by studying the differential effect of a treatment on a 'treatment group' versus a 'control group' in a natural experiment. It compares the average change over time in the outcome variable for the treatment group, compared to the average change over time for the control group.

Table 5. Overview of research-oriented evaluation approach

Evaluation Questions	Domain	Type of Evaluation	Type of Data	Methods

1) Do the following indicators change after deployment of eMTCT-R:
  • % of HIV-positive deliveries with a woman on ART; and
  • % of women continuing ART medication 3 months post-partum?
 	
Value claim:
• *Improved initiation to HIV care and treatment among patients*)
	Health	Outcome	Quantitative	• Interrupted time series analysis of the % of HIV-positive deliveries with a woman on ART and the % of women continuing ART medication three months post-partum, comparing these indicators from the pre/post deployment of the eMTCT-R with those from the control districts

2) Does the use of eMTCT-R improve the timeliness of ART initiation?	Health, Human	Outcome	Quantitative	• Comparison of timeliness of ART initiation between data recorded in paper-based

				tools and those captured by eMTCT-R
Value claim: • *Improved efforts for conducting outreach for patients lost to follow-up due to increased data accessibility*				
3) What are the user perceptions of the eMTCT-R and its implementation context (setting)? *Value claim:* • *Improved monitoring of the use and effectiveness of the country's PMTCT system*	Human	Process	Qualitative	• Key-informant interviews collecting information on contextual factors that could influence intended outcomes of the eMTCT-R

Domains of measurement

As with the operational evaluation, resource constraints limited the domains covered by this research-oriented evaluation. It focuses on the health and human domains. For descriptions of these domains and why it is important to evaluate them, see 'Domains of measurement' in the Operational Evaluation description above.

Design

This research-oriented evaluation uses mixed methods. The quantitative methods aim to generate evidence about the effectiveness of the eMTCT-R on HIV treatment initiation and timeliness. Key-informant interviews with stakeholders supplement the quantitative data with a comprehensive picture of whether the eMTCT-R is effective, as well as how and why it is effective.

To gather quantitative data, the country's evaluators employ a quasi-experimental study design[v] that leverages the availability of monthly estimates of HIV surveillance indicators, along with the knowledge of exactly when the eMTCT-R was deployed in each facility. Additionally, the use of a sample of control facilities allows for the true effect of the eMTCT-R on HIV treatment initiation and timeliness to be observed.

> **KEY TERMS DEFINED**
>
> **Quasi-experimental study design**:
> An empirical study used to estimate the causal impact of an intervention on its target population without random assignment. Quasi-experimental research shares similarities with the traditional experimental design or randomized controlled trial, but it specifically lacks the element of random assignment to treatment or control. Instead, quasi-experimental designs typically allow the researcher to control the assignment to the treatment condition, but she uses some criterion other than random assignment (e.g., an eligibility cutoff mark).

The control facilities should ideally be selected based on criteria set *a priori* of the study; readily available information on facilities in the district can be used to identify control facilities that are similar to the project facilities. Criteria may include size of facility, type of facility, patient load, or

location. In order to identify facilities with similar characteristics, those located outside the eMTCT-R pilot district may need to be used as controls, if no similar types of facilities can be found within the pilot district.

Processes and outputs are not included in this research-oriented evaluation study design as the country's operational evaluation will assess how the eMTCT-R was deployed. If the operational evaluation approach is not done, however, an evaluation team should ideally include process indicators and evaluation methods in the design.

In addition, this evaluation methodology could be modified to also assess some of the indicators listed in the operational evaluation design. Indicators such as data quality could be evaluated before and after the introduction of the eMTCT-R. Doing so would introduce more rigor to the study design because it utilizes information from the "control" time period, before the eMTCT-R was implemented.

Timing and resources

Each evaluation question uses different data sources and different time frames for data collection. See Table 6 for the specific sources and timing for each question. In terms of the data collection burden, the use of digital information systems such as eMTCT-R and HMIS greatly reduces the burden compared to conducting this evaluation using paper-based records.

Overview of evaluation methods

Table 6 summarizes the methods chosen to answer the evaluation questions.

Table 6. Research-oriented Evaluation: indicators and methods to address evaluation questions

Evaluation question	Indicators	Methods	Data Sources
1) Do the following indicators change after deployment of eMTCT-R: • % of HIV-positive deliveries with a woman on ART; and • % of women continuing ART medication 3 months post-partum?	ART coverage will be assessed by: Separate interrupted time-series analyses using linear regression for HIV testing and ART initiation	Method: Interrupted time series analysis Description: Compare the proportion of HIV-positive deliveries in which a woman is on ART with the proportion of women continuing ART medication three months post-partum. Do this comparison six months prior to eMTCT-R deployment and throughout one year post deployment, assessing statistically significant change between pre- and post- periods as well as between project and control facilities.	• eMTCT-R • HMIS
2) Does the use of eMTCT-R improve the timeliness of ART initiation?	Timeliness will be assessed by: Difference in differences of the proportion receiving on-time ART treatment between project and control facilities *Note: "On-time" is defined as ART initiation immediately following case identification.*	Method: Difference in differences analysis Description: Randomly sample mothers and infants for whether they received ART on time six months pre eMTCT-R deployment and at six months post eMTCT-R deployment. Describe if there is a statistically significant difference in proportions.	• eMTCT-R • ANC registries used during post-deployment survey
3) What are the user perceptions of the eMTCT-R and the implementation context (setting)?	Perceptions and context/settings will be assessed by: Thematic summary of key themes identified from interviews	Method: Post-deployment key informant interviews Description: Six months after the eMTCT-R deployment, identify a purposive sample of key users and stakeholders who can provide insights into the use of the eMTCT-R along with details on any change occurring in the implementation setting.	• Interview transcripts

Sampling Strategy

Indicators can be compared between project and control facilities in the same district. Using sites in the same district can help control for district-level influences such as infrastructure, stock-outs, and MOH supervision which may differ in other districts. However, identifying statistically significant differences in estimates could be limited by the sample size and total number of health facilities in the district.

To compare the HIV treatment initiation between pilot and control facilities, control facilities from the district will be sampled based on:

- type of facility (public vs. private and level of care provided) and
- health facility size (defined as the number of patients receiving HIV treatment or counseling per month)

The sample size is contingent on the baseline rates of the outcomes of interest and the difference in outcomes that one expects to observe if the intervention is effective (also called the "effect size"). The sample size should be determined based on these parameters, keeping the type I and II errors consistent and rational. Control facilities will be sampled using a 1:3 ratio, therefore, for each pilot site, three control facilities will be selected. Using this 1:3 ratio helps increase the statistical power to detect differences in our outcomes of interest should those differences truly exist. Table 7 summarizes the sampling strategies for this evaluation.

Table 7. Summary of sampling strategies for research-oriented evaluation

Data source	Person collecting data	Sampling strategy
eMTCT-R	Data manager	**10 pilot health facilities: 12 months** Data from all pilot facilities will be analyzed for the year following deployment of the platform.
HMIS	Registered user for downloading data	**10 pilot health facilities and 30 control health facilities in district: 15 months** Data reported from the pilot health facilities will be pulled for the six months pre-deployment of the eMTCT-R and the 12 months following deployment. A sample of control health facilities in district will be selected using a 1:3 ratio with matching based on facility size. Data from control facilities will be pulled for the same time period.

Post-deployment key informant interviews	eMTCT-R users, MOH staff at sub-district, district, and national levels	**Interviews of eMTCT-R users by stakeholder group** eMTCT-R users will be interviewed on eMTCT-R use and perception of the eMTCT-R's effectiveness for improving HIV treatment initiation and timeliness. These interviews will also ask users' perceptions of any other factors that may have influenced observed changes in outcomes.

Analysis Plan

The value of this evaluation design partly lies in its use of control facilities, but also with the use of both quantitative and qualitative data. When writing the analysis plan, the country's evaluators need to consider how both types of data and how data from both groups of facilities will create a coherent story about the effect of the eMTCT-R on HIV surveillance outcomes and why this effect was observed. Determining how to synthesize the data should be decided upon prior to the analysis and ideally, data collection. It is important to determine how conflicting evidence will be presented ahead of time.

Evaluation question #1: How eMTCT-R improves ART adherence
The country's interrupted time-series analysis will use multiple observations over time from the same facility to assess changes in the outcomes of interest. Prior to the deployment of the eMTCT-R, the evaluators anticipate a consistent rate in the outcomes on a monthly basis (slope of 0). After eMTCT-R deployment, they expect to observe improvement in these outcomes over time (positive slope), with a short lag in improvement observed for the time needed for HCWs to learn how to use the new eMTCT-R software (where they will possibly see no change or worse outcomes). Figure 5 shows the country's impact model in which a change in the slope of the outcomes is expected over time, following a 2 month lag after eMTCT-R deployment.
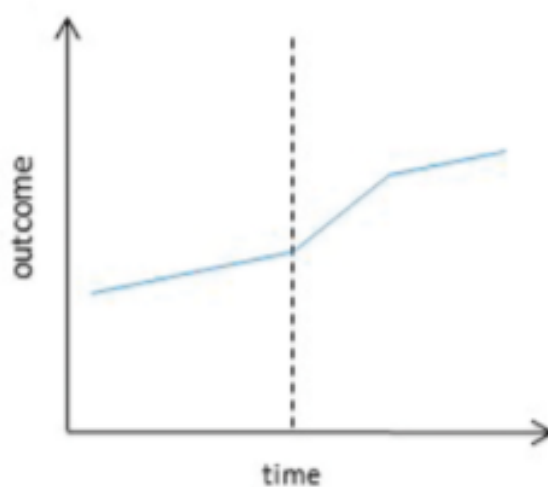
Figure 5. Example of interrupted time series with temporary slope change[vi]

When conducting an interrupted time-series analysis, the country's evaluators will first provide summary statistics and plots of the data to both understand the observations and determine if any additional factors need to be investigated or controlled for. A regression analysis using ordinary least squares can then be used to assess each outcome using predictor variables for time -- pre- versus post- deployment of the eMTCT-R, and pilot versus control facility -- along with the corresponding interaction terms. Often with interrupted time-series analyses, data used for the regression model are correlated. This means individual data points or observations are related to one another and are not independently observed; observations can be related over time (autocorrelation) or based on some other programmatic factor or the setting. The observed individual HIV treatment initiation rates may be related if characteristics within a facility influence the observed outcome for multiple individuals, so data would be correlated by facility. The correlation structure must be accounted for in the regression model.

Evaluation question #2: How eMTCT-R improves timeliness of ART initiation
While an interrupted time series analysis could also be used here, the evaluators chose to use a difference in differences approach because it requires fewer data points. This approach requires data from two time points for both the pilot and control facilities. Doing so allows for comparisons to be made over time, thereby allowing each facility to act as its own control. Comparisons are also made between pilot and control facilities at each point in time. In this analysis, they will take the average difference in the outcome for each group and then compare the difference in differences between pilot and control facilities during the pre- and post- time periods. Although the evaluators will lose information on changes over time by only collecting from two points in time, this approach allows them to test for true differences in outcomes due to the eMTCT-R. (Figure 6)
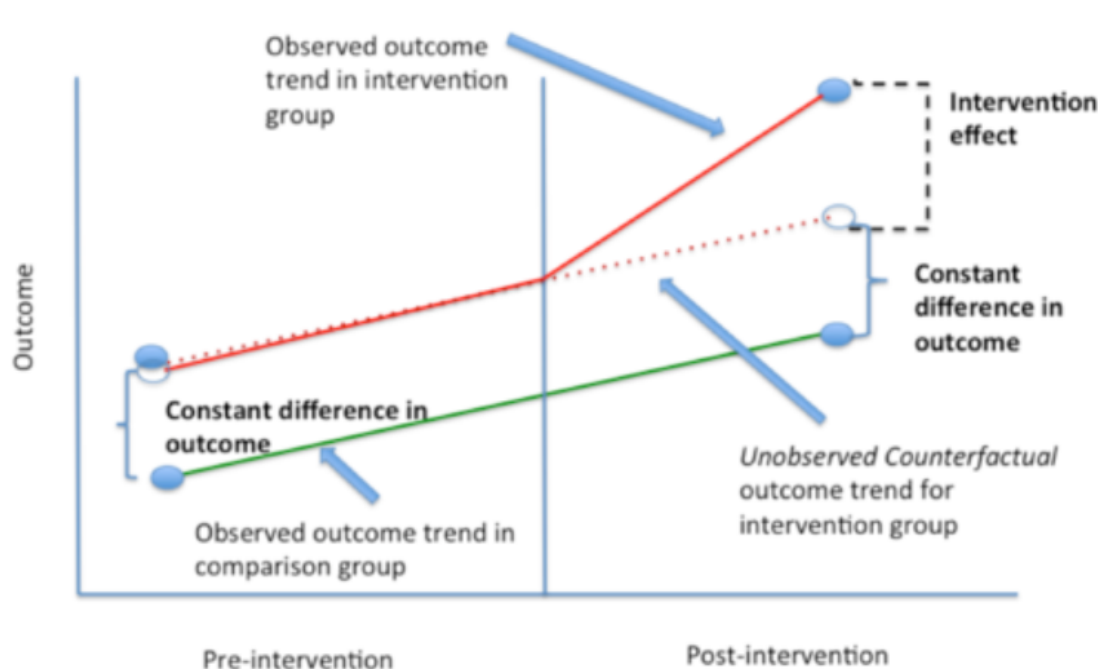
Figure 6. Example of difference in differences analysis[vii]

Evaluation question #3: User perceptions of eMTCT-R and its implementation context
Thematic analysis is conducted on the qualitative evidence gathered from the post-deployment key informant interviews of staff from each pilot facility. Data collected focuses on the attitudes, behaviors, and challenges of working with the eMTCT-R, as well as any changes occurring within the facility or those affecting the facility during the project period. The latter may influence the health outcomes seen after the deployment of the eMTCT-R. Table 8 below summarizes all of the steps involved in the data analysis of the qualitative data. For further reading on qualitative data analysis, see the resources in the bibliography.

Table 8. Overview of Analysis Plan for Research-Oriented Evaluation

Evaluation question	Method	Analysis steps
1) Do the following indicators change after deployment of eMTCT-R: • % of HIV-positive deliveries with a woman on ART; and • % of women continuing ART medication three months post-partum?	Interrupted time-series analysis	1. Select impact model: slope change following a 2-month lag 2. Conduct descriptive analysis: summary statistics and plots 3. Select model type, outcomes, and predictors: Separate ordinary least squares (linear) regressions for ART adherence and ART use during delivery for HIV positive women *Variables:* Outcome: ART coverage (Y_T) Predictors: time (β_1), dummy variable for pre-deployment or post-deployment (β_2), dummy variable for project or control facility (β_3), interaction term for time and dummy variable for deployment period (β_4), interaction term for dummy variable for facility group and time (β_5), interaction term of dummy variable for facility and deployment period (β_6), interaction term for all predictors (β_7) $$Y_T = \beta_0 + \beta_1^* time + \beta_2^* deployment + \beta_3^* control + \beta_4^* time * deployment + \beta_5^* time * control + \beta_6^* control * deployment + \beta_7^* time * deployment * control + e_t$$ 4. Identify the correlation structure of your variables and account for any correlated data in your regression in addition to errors (e_t) 5. Select model type*:* generalized estimating equations (GEE), segmented regression, autoregressive integrated moving average (ARIMA), linear
Does the use of eMTCT-R improve the timeliness of ART initiation?	Difference in differences analysis	For both the project and control facilities, follow these steps: 1. Define time period based on case identification date: 6 months prior to eMTCT-R deployment 2. For all 1st ART administration during time period, record whether or not the treatment was administered on-time for every third individual

<table>
<tr><td></td><td></td><td>3. Calculate % of on-time treatments from observations</td></tr>
<tr><td></td><td></td><td>4. Define post-deployment time period for case identification date: 6-9 months post eMTCT-R deployment</td></tr>
<tr><td></td><td></td><td>5. For all 1st ART administered during time period, record whether or not the treatment was administered on-time for every third child</td></tr>
<tr><td></td><td></td><td>6. Calculate % of on-time treatments from observations</td></tr>
<tr><td></td><td></td><td>7. Calculate difference in % of on-time treatments pre versus post deployment for the project and control facilities separately</td></tr>
<tr><td></td><td></td><td>8. Calculate difference in differences of % of on-time treatments between project and control facilities</td></tr>
<tr><td></td><td></td><td>9. Alternative method: use linear regression with interaction terms for time and facility group</td></tr>
<tr><td>What are the user perceptions of the eMTCT-R and the implementation context/setting?</td><td>Thematic summary</td><td>For key informant interviews of staff at pilot facilities using eMTCT-R, follow these steps:
1. Identify major themes
2. Create codebook
3. Have two coders review each interview and discuss discrepant codes until a consensus is reached
4. Summarize the major codes</td></tr>
</table>

Use of findings

The country will use the research-oriented evaluation findings to:
- Describe changes in ART initiation and adherence within the eMTCT-R implementation context and setting
- Describe changes in timeliness of ART following the introduction of the eMTCT-R
- Inform future updates and needs for scale-up in the district and country
- Provide a "proof of concept" for deployment of electronic registries in the country
- Provide evidence for MOH decision making concerning future investments in eMTCT-R in the country

Considerations for both types of evaluations

Pitfalls and limitations

Evaluation activities

The evaluation approaches described above use time and control facilities as comparison groups for data quality, HIV treatment initiation, timeliness, and loss to follow-up. The use of these controls aims to provide baseline data, or the counterfactual experience of what would happen to our indicators of interest if the eMTCT-R were not implemented and everything else about the implementation setting stayed the same. While controls are used to account for unmeasured factors within the implementation setting, it should be noted that we often cannot control for everything; unanticipated events may occur which may affect the results.

HIS-specific limitations

Within new software systems, especially those collecting individual level data, a lot of data cleaning may be required in advance of starting any of the evaluation analyses. With the introduction of the eMTCT-R, guidance on what should be considered a duplicate record or a false record needs to be decided upon to have accurate counts of individual entries. In addition, system use metrics may need to be developed to be able to determine the difference between a user only logging into the system to check some information versus a user entering a new patient's data.

Analytics and statistics

Due to the small sample sizes and wide variability in the number of patients receiving care at health facilities in the pilot project, it may be difficult to show statistically significant changes in HIV treatment initiation over time at small facilities. We will use an interrupted time-series analysis to assess changes in initiation trends before and after implementation of the eMTCT-R, in order to allow the pilot facilities to serve as their own controls. Additionally, we will also use control facilities as a comparison group.

Biases

There are a number of biases that may affect evaluation results.

Table 9. List of Potential Biases

Type of Bias	Description
Information bias/observer bias	May produce errors if survey questions are not asked in a standardized manner. If survey questions are asked in different ways, the responses may not be comparable or may answer different questions than intended.
Selection bias	May produce errors if the correct staff are not identified for completing the surveys. As a result, the target population will not be well represented in the survey results. Also, data will not reflect the true perceptions of the study population because only those staff

	who would provide "good" answers were chosen for the survey.
Confounding bias	May produce erroneous results if factors related to the implementation of the eMTCT-R influence the outcomes of the evaluation, but are not controlled for in the evaluation methods. For example, if HCWs are trained on improving record keeping for HIV surveillance during the eMTCT-R's implementation, it will be difficult to determine whether the eMTCT-R, the training, or a mixture of the two, produced the observed results.

Ethics/IRB

For both evaluation approaches, the country evaluators note the following ethics issues:

- Sensitive patient-data needs to remain protected throughout the data collection, analysis, and dissemination activities. Data security should be considered prior to the start of the evaluation, with all necessary permissions and data sharing agreements in place.
- Anonymity of survey responders and health facilities is important to maintain throughout the evaluation since some of the evaluation questions may be politically sensitive or put the performance of the HCW or facility into question. Results should be anonymized and presented in aggregate whenever possible.
- Results should be presented as agreed upon by the owners of the data and in line with data sharing agreements. Plans for dissemination of the evaluation results should be agreed upon by the stakeholders ahead of time.

Dissemination of findings

Results of the evaluation will be disseminated to the pilot health facilities, district HIV program managers, and the national MOH managers through reports, calls, and presentations. Additional stakeholders working in HIV surveillance, as well as those working in the open-source software community, will be notified of findings through regular channels of communication (e.g., blog posts, online forums, online communities). Results of the evaluation may be submitted for publication in a peer-reviewed journal or for presentation at an international conference.

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[i] https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/registries-guide-3rd-edition_research.pdf
[ii] Top portion of figure adapted from: https://www.researchgate.net/figure/289586627_fig3_Figure-1-PMTCT-cascade-of-services-for-mothers-and-infants-ANC-antenatal-clinic-ARV
[iii] https://www.ipr.northwestern.edu/workshops/past-workshops/quasi-experimental-design-and-analysis-in-education/2010/docs/QE2010-Day3ppt.pdf
[iv] https://en.wikipedia.org/wiki/Difference_in_differences
[v] https://en.wikipedia.org/wiki/Quasi-experiment
[vi] https://academic.oup.com/ije/article/46/1/348/2622842
[vii] https://www.mailman.columbia.edu/research/population-health-methods/difference-difference-estimation

Health Information System Evaluation Case Scenario #2

Title

Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility

Overview of Case Scenario

HIS system type: Electronic Medical Record

Stage of maturity: Level 2- Emerging

Project type: Pilot EMR system at the point of service delivery in outpatient HIV clinic

Domains: Health, Human, Technology, Organization & Governance, Business Process, Economic

Study designs:

Operational evaluation- Pre-post cost analysis
Purpose:

- Enumerate the costs of owning and operating the EMR compared to the paper-based system

Research-oriented evaluation- Cost-effectiveness analysis
Purpose:

- Compare incremental costs of the EMR vs the paper-based system

- Differences in clinic processes such as the total time spent per patient or health outcomes such as number of virally suppressed patients are compared to the period in which the paper-based system was used

Results:

- Findings will be disseminated to stakeholders through policy briefs, reports, presentations, and mobile methods (teleconference and videoconference)

- The evaluation will provide information about the affordability and cost-effectiveness of updating a paper-based system to an electronic format

1. Introduction

a. Background

Economic evaluations of healthcare programs are performed to inform policy makers and other stakeholders about the degree to which alternative interventions improve outcomes given their costs. These evaluations also help determine whether or when to change the intervention mix or intervention coverage levels for a given health care problem. [1]

Economic evaluations are important because resources are scarce. Although resource scarcity is pervasive across countries, low-income countries face severe resource constraints: the mean per capita healthcare expenditure in low-income countries is $US 164 compared to $507 in lower-middle-income countries, $1,935 in upper-middle-income countries, and $9,019 in high-income countries.[2] Given resource scarcity, decisions about alternative uses of available resources for health care should be made after explicit considerations of costs and benefits. [1] This allows a consideration of the opportunity costs, or benefits foregone by taking the alternative course or courses of action. Therefore, economic evaluations can answer questions about the value of health care programs.

> **Range of projects to which this scenario can be applied**
>
> Ministries of Health and donors care about the cost of ownership of HIS systems, and the returns in quality of health care services or efficiency that these systems may bring. The health economic evaluation methods covered in this scenario could be applied to many types of HIS interventions besides the point of service electronic medical record described here. These interventions may include implementation of other HIS tools, such as pharmacy data, laboratory information, logistics management information, or human resource information systems. They may also include integration of mHealth tools within existing paper-based, hybrid, or electronic data systems. The concepts related to estimating cost and cost-effectiveness can be applied to these other types of interventions.

Economic evaluations may also be conducted to assess affordability. Also known as **budget impact analyses** (BIAs), these evaluations compare net costs under the new intervention with those during the old intervention/pre-intervention period over one to three years.

The objective of an economic evaluation of an **electronic medical record** (EMR) system at a district-level outpatient clinic would be to inform health sector policy makers in a given country about the potential benefits of introducing the EMR system, given its likely higher cost compared to the standard of care (SOC) in which there was no EMR system. Given the advantages and downstream benefits of the EMR system, would the added cost represent value for money to different stakeholders?

An economic evaluation would also answer questions about the costs of owning and operating the EMR system. Given evidence that an EMR system represents value for money, can the outpatient clinic afford the initial investment and the ongoing costs of running the system?

b. Setting

The setting for this case study is a public-sector secondary (district-level) outpatient HIV clinic in a low-income country. The clinic has a monthly patient load of up to 5,000 patients. The clinic currently used a paper record system to manage patient data. The leadership of the clinic has directed the management to plan and introduce an EMR system at the point of service delivery to replace the paper record system.

The EMR system will be deployed at the outpatient HIV clinic. The clinic is divided into administrative and clinical units. The administrative unit is responsible for day-to-day management functions such as administration and patient outreach including community follow-up of patients that need ongoing care. The clinical unit is responsible for patient care and is divided into the outpatient care, laboratory, and imaging centers. The EMR is planned for deployment to all units to ensure comprehensive access to patient data for clinical and administrative use.

c. Description of HIS- functionality and technical attributes

The EMR system is an open-source system which has been implemented in other countries, and which has been customized by the technology partner for use at point of service in HIV outpatient clinics. The system operates from a local server and uses "thin client" terminals networked via a local area network. Health workers use the system via terminals located at the reception desk, in clinic consult rooms, and other points of service.

Clinicians are expected interact with the system as they care for patients, as well as via patient summary reports or patient cohort reports. Mandatory variables such as demographic data, vital signs, and medications must be entered into the computer during each clinical encounter. It takes about 10 min to enter the records of a new patient and about 5 min to update the records of a repeat visit patient if all required information is available.

The system contains alerts and reminders to flag patients who have missed appointments, who have HIV viral load monitoring or other tests due, and patients with abnormal lab values, through individual alerts and group reports. Reports include quality of care indicator reports intended to be used regularly in clinical quality improvement processes. The system also includes functionality for automated indicator reporting to the national HMIS system.

d. Purpose

The EMR system is a **health information system** (HIS) that will be used for the following tasks:

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- Patient registration
- Clinical data collection
- Tracking of lab orders and results
- Clinical decision support (alerts and reminders)
- Automated report generation
- Automated tracking of quality metrics

The project goal is to implement the EMR in the target district hospital, evaluate results, and then scale up the system to other district hospitals.

e. Stakeholders

Table 1 is a summary of stakeholder roles and priorities.

Table 1 — Stakeholder roles and priorities

Stakeholder	Role	Priorities
National MOH and HIV surveillance managers	Setting standards Creating data reporting tools National-level governance Evaluation of EMR technologies	Long-term nation-wide scale up of EMR system
Technology partner	Customizing EMR to local setting: design, testing, deployment	Efficient operationalization of EMR
Pilot healthcare workers (HCWs) at facilities	Implementation and use of EMR	Improvement in day-to-day clinic operations

Sub-district and district managers and supervisors	Data quality Training and support Infrastructure maintenance	Uniformity and consistency in EMR operations across facilities
Funder	Provision of monetary resources	Value for money

f. Value claims

In the context of this new EMR system, the leadership of the outpatient HIV clinic is interested in improving three key outcomes. Compared to the current paper-based system, the new EMR system would be expected to:

1. Improve completeness of data records due to consistent data recording
2. Increase adherence to clinical guidelines by clinical staff due to clinical decision support tools
3. Improve overall quality of clinical care due to increased access to clinical information

The leadership of the outpatient clinic is also interested in an analysis of the costs of owning and operating the HIS system as it relates to the potential benefits in terms of improvement of the outcomes above.

The main value claim of many HIS projects is that they improve productivity of health care workers and (by extension) efficiency of health care services by making information easier to find and act upon.

2. Logic and Maturity Models

An economic evaluation of the HIS (EMR) system might follow a logic (conceptual) model as shown in Figure 1 (below). The **inputs** are the hardware, software, and resources for operationalizing the new HIS. The **activities** include the installation and testing of the HIS system, as well as the training of personnel. The expected **outputs**, as described above, are improved completeness of patient records, improved adherence to clinical guidelines, and improved quality of clinical care. These improved outcomes would be expected, ultimately and

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in the medium- and long-term, to improve health outcomes (life expectancy and quality of life) and improve efficiency of clinic operations (cost-effectiveness and affordability).

Figure 1. Logic model
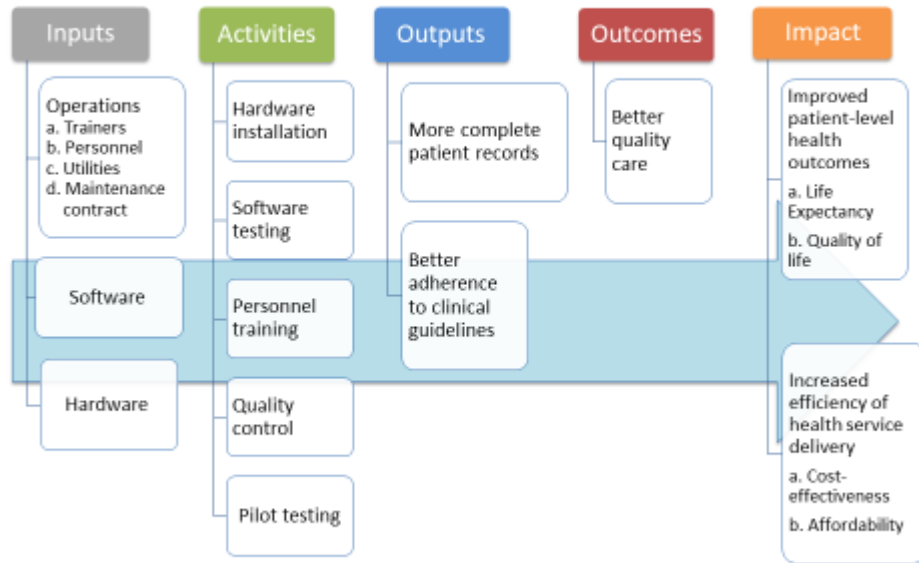
The logic or conceptual model guides the economic evaluation. [3] It clearly outlines the event pathway stemming from the use of a new intervention and its impact on outcomes. The logic model usually translates into the decision model for purposes of conducting model-based analyses, and should be designed with this in mind.

The EMR system deployed at a single HIV clinic is nascent in both scale and maturity (figure 2). Initially non-existent, the EMR system will need to be deployed specifically to replace the current paper based record system, corresponding to level 1 on the x axis and pilot (1 clinic) scale on the y axis in figure 2.

Figure 2. Maturity model

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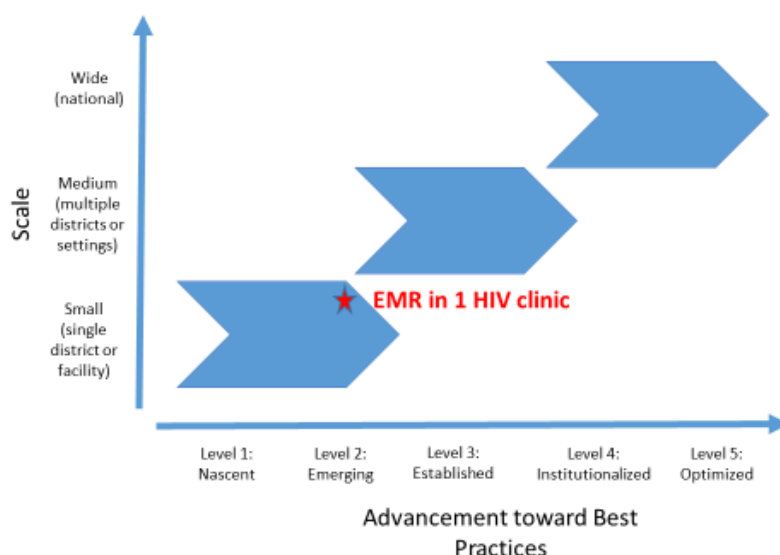
3. Evaluation Approaches

Economic evaluation (of health care programs) is defined as the comparative analysis of alternative courses of action within the health sector in terms of both their costs and consequences. [1] In the context of a new EMR system deployed at a district-level outpatient clinic, an economic evaluation would compare the costs and consequences of deploying the new EMR system, compared to the standard of care (SOC) before the EMR system was deployed.

Economic evaluations of healthcare programs can be divided into partial and full economic evaluations [1]. To qualify as **full economic evaluations**, studies must fulfill two criteria: (1) they must consider both costs and consequences of interventions, and (2) they must compare an intervention to one or more comparators. Full economic evaluations include cost-effectiveness analysis, cost-utility analysis, cost-minimization analysis, cost-consequences analysis, and cost-benefit analysis. **Partial economic evaluations** do not fulfill both criteria above and include cost description, cost analysis, cost-outcome description, return-on-investment analysis, and budget impact analysis.

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For purposes of this case study, we will consider the partial evaluations as applicable to an operational evaluation and full economic evaluations as applicable to a research-oriented evaluation.

a. Domains of measurement in economic evaluation

Economic evaluations involve multiple domains since they seek to measure how resources (including human resources, financial resources, and infrastructure investments) are used to produce healthcare services as well as the outputs or consequences of those services (table 2).

- **Health:** It is important to plan for and collect data on the impact of the EMR process to improve intermediate outcomes that affect health. This is critical to the successful downstream conduct of research-oriented evaluations. For example, operational evaluations might collect data on the impact of the EMR to improve adherence to antiretroviral medications through the clinical decision support function. Data on adherence may then be used to model the impact of the EMR system on life expectancy through improved adherence.
- **Human:** The human domain is critical to both costs and consequences assessment. A new EMR requires a redistribution of human resources with impact on both costs and effectiveness of service delivery. Due to the learning period of getting HCWs up to speed on using the EMR, the initial period following deployment of the EMR is likely to both increase cost and reduce effectiveness of service delivery. In the long run, following the initial learning period, the new EMR may improve the efficiency of human resources use leading to lower costs and improved outcomes.
- **Technology:** Given that a new EMR system is heavily technology dependent, the technology domain is front and center of the assessment of cost and consequences of the new EMR including impacts of the technology on business processes, staff roles, staff time use, and staff training and professional development.
- **Organization and governance:** The organization and governance domain is captured in operational economic evaluations of the new EMR system because different resource consumption and health services utilization patterns are associated with different costs and outcomes. Additionally, data generated by the EMR system may be used to improve organization and governance.
- **Health-sector business process:** A new EMR system would affect health sector business process including such activities as access to and archiving of patient records, creation of reports, and ordering of tests and transfer of results. Therefore, personnel time use is expected to change and may be tracked using time-motion surveys.
- **Economic:** The economic domain—the balance of costs and consequences of investment in an EMR is the main domain of interest in all economic evaluations.

Table 2 – Overview of operational evaluation domains and approaches

Evaluation type	Question	Domains	Data	Elements
Cost description Cost analysis Cost-outcomes description	What is the cost of owning and operating the new EMR system or the existing paper record system?	Human Technology; Organization and governance; Health-sector business process; Economic	Resource use Unit cost	Resource use inventory Unit cost data
Cost-outcomes description	What are the consequences of owning and operating the new EMR system?	Health Human Organization and governance; Health-sector business process; Economic	Outcomes data	Inventory of impacts of EMR system on health center operations
Return-on-investment analysis	What is the financial benefit of owning and operating the new EMR system over a given, fixed period?	Human Organization and governance; Health-sector business process; Economic	Expenditure data	Accounting records
Budget impact analysis	How would owning and operating the new EMR system affect the budget of the outpatient HIV clinic?	Economic; Health-sector business process	Budget, forecasting, and planning data	Budget records

b. Operational evaluation

i. Questions

The relevant questions for partial economic evaluations, considered as applicable for operational economic evaluations in this case study, are as follows:

- **Cost description**: What is the cost of owning and operating the new EMR system?
- **Cost analysis**: What is the cost of owning and operating the new EMR system compared to the costs of operating the existing paper record system?
- **Cost-outcomes description:** What are the costs and consequences of owning and operating the new EMR system?

- **Return-on-investment analysis:** What is the financial benefit of owning and operating the new EMR system over a given, fixed period of time?
- **Budget impact analysis:** How would owning and operating the new EMR system affect the budget of the outpatient HIV clinic?

ii. Economic evaluation methods overview

The operational economic evaluation for purposes of this evaluation do not meet the criteria of full economic evaluations. The different types of partial economic evaluations that are considered for operational economic evaluation of an EMR system at an outpatient HIV clinic are summarized below:

- In **cost description**, the cost of a given intervention is assessed independent of the existing standard of care. The cost of the new EMR system would be assessed independent of the existing paper record system.
- In **cost analysis**, the cost of a given intervention is assessed in comparison to the existing standard of care. The cost of the new EMR system would be compared to the cost of the existing paper record system.
- In **cost-outcomes description**, the costs and consequences of a given intervention are both assessed but the assessment is independent of the existing standard of care. Both the costs and consequences of the new EMR system would be assessed independent of the existing paper record system.

- **Return-on-investment** (ROI) **analysis** estimates the financial return of investment in an intervention over a given period of time. [3] ROI analysis compares the timing and quantity of financial returns to the timing and quantity of costs, and is therefore dependent on time horizon. ROI analysis is not recommended for economic evaluations of health care programs, because health effects are not considered. [3] For an EMR system however, ROI analysis may have a role, given the difficulty of ascribing health effects to a system-level or provider intervention.
- **Budget-impact analysis** (BIA) [3, 5] estimates the expected change in the expenditures of a health system after the adoption of a new intervention; it can be used for budget or resource planning.[5] In a BIA, the costs of health care in the new (post-intervention) environment are compared with the costs under the old (pre-intervention) environment. The difference in costs is the **budget impact**. A BIA can be conducted to assess affordability of the new HIS system for planning purposes. The estimate of the expected change in costs between the pre- and the post-HIS periods can be used to determine cash flow from revenues or government disbursements. In the context of planning, the BIA can be the main input into whether the HIS is implemented.

> **Example of ROI Analysis**
>
> Driessen, et al. modeled the potential ROI in a hospital-wide EMR system.[4] Although they considered a limited set of savings—length of hospital stay, transcription time, and laboratory time—Driessen estimated a net financial gain in the third year of operation of the EMR system, and a financial return of over $600,000 over five years.[4]

iii. Design

Multiple study design options are possible for conducting operational economic evaluations (table 2). The choice of method depends on the timing of study activities compared to the introduction of the intervention as well as available data or available resources for data collection. Both prospective and retrospective analyses are options. In the evaluation of the EMR system at an outpatient HIV clinic compared to the standard paper record system, a prospective design would be ideal if the evaluation is planned before the introduction of the EMR system. If the evaluation is planned post hoc, a retrospective analysis is performed. For the operational economic evaluation of an EMR system, a post-intervention only design would be chosen for cost description and cost-outcomes description.

To perform a **cost analysis** of a new EMR, the costs of owning and operating the EMRS system need to be compared to the paper-based record system. Given that the new EMR would replace the paper-based record system, a pre-post design would be chosen. The cost analysis would compare the monthly or annual cost of the paper-based record system before the implementation of the EMR system and then compare these costs to the monthly or annual cost of operating the EMR system. A cost analysis would not seek to compare the outputs or outcomes of the paper-based or EMR systems.

iv. Timing and resources

Operational economic evaluations are ongoing given that costs are incurred continuously. For cost descriptions and cost-outcomes descriptions, data collection commences at initiation of the EMR system and continues until sufficient data have been collected and analyzed to ascertain the steady state costs of the EMR system. For the comparative analyses—cost analysis, return-on-investment analysis, and budget impact analysis—there is a need for a comparator. Given that the EMR system would completely replace the paper record system, a **period of three to six months** before the intervention would be required during which data are collected to ascertain the steady state cost of managing the paper record system.

A cost analysis of an EMR system should be designed to leverage existing human resources and existing data. Additional training through short courses may be required to prepare health and administrative workers at the health center to participate in the cost analysis.

v. Metrics

Table 2 shows the metrics used for operational economic evaluations by the different research questions.

Table 3 – Metrics used to answer operational economic evaluation questions

Question	Metric
What is the cost of owning and operating the new EMR system or the existing paper record system?	Cost per month or year of EMR system Cost per client served
What are the consequences of owning and operating the new EMR system?	% improvement in completeness of data records % improvement in adherence to clinical guidelines % increase in quality-of-care score
What is the financial benefit of owning and operating the new EMR system over a given, fixed period?	Savings per month or year accrued from using EMR system
How would owning and operating the new EMR system affect the budget of the outpatient HIV clinic?	% increase or decrease in health center budget as a result of introducing the EMR record system

vi. Data collection and costs

The unifying theme of the operational and research-oriented economic evaluation methods is the estimation of the costs of the new EMR system. Costs are a product of quantity of resource use and unit cost/price. As an example, personnel costs are a factor of time spent performing certain tasks (in hours, say) and unit costs or hourly wages.

The choice of which costs to include in a cost analysis of an EMR depends on the perspective of the analysis. In general, there are three kinds of costs incurred for healthcare interventions: **direct medical costs**, **direct non-medical costs**, and **indirect costs**. **Direct medical costs** go to providing patient care, and include such costs as those incurred to procure medicines, diagnostics, and other medical supplies. In introducing a new EMR system, the main direct medical cost to estimate is the cost of additional clinical personnel time as clinicians will need to spend time creating and updating medical records.

Direct non-medical costs are those incurred by facilities (overhead costs and capital costs) or by patients (transportation and upkeep while seeking care). An electronic medical record system itself would amount to a significant upfront capital expenditure and would be associated with

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overhead costs such as additional electricity, additional maintenance costs and additional space.

Indirect costs are the (opportunity) costs of productivity lost as a result of care, or while seeking care. This cost category would apply mainly to patients due to additional patient waiting to allow clinical personnel to create and update medical records. Although waiting time may increase initially, a well-executed EMR program is expected to lead to reduced patient waiting in the long run.

Costs can also be categorized as **startup (fixed) costs** and **recurring costs**. This is relevant to an evaluation of the HIS: the hardware and software to run the HIS and the HIS-dedicated personnel (costs and training) may be considered capital costs; the ongoing costs (e.g., salaries, utilities, etc.) may be considered recurring costs. For an intervention that depends on the purchase of equipment, the first-year costs are usually higher than the recurring costs for subsequent years.

There are two approaches to cost estimation: micro costing and gross costing. In micro costing, all individual resources that go into the performance of an intervention are estimated and their unit costs applied to estimate the cost of the intervention. In gross costing, interventions are valued in bundles e.g., costs of one day of ownership of the EMR.

Cost estimation using micro costing methods proceeds through the three steps of **identification** (of resources used to achieve an intervention), **valuation** (of the quantity of resources used), and **measurement** (the combination of resource use and unit costs).

For the costs of personnel required to run an HIS, the quantity of resource use would be measures in a time-motion survey, a method of tracking health worker and patient time use as they progress through the caregiving or care-seeking process. These times, measured using paper forms or electronic devices—such as low-power Bluetooth and near-field communication—are multiplied by the hourly wage of providers and patients to estimate the cost of care provision, and the (opportunity) cost (to the patient) of seeking care.

For the evaluation of the HIS system at the outpatient clinic, data would be collected from administrative and accounting records for both fixed and recurring costs.

Table 4 summarizes the different kinds of cost categories as they apply to a cost analysis of an EMR system and how they can be estimated.

Table 4—Cost categories and applicable costs in the cost analysis of an EMR system

Cost category	Example	Estimation
Direct medical cost	Clinician personnel costs	Time-motion surveys

		(resource use) and wage data (unit costs)
Direct non-medical costs	• Utilities • Maintenance costs	Accounting records (resource use and prices)
Indirect costs	Cost of patient waiting	Time-motion studies (unit costs) and patient wage
Fixed startup costs	• Hardware • Software • Training	Accounting records
Recurring costs	• Electricity • Salaries	Accounting records

Analysts also need to consider the <u>currency</u> and <u>date</u> for cost estimation purposes. Most evaluations use US dollars to allow for comparison with other studies in the literature. However, it may be necessary to report in local currency units. Cost estimates need to be converted to a given year, using the appropriate, country-specific consumer price index. Analysts also need to consider the <u>discount rate</u> for purposes of estimating costs and outcomes that occur across multiple years. The discount rate is a representation of time preference for money and health—i.e., individuals prefer money today rather than tomorrow, on account of the ability to invest in better health today. The recommended discount rate is 3%. [3]

vii. Findings

The findings of operational evaluations may be used to inform different stakeholders on:

- the cost of interventions,
- possible impacts of an intervention,
- financial savings from introducing the intervention, or
- impact of the intervention on the budget of a given budget holder.

The results of a cost analysis of a new EMR system would be presented as:
- monthly or annual costs of owning and operating the new EMR system compared to the paper-based record system
- cost per patient record started and patient record updated comparing the new EMR system to the paper-based record system.

For a new EMR system at a health center, the leadership and management of the health center will use the results to ascertain the cost of the new EMR, the possible impacts of the new EMR, the potential return on investment of the new EMR, and the impact of the new EMR on the health center budget.

c. Research-Oriented Evaluation

i. Question

For full economic evaluations, considered as applicable for research-oriented economic evaluations in this case study, ask the question: Is the new EMR system cost-effective compared to the existing paper based record system? The full economic evaluations include cost-minimization analysis, cost-consequences analysis, cost-effectiveness analysis, cost-utility analysis, and cost-consequences analysis.

ii. Domains of measurement

As described under operational economic evaluations, a broad range of domains are relevant to economic evaluations given the wide range of activities related to the inputs and outputs as well as the supply and demand for healthcare. Therefore, all the domains—health, human, technology, organization and governance, health-sector-business process, and economic—are relevant to research-oriented economic evaluations.

The specific domains covered in a given research-oriented evaluation depend on the type of evaluation and the perspective of the analysis. The perspective of an economic evaluation is the viewpoint, for purposes of estimating costs and consequences, from which an analysis is performed. The following perspectives exist and may be considered for an economic evaluation of an EMR system:

- The payer perspective includes costs and consequences specific to a given payer. In low-income countries, the payer is often the government, through the MOH. For a new EMR system at a secondary health facility the perspective would be a payer perspective. This implies that direct medical costs (such as costs of clinical personnel) and direct non-medical costs (such as utilities) that are borne by a given payer would be considered but indirect costs (such as costs of patient waiting) would be excluded. Multiple payer perspectives are possible given that the HIS is a partnership between the MOH, the district health authority, a technology partner, and the clinic. Depending on the interest of the analyst, the evaluation can be performed from one perspective, more than one perspective, or all perspectives—i.e., the MOH, the district health authority, the technology partner, and/or the clinic.

- The societal perspective is the all-inclusive perspective includes all costs that accrue from, and consequences that occur as a result of, a given intervention. In addition to costs from a payer perspective, an evaluation of a new EMR system from a societal perspective would include indirect costs such as costs of patient waiting.

iii. Economic evaluation methods overview

Analysts performing research-oriented economic evaluations of health care programs have a choice between **trial-based analysis**, where data for the evaluation come from a single study, and **model-based analysis**, where data from multiple sources are used. Given that the EMR system is a facility-wide intervention, a model-based analysis would be the most appropriate method of evaluation; data from multiple sources would be used.

Decision models provide a framework for decision-making—in this case, about whether to implement and continue to invest in an EMR—under uncertainty. Decision models help analysts to structure the decision problem, and organize and collate data from multiple sources. As an example, a simple decision-tree model might be used to estimate the likelihood that each event in a chain of events will occur under the SOC, versus under the EMR system (figure 3).

Figure 3—Simple decision tree to estimate cost per viral load result promptly relayed to a clinician

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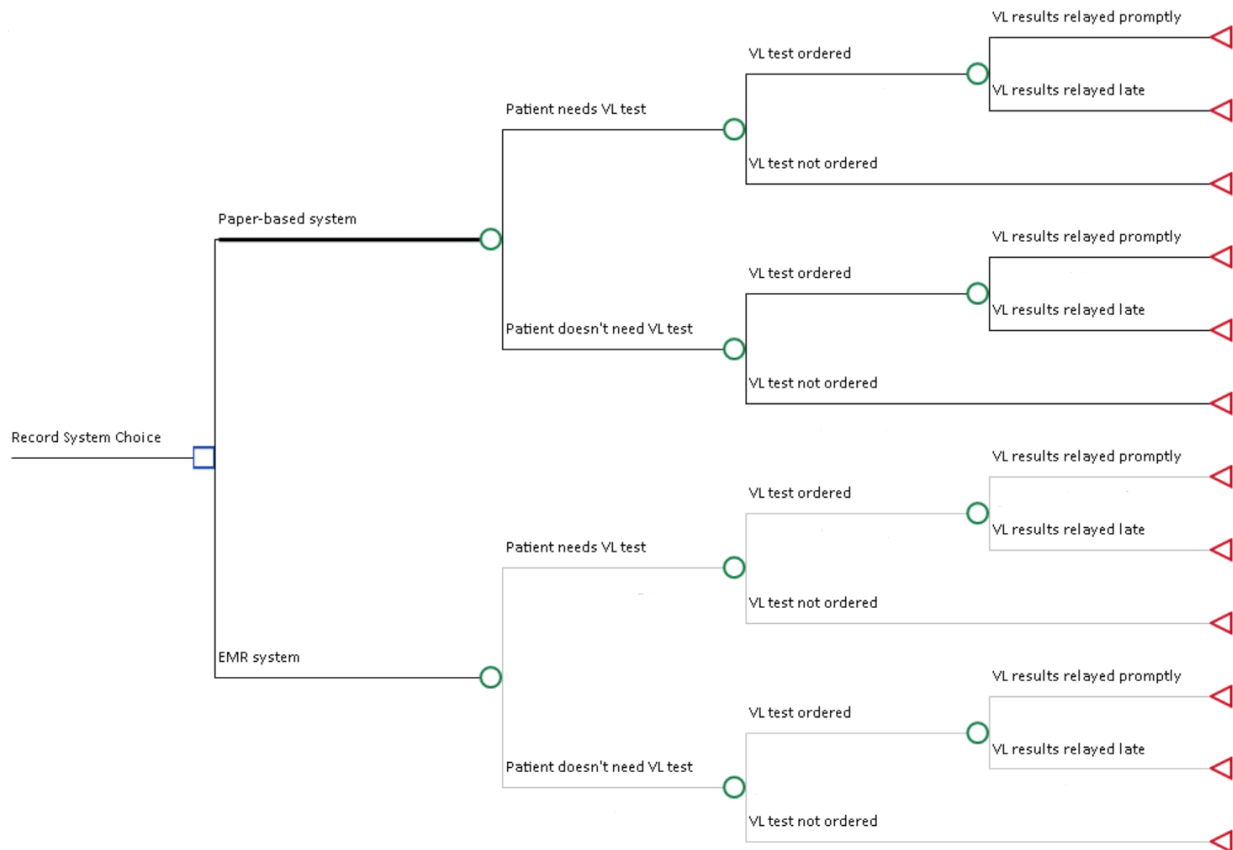
As shown in figure 3, the outcome of interest to an analyst in a CEA is the percentage of ART patients receiving timely viral-load monitoring tests. The analyst may define the probability that a patient needs a test, the probability that the provider would order the test, and the probability that the test result would be relayed back to the clinician and the patient promptly.

Data to parameterize the model are obtained from clinic records or from published and unpublished sources. The model is analyzed using a spreadsheet or proprietary software to calculate the cost per prompt viral load test relayed to the clinician and the patient.

Analysts performing economic evaluations would choose from one of five types of decision models: decision trees, Markov models, microsimulations, dynamic transition models, and dynamic simulations. [3]

Before performing an economic evaluation, an analyst would need to clearly describe both the **intervention**—in this case, the EMR system to be deployed at the outpatient clinic—and its components. The specification of the EMR system intervention may consider such factors as the specific technologies used (e.g., computer system, software type), or the types of personnel needed (e.g., IT specialist, clinicians entering individual patient records).

The ideal **comparator** consists of a set of all possible interventions and all their variations, including a "do-nothing" option. [3] The appropriate comparator in the EMR system deployed at a secondary outpatient clinic is the status quo or do-nothing option, which is the prevailing data capture system in use prior to deployment of the new EMR system, such as paper records.

The **target population**—the population for whom the interventions is intended—is all patients attending the outpatient clinic at which the EMR is deployed.

The **scope** (or boundaries) of the economic evaluation refers to the extent to which different groups of people, different types of outcomes (including cost sub-groups), and different non-health effects are included in the analysis. In the context of an EMR system, the scope of the analysis would include all patient groups. The inclusion of different outcomes and non-health effects would depend on the perspective of the analysis.

The **time horizon** of an economic evaluation should extend far enough into the future to capture the entire range of costs and consequences of the intervention and comparator. For an EMR, the time horizon might be tied to a single disease, if a substantial proportion of the patients in the clinic seek care for that disease area. For example, a given clinic might serve predominantly HIV patients; the time horizon might then be the lifetime horizon. Another clinicmight serve predominantly mothers attending antenatal care, in which case the time horizon is that of a pregnancy—i.e., nine months.

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Given appropriate definition intervention, comparator, target population, scope, and time horizon of a research-based economic evaluation, the analysts would have a choice of methods: (1) cost-minimization analysis, (2) cost-consequences analysis, (3) cost-effectiveness analysis, (2) cost-utility analysis, and (5) cost-benefit analysis.

All these types of research-oriented economic evaluations have one characteristic in common: they estimate the costs of interventions. What differentiates the different types of analysis is the characterization of health and other benefits that accrue because of implementing an intervention. For a research-based economic evaluation of an EMR system, a cost-effectiveness analysis is the most appropriate choice.

Cost-effectiveness analysis (CEA) measures outcomes in "natural units," and allows comparison of interventions in a given indication, or for a particular setting. In a clinical intervention setting, CEA may estimate outcomes for an indication such as management of hypertension, in which the outcome is the percentage of reduction in mm Hg as a result of a given intervention. In an EMR system setting, system-level outcomes, such as reductions in the total time spent per patient in the clinic, or reductions in the percentage of patients not reminded of the dates of their next visits, may be assessed.

For an economic evaluation of an EMR in which analysts were interested in measuring the impact of an EMR system on completeness of records, adherence to guidelines, and quality of care, a cost-effectiveness analysis would be the most appropriate method. Other outcomes of interest for a CEA include:

- o linkage to care if the EMR is connected to testing data or if there is a clear reference pathway
- o occurrence and timeliness of testing for say, HIV
- o timeliness of initiation of antiretroviral therapy
- o timeliness of detection of treatment failure
- o appropriateness of regimen
- o detection of drug-drug interactions
- o detection of adverse events and allergies

Table 5 summarizes the outcomes that define the other types of research-bases economic evaluations as applied to the evaluation of an EMR system.

Table 5 – Summary of research oriented economic evaluations

Method	Outcome (generic)	Example applied to EMR evaluation
Cost-minimization analysis	• Equivalent outcomes comparing intervention and comparator • Analysis focuses on difference in	• Evidence of equal completeness of medical records in paper-based system and EMR system

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	costs	• Cheaper system is recommended
Cost-consequences analysis	• Multi-dimensional listing of outcomes and cost categories • Different stakeholders choose outcome of interest and compare intervention and comparator as required	• Multiple costs (personnel, overhead) compared between paper-based system and EMR system • Multiple outcomes (completeness of records, patient waiting, adherence to clinical protocol) compared between paper-based and EMR system • Different stakeholders use cost categories and outcomes of interest to them
Cost-utility analysis	• Outcome combines morbidity and mortality into a single metric • Two possible metrics: cost per quality-adjusted life-year (QALY) gained and cost per disability-adjusted life-year (DALY) averted	• Economic evaluation model extrapolates impact of paper-based record system and EMR on likelihood of children completing measles immunization schedule to life expectancy and quality of life • Cost per QALY gained calculates comparing paper-based system and EMR system
Cost-benefit analysis	• Outcomes estimated in monetary units comparing paper-based system and EMR system	• Costs and total wages (as outcomes) of medical transcriptionists comparing a paper-based system and an EMR system

iv. Design

As with operational economic evaluations, multiple study design options are possible for research-oriented economic evaluations and the choice of method depends on the timing of study activities compared to the introduction of the intervention as well as available data or available resources for data collection. Given that the research-oriented evaluations are by definition comparative, EMR versus-paper based system, a pre-post design would be chosen for the economic evaluation of an EMR system.

v. Timing and resources

Research-oriented economic evaluations like operational economic evaluations are ongoing given that costs are incurred continuously. Given that the planned EMR system is comprehensive and is planned to completely replace the paper system, a pre-intervention period of **three to six months** would be required to ascertain costs and consequences of the paper system before the initiation of the EMR system.

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Research-oriented economic evaluations of an EMR system should be designed to leverage existing human resources and existing data. However, research-oriented economic evaluations require substantial training or the addition of analysts with advanced training. Therefore, it is recommended that such evaluations be performed in collaboration with agencies and individuals with the requisite training.

vi. Metrics

Table 3 shows the metrics used for operational economic evaluations by analysis type (see part 2 v—economic evaluation methods overview).

Table 3 – Metrics used to answer research-oriented economic evaluation questions

Analysis type	Metric
Cost-minimization analysis	Cost difference
Cost-consequences	Cost per (specific) outcome
Cost-effectiveness	Incremental cost-effectiveness ratio
Cost-utility analysis	Incremental cost-utility ratio
Cost-benefit analysis	Benefit-to-cost ratio

vii. Analysis plan

What is considered cost-effective? As mentioned above, economic evaluation compares two or more interventions in terms of their costs and consequences or outcomes. In the case of an economic evaluation comparing two interventions—for instance, a new EMR program (EMR) to the paper-based record system—there are four possible outcomes (Figure 2):

- In the northwest quadrant, the EMR system leads to higher costs and lower effectiveness. The EMR system is said to be "dominated," and is not recommended for implementation.
- In the northeast quadrant, the EMR system leads to higher costs and greater effectiveness. The extent to which the increase in effectiveness is worth the increase in costs is subject to additional analysis. The additional analysis involves calculation of an incremental cost-effectiveness ratio (ICER) or incremental cost-utility ratio (ICUR): *(cEMR – cPaper-Based)/(eEMR – ePaper-Based)*.
- In the southwest quadrant, the EMR system leads to lower costs and reduced effectiveness. The extent to which the reduction in effectiveness is worth the additional cost savings is subject to additional analysis. The additional analysis involves the calculation of a decremental cost-effectiveness ratio (DCER): *(cEMR – cPaper-Based)/(eEMR – ePaper-Based)*.

- In the southeast quadrant, the EMR system leads to lower costs and higher effectiveness. The EMR system is said to be "dominant" and is recommended for implementation.

Figure 2. Cost-effectiveness plane comparing an EMR system to the SOC
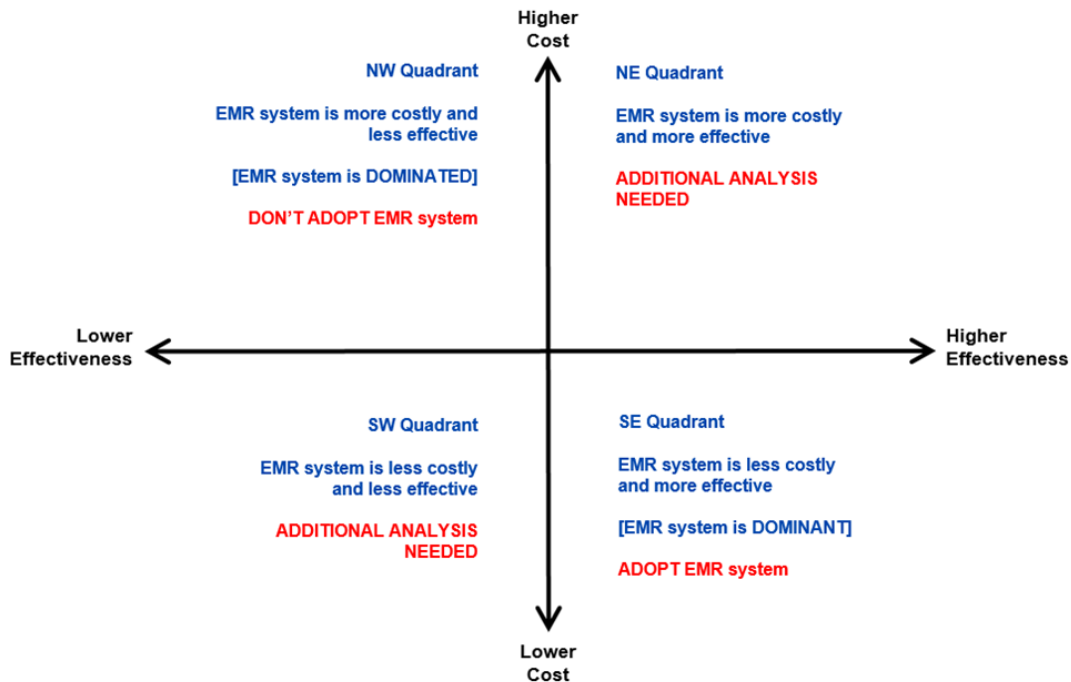
Most interventions are expected to increase costs and increase effectiveness (northeast quadrant). Given ICER values, there are three ways to determine whether the ICER meets the criteria for cost-effectiveness:

- **Thresholds**—pre-specified ICER values that are acceptable in a given setting.
- **Benchmarks**—ICERs for other interventions that are considered broadly acceptable in a given setting
- **League Tables**—listings of interventions by increasing ICER, with the interventions implemented in order until the budget is exhausted.

Thresholds, benchmarks, and league tables are commonly applied to economic evaluations that measure combined length-of-life and quality-of-life—i.e., QALYs and DALYs. For other outcomes, the decision as to what is considered cost-effective has to be made by the relevant stakeholder or budget holder.

Data on effectiveness would be collected from the outpatient clinic. In the ideal situation, a pre-planned evaluation would collect data on quality of clinical care, adherence to clinical guidelines by clinical staff, and completeness of data records for a fixed period before installation of the HIS. Comparable data would then be collected after installation of the HIS. The data might be collected from primary sources (e.g., from clinical trials), or from secondary sources (e.g., published studies, unpublished reports, administrative databases, expert opinion).

viii. Findings

The findings of research-oriented evaluations may be used to inform different stakeholders on the value of different interventions. The leadership and management of the health center will use the results to ascertain the cost-effectiveness or value-for-money associated with implementing a new EMR system.

d. Considerations

i. Pitfalls

Estimating impacts of HIS interventions on health care provider and patient time use is important, because the main value claim of many HIS projects is that they improve productivity of health care workers and (by extension) efficiency of health care services by making information easier to find and act upon. Determining whether this value claim is true in practice is important. However, time-motion surveys to estimate provider and patient time use are usually imprecise when conducted on paper, because people may not have sufficient ability to quantify precisely how they use their time, or to remember what their time use was like in the past. Therefore, it is ideal to do time and motion studies, where time use is formally measured based on observation, or to use electronic technology, such as low-power Bluetooth and near-field communication.

Measuring costs of software development, hardware procurement, hardware maintenance, training of health workers to use a new tool or system, and other categories of costs in economic evaluation of HIS is not something that key informants can do "off the top of their head." It is typically best to avoid simply asking key informants to provide costs by categories of interest, because each informant may think differently about what goes into costs, and their assumptions or methods of estimating costs may not be transparent. Therefore, measuring these costs typically requires reviewing accounting records and other types of documents, carrying out primary data collection (as with a time motion study), or both, to obtain cost estimates.

ii. Biases

The biases that are attendant to observational studies apply to the estimation of outcomes in economic evaluations. For instance, in quasi-experimental (before-and-after) studies as recommended for the research-oriented economic evaluations in this case study, are subject to the traditional biases (threats to internal validity) of history, maturation, and testing.

- History: The benefits attributed to the new EMR program may be a result of other changes to the health center as part of a recent quality improvement process. For example, training of personnel may have covered use of the new EMR as well as general analytic competences.
- Maturation: The benefits attributed to the new EMR program may be a result of general improvement in health services countrywide. For example, recent increases in country per capita income may be accompanied by improvements in health services delivery.
- Testing: The benefits attributed to the new EMR program may be a result of priming of personnel to improve services because of the evaluation.

Trial-based economic evaluations suffer from threats to external validity because they include patient populations that are pre-selected to maximize efficacy and may not reflect real-world conditions. Model-based analyses may suffer limitations of modeling including non-transparency, lack of standardization and regulation, and the potential for "gaming" to produce desired estimates.

iii. Ethics and Institutional Review

Operational evaluations are usually subject at most to minimal ethical review since they are performed as part of operations in a given clinic. However, studies involving primary data collection for trial-based economic evaluations or primary data collected to parameterize model-based analyses are subject to ethical review. Exclusively model-based analyses using data from publicly available or published estimates are usually exempt from ethical review.

iv. Planning

The ideal economic evaluation should be planned before the initiation of an intervention such as an EMR system. However, it is often the case that the evaluation is planned after the intervention has been initiated. In both cases, pre-planning is critical to the performance of a successful economic evaluation including the development of a well-written protocol.

v. Dissemination of findings

Results of operational and research-oriented economic evaluations would be disseminated to the different stakeholders including health facility managers, health facility leadership, district health leaders, and national (Ministry of Health) officials through policy briefs, reports, presentations, and mobile methods (teleconference and videoconference). Publication of

results in academic and lay publications would be of value to the broader evaluation fraternity, particularly if additional scale up and evaluation were planned.

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Practical Toolkit for Health Information System Evaluation

Appendix 1: HIS Evaluation Domains

Working Draft: November 30, 2017

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Literature Review: HIS Evaluation Domains

Overview

This document provides a literature review to describe the meaning of the six primary domains or HIS "ingredients" we use within this Toolkit: health, economic, technology, human, business process, and organization and governance. These domains come into play when implementing HIS and they affect the success of HIS projects across each stage of maturity.

There are multiple ways of classifying HIS domains. Any classification scheme is like an organizing system. Imagine a desk covered with papers, but without any scheme for organizing the papers. It is very difficult to think in an orderly way about the work that takes place at that desk, let alone how to evaluate the work. Now imagine a desk with a filing system that uses clearly labeled categories and subcategories to organize the papers. These categories can make it much easier to understand the work being done, and how one thing relates to another. There are many different possible ways to organize ideas—meaning that more than one classification scheme could always be imagined.

Our classification scheme with the 6 primary domains arose from the recommendations of an HIS evaluation expert consultation meeting sponsored by the US Centers for Disease Control and Prevention in San Francisco, CA in 2011. The purpose of this literature review is to provide a fuller description of each of the 6 domains. The literature review covers: 1) published HIS success theories; and 2) published HIS evaluation frameworks and descriptions of best practices in HIS evaluation. The Annotated Bibliographies summarizes the reviewed articles.

Table 1 summarizes the domains emphasized by selected theories of information systems and health information systems. A description of each domain, along with a summary of the ways in which various theories have discussed the domains, then follows.

Table 1: HIS Evaluation Domains as Addressed by Selected IS and HIS Theories

Theory	Health	Economic	Technology	Human	Business Process	Organization & Governance
User Acceptance of Information Technology (UTAUT) (Venkatesh et al, 2003)				░░	░░	
Technology Acceptance Model (TAM) (Davis, 1989)			░░	░░	░░	
Fit framework for			░░	░░	░░	░░

interaction of individuals, task, technology (FITT) (Ammenworth et al, 2006)						
PRISM Framework (Aqil et al, 2009)						
IS Success (DeLone and McLean, 2002)						
human, organization and technology-fit (HOT-Fit) (Yusof et al, 2008)						
Khoja, Durrani, Scott eHealth Evaluation Framework (KDS) (Khoja et al, 2013)						

Health Domain

This domain encompasses measurement of proximal indicators of health, such as quality of data used in health care delivery, quality of care, or accessibility and coverage of health services. It also encompasses distal indicators that can be more difficult to measure, such as quality of life, functional status, morbidity, and mortality.

Literature Review: Clarke (1994) describes 4 stages of HIS evaluation: 1) evaluation of early prototype; 2) evaluation of validity; 3) evaluation of functionality; and 4) evaluation of impact. In the last stage, it is possible to examine changes arising from HIS use, including changes in the health domain such as: changes in job satisfaction among providers; changes in health worker behaviors and decisions based on clinical decision support features; changes in number and type of procedures ordered, diagnoses made, or treatments ordered; changes in time spent with patients; changes in manner of interacting with patients; changes in length of stay; changes in error rates in treatment; and changes in patient morbidity and mortality.

Khoja, Durrani, and Scott (2013) identify health-related outcomes for evaluation by stage of maturity. During the system development phase, assessment of health status and existing services can inform the understanding of needs and opportunities. During the implementation stage, it is possible to evaluate intermediate health indicators such as indicators related to clinical safety, quality of care, decision-making about diagnosis and treatment, access and equity of care, and stability of services. Later, during the stages of integration and sustained operation, it is possible to evaluate morbidity, mortality, and quality of life.

Economic Domain

Economic: This domain encompasses measurement of the resources required to deploy and use the HIS, the system's impact on time use of patients and health care providers, and other efficiencies and opportunity costs. Depending on the type of economic evaluation, this domain may seek to quantify total cost of ownership, return on investment (ROI), and cost effectiveness of HIS investments.

Literature Review: Clarke (1994) and Delone and McLean (2003) both refer to the efficiency goals of information systems as targets for evaluation. Clarke refers to analysis of costs and benefits as part of the final phase of impact evaluation, while Delone and McLean advocate for measurement of time savings, expenditure savings, and expansion of revenue. Khoja et al (2013) refer to assessment of cost outcomes across the stages of HIS projects, covering affordability, cost-efffectiveness, cost-utility, and cost-benefit. However, none of these authors provides detail on the sub-categories which can be measured as part of economic evaluation of HIS.

In a scoping review of economic evaluation of HIS, Bassi (2013) identified the inputs and economic outcomes identified in various published HIS economic evaluations, from resource-rich and resource-poor settings. Inputs included one-time direct costs (e.g. hardware, network peripherals, software application development and configuration, user training, implementation project management, facilities upgrades, data conversion for legacy data, quality assurance services), on-going direct costs (e.g. software and hardware maintenance and replacement, on-going training, services for reviews and audits, and data storage), and indirect costs (e.g. IT security procedures, IT policy management, and routine IT help desk services). Economic outcomes include direct effects on revenues (e.g. from increases in patients served), effects based on labor savings and efficiencies (e.g. from health worker time savings for documentation, data entry, reporting, managing of archives), effects based on reduced resource utilization (e.g. reduced duplication of lab testing), and effects based on clinical events or events averted (e.g. improved compliance with guidelines in disease management, reduced adverse drug events, reduced violations of patient safety).

Luzi et al (2016) present a framework for economic evaluation of HIS whereby it is necessary to clarify perspective (individual, organizational, societal), research method (exploratory vs. explanatory), type of assessment (formative vs. summative), type of study (cross-sectional vs. on-going), comparator (prior paper-based system vs. novel tool doing something not previously done), and time horizon (short vs. long term). The authors classify cost categories as tangible vs. intangible, direct vs. indirect, health related vs. non health, one-time vs. ongoing, average vs. marginal, and fixed vs. variable.

Technology Domain

Technology: This domain encompasses measurement of system usability, technology infrastructure, technology performance, application of technical standards, data integrity, degree of integration across technology platforms and tools, data security outcomes, and other aspects of a system's technical quality.

Literature Review: The Delone and McLean theory (2003) of information system success, a widely-cited theory which is not specific to HIS, identifies "systems quality" (e.g. usability, functionality, flexibility, portability, integration, and reliability of technical performance) and "service quality" (e.g. ease of

updates, responsiveness and competence of help-desk services, reliability of service) as necessary conditions for intention to use a system, user satisfaction, and actual system use. In turn, those are precursors to the net benefits of information systems. Yusof's HOT-Fit framework (2008) applies the Delone and McLean model to HIS, and calls out sub-domains including ease of learning, usefulness of system features and functions, database design and storage capacity, and security features.

The FITT framework (Ammenworth et al, 2006), identifies that fit between individuals, task, and technology determine a system's success. Attributes of technology as highlighted by this theory include usability, functionality, and performance. The PRISM model (Aqil et al, 2009) recognizes technical factors including complexity of procedures, IT complexity, usability, and technical accuracy of data processing as key determinants HIS outcomes and impact.

Khoja et al (2013) differentiate technology factors by maturity stage. During the development stage key factors include degree of standardization, software design, reliability of hardware and networking, technical efficiency and performance, adaptability to different settings, and cultural acceptability. During the implementation phase, similar considerations apply but with a greater importance of interoperability, usability, flexibility for use in different settings, technical performance and error/fail rates, and accuracy of data capture. During integration and sustained operations phases, broad interoperability and scalability are dominant considerations.

Boland et al (2013) provides a more in-depth description and case study of usability assessment methods. During the prototype phase, it is useful to identify tasks, how users perform these tasks, and if the system supports the relevant task. To identify usability and design issues for pre-defined tasks, cognitive walk through analysis can be used. Next, time motion analyses, think-aloud exercises, user surveys, and analysis of system logs can be used to study interactions of users and systems in real-world environments. They advocate a two-level process during iterative development of digital health solutions, with the first phase driven by usability experts collecting information and the second phase drawing on system end-users sharing information and feedback. Both phases should use a mix of qualitative and quantitative methods.

Human Domain

Human: This domain encompasses measurement of knowledge, attitudes, beliefs, skills, motivation, self-efficacy, and satisfaction of system users.

Literature Review: The human domain is universally called out as central to HIS success, as seen in Table X. Several IS and HIS success theories can be classified as behavioral theories which put humans at the center, such as the Technology Acceptance Model (TAM) (Davis, 1989), the Information Technology Adoption Model (ITAM) (Dixon, 1989), and the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al, 2013). TAM posits that perceived usefulness and perceived ease of use of computer systems jointly contribute to attitudes towards use, which then determines behavioral intentions, and eventually determines actual use of an HIS. ITAM calls out perceptions about ease of use and acceptance of technology as key concepts at the interface of the human and technology domains. UTAUT recognizes the concepts of extrinsic (external) motivation, intrinsic (internal) motivation,

expectations about the level of effort to use a system, anxiety, self-efficacy, expectations about outcomes, and social influences within the human domain.

In Ammenwerth's FITT model (2006), which posits that success depends on fit between individuals, tasks, and technology, the individual component of the model is synonymous with the human domain. According to FITT, attributes of individual users, including IT knowledge, motivation and interest, flexibility to new ways of working, and computer skills are all critical HIS success factors. In the PRISM model, Aqil et al (2006) highlight HIS user motivation, data demand, data quality checking skill, problem solving skills for HIS, HIS competence, and HIS confidence as aspects of the behavioral or human domain which determine success of RHIS.

Delone and McLean's classic IS success theory (2003) describes a cyclical relationship between intention to use a system, user satisfaction, actual use, and the net benefits of the system as experienced by its users. To Delone and McLean, positive use and positive benefit are consequences of positive intention to use a system and positive user satisfaction, but they also contribute to further positive intentions and user satisfaction. In other words, these are interdependent, mutually-reinforcing concepts within the human domain. Clarke (1994) recognized that human considerations not only determine system use, but also are further shaped by system use. Specifically, Clarke called out changes in job satisfaction among providers as an important impact to consider during the final stage of HIS impact evaluation.

Business Process Domain

Business Process: This domain encompasses the fit between the HIS and specific health-sector business processes, such as clinical care, laboratory services, logistics management, or surveillance. The domain covers the fit between HIS functionality and the business workflow; linkage and flow of information between business units or actors; unintended consequences to business process; and data quality arising from system use in business settings.

Literature Review: Several theories and frameworks directly address business process, although some consider business process subsumed within the technology domain. The FITT framework, by Ammenwerth et al (2006), highlights aspects of tasks which affect HIS success: attributes of task; organization of tasks; interdependence of activities; and complexity of tasks. In their discussion of usability testing, Boland et al (2013) describe key activities during the prototype phase, when it is important to identify tasks, how users perform these tasks, and if the system supports the relevant task. Similarly, Effken (2002) elaborates considerations for the design of digital health tools, based on careful cognitive work analysis of the work domain as well as the roles of the health workers who must solve specific problem. The UTAUT theory by Venkatesh et al (2003) emphasizes compatibility between IS and business processes.

The PRISM model (Aqil et al, 2009) describes organizational, behavioral and technical determinants of RHIS as the "inputs" which then feed into business processes of data collection, data transmission, data processing, data analysis, data display, data quality checking and feedback.

While they do not specifically call out business process as a major domain, Khoja et al (2013) refer to adaptability of technology to different settings and accuracy of data capture as key areas for evaluating HIS outcomes. Similarly Delone and McLean's IS Success Model (2002) and Yusof's HOT-Fit framework

(2008) both call out data accuracy and data currency as aspects of success. While not labeled as such, these concepts are aligned with the business process domain.

Organization and Governance Domain

Organization and Governance: This domain encompasses organizational readiness for change, change management, inner setting of the organization culture and structure, outer context of implementation (including incentives and competitive pressure), policy development and policy practice, governance of ethics and security, mechanisms for engagement with standards, and enterprise or sector-level business planning.

Literature Review: In the FITT model (Ammenwerth et al, 2006), the authors acknowledge that group and organizational attributes come into play in the fit between individuals, tasks, and technology. This is because individual's roles reflect broader role definitions within the organization, and individual attitudes and skills are influenced by team culture, level of team cooperation, supervision, leadership, and other aspects of the broader organizational environment. In the PRISM model, Aqil et al (2009) characterize governance, planning, resource availability, training, supervision, finances, information distribution, and culture of information as organizational determinants of RHIS success.

In their comprehensive HIS evaluation framework, Khoja et al (2013) identify several outcome domains which fall within the realm of HIS governance. Specifically, they call out ethical outcomes, readiness and change outcomes, and policy outcomes. Within the ethics category, they note justice and equity, selection of beneficiary populations, data security, and confidentiality of patient information as important sub-domains. Within the readiness and change category, they note change management plans, readiness at individual, organizational and societal levels, and involvement of end-users in requirements gathering and design or selection of a solution, training planning, quality improvement, and customization as important sub-domains. Within the policy category, they note policy development and knowledge sharing across organizations as sub-domains.

Summary

Each of the six domains come into play on the pathway between a digital health intervention and its goals, and each represents an area of possible inquiry and measurement in HIS evaluation. Khoja, et al. (2013) argue that strong evaluations should include assessment across as many of the domains as possible.

Appendix 1B

HIS Evaluation Domains and Sub-Domains

Health	Economic	Technology	Human	Business Process	Organization & Governance
adherence	affordability	architecture	acceptability/ satisfaction	availability of data	change management
clinical decision making	budget impact	core clinical information	attitudes: anxiety	business transaction quality	compatibility of HIS with tasks
clinical safety	cost benefit	data error rate	attitudes: trust	changes in business process	confidentiality
compliance with care guidelines	cost effectiveness	data security	attitudes: usability	complexity of tasks	culture of information
continuity of care	cost minimization	data standards	attitudes: usefulness	consistency	effects of infrastructure
coverage	cost utility	development process	capacity/ competence	critical steps in business process	equity of access
improved diagnosis and treatment	costs: direct	flexibility	confidence	data management practices	feedback process
quality of care	costs: fixed	functionality	cultural readiness	data quality: accuracy/validity	governance readiness
sensitivity/accuracy	costs: indirect	functionality: clinical decision support	intention to use system	data quality: completeness	human resources development
volume	costs: recurrent	functionality: order entry	interest/motivation	data quality: integrity	incentives/rewards
	perspective of economic evaluation	functionality: reporting	knowledge management	data quality: reliability	infrastructure
	resources	interoperability	learning readiness	data quality: timeliness	institutional support
	time use	privacy protections	self-efficacy	efficiency of business process	M&E structures and functions

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		requirements definition	skills: computer use	flexibility	management and leadership readiness
		scalability / extensibility	skills: problem solving	implementation process	organizational readiness
		service quality	social influence	indicator definitions and reporting guidelines	organizational structure
		stability (data synchronization)	social norms	information flow	policies and procedures
		standards conformance	training	operational readiness	policy readiness
		storage capacity	usage patterns	simplicity	political context
		system attributes	user performance	workflow	societal readiness
		system quality			staffing
		system performance			stakeholder involvement
		system reliability			standard operating procedures
		technical readiness			teamwork
		terminologies			
		usability			

Practical Toolkit for
Health Information System
Evaluation

Appendix 2: Resources for Protocol
Development

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Checklist for Scientific and Ethical Review: Case Scenario #1

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
Engage stakeholders	
☐ Stakeholders and their engagement in the planning and implementation of the evaluation (e.g., selecting evaluation questions, reviewing evaluation design, reviewing report) are described in the overview/background.	**Tip:** A table is a clear, concise way to outline the roles and priorities of the various stakeholders involved in an evaluation. See Table 1 in the case scenario. **Sample language:** The stakeholders for the eMTCT register evaluation are national MOH and HIV surveillance managers, implementing partners, healthcare workers, district managers and supervisors, patients, software developers, the HIV surveillance global community, and the funder of the evaluation. The stakeholders are involved throughout the evaluation and represent different priorities and goals for the evaluation. The national MOH and HIV surveillance managers help define evaluation questions, ensure that the evaluation will provide information they can use for decision making, and disseminate findings. Implementing partners are those responsible for eMTCT-R deployment, training, and supervision of system use. Data collected from patients will be used to answer evaluation questions about acceptability and use of data. The healthcare workers will provide feedback through data collection instruments in order to answer some of the evaluation questions. The software developers will be informed of software updates and bugs that need to be fixed. The global HIV surveillance community will receive the results of the evaluation to take away lessons learned for future deployments. The funder will provide the monitoring of the evaluation progress to ensure good value for the resources invested in the intervention and the evaluation.
Clearly state evaluation questions, purpose, and objectives	

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
❑ The intent of the evaluation and justification are explained.	**Sample language:** Using a mixed methods approach, this evaluation aims to compare changes in HIV case-based surveillance indicators following the introduction of the eMTCT-R. Value claims of the eMTCT-R include improved: disease surveillance, initiation of HIV care and treatment, outreach efforts for those patients lost to follow-up, and data quality and accuracy. The intent of the evaluation is to assess whether the eMTCT-R meets its value claims and can be implemented with fidelity. This evaluation seeks to describe the implementation of the eMTCT-R as well as compare intermediate health outcomes between facilities using the electronic registry to those not using it. The results from the evaluation will help stakeholders to identify whether they should anticipate seeing improved intermediate health outcomes if eMTCT-R is scaled up.
❑ Evaluation questions are specified.	**Sample language:** 1. Does the eMTCT-R improve the quality of reported HIV surveillance data? 2. What is the acceptability of the eMTCT-R for health facility, district, and national MOH staff? 3. What are the major strengths and weaknesses of introducing and implementing the eMTCT-R? 4. What is the fidelity of the eMTCT-R? How is the system being used and is it being used as intended? 5. Do the following indicators change after deployment of eMTCT-R: % of HIV-positive deliveries with a woman on ART; and % of women continuing ART medication 3 months post-partum? 6. Does the use of eMTCT-R improve the timeliness of ART initiation? 7. What are the user perceptions of the eMTCT-R and the implementation context (setting)?

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
❑ There is a description of how evaluation results will be used and by whom.	**Tip:** This information can be presented in a table, especially if there are many stakeholders, deliverables, and uses for the findings. **Sample language:** The findings of this evaluation will be used to inform Ministry of Health and funders on: ● any future software updates of the eMTCT-R and training improvements, ● evidence of the eMTCT-R as a "proof of concept" for electronic registries, ● effects of the eMTCT-R on intermediate health outcomes.
Use appropriate evaluation design, methods, and analytical techniques	
❑ The type of evaluation is correctly specified (i.e., process, outcome, impact, economic).	**Tip:** Specify the type of evaluation early in the evaluation protocol under the section describing the evaluation approach. The specific data collection and analysis activities described in the protocol will follow from the type of evaluation. **Tip:** Clearly identify the evaluation type from among the possibilities as well as the evaluation focus. Process evaluation • Implementation process • Context • Mechanisms Outcome evaluation • Data quality outcomes • Data use outcomes • Quality of care or program quality outcomes • Person and population health outcomes
❑ The type of design (e.g., experimental, quasi-experimental, non-experimental, qualitative, mixed design, etc.) and corresponding methods (e.g., survey, focus groups, interview, etc.) are specified.	**Tip:** Identify whether the study design will need to include experimental elements to address an evaluation question. **Tip:** For research-oriented evaluation, identify whether an experimental or quasi-experimental design will be used and whether this design will be qualitative, quantitative, or mixed methods.

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
	Sample language for operational evaluation: The operational evaluation seeks to analyze the eMTCT-R implementation after deployment. Therefore, it uses mixed methods – a retrospective analysis of quantitative data and a cross-sectional qualitative survey – to provide a rich snapshot of how well the eMTCT-R has been implemented in the pilot facilities. Quantitative analysis of programmatic monitoring data on technical problems and troubleshooting needs will provide additional information on registry use. To determine any change in data quality from the eMTCT-R intervention, the country's evaluators will compare patient data collected on the paper registers with the same data input into the electronic registry via the tablets. The survey findings will help contextualize the introduction and use of this type of intervention, as well as help identify opportunities for future improvements.
	Sample language for research-oriented evaluation: This research-oriented evaluation uses mixed methods. The quantitative methods aim to generate evidence about the effectiveness of the eMTCT-R on HIV treatment initiation and timeliness. Key-informant interviews with stakeholders supplement the quantitative data with a comprehensive picture of whether the eMTCT-R is effective, as well as how and why it is effective.
	To gather quantitative data, the country's evaluators employ a quasi-experimental study design[i] that leverages the availability of monthly estimates of HIV surveillance indicators, along with the knowledge of exactly when the eMTCT-R was deployed in each facility. Additionally, the use of a sample of control facilities allows for the true effect of the eMTCT-R on HIV treatment initiation and timeliness to be observed.

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
❑ Design and methods are appropriate given the evaluation questions.	**Tip:** An evaluation team with diverse skill sets and backgrounds can help determine if the design and methods are appropriate for the evaluation questions. It is best to have several team members consider alternative designs and methods to ensure that the ones chosen fit the given interests, goals, and available resources.
❑ A clear data analysis plan to classify, interrelate, compare and display information is provided.	**Tip:** Consider developing "dummy" tables prior to the evaluation to show how you anticipate presenting your results. This can help inform your data analysis plan. **Sample language for research-oriented evaluation:** In the case of an interrupted time series analysis comparing a new eMTCT-R to the paper-based register, we will use the percentage of HIV-positive deliveries with a woman on ART as out health-related outcome of interest. There are three possible outcomes: ● Change observed: The eMTCT-R leads to a higher percentage of women delivering and on ART than facilities using the paper based register. Therefore, the eMTCT-R has an effect on the intermediate health outcome. Note: *One may observe a lag in time before improvements are observed, a change in outcome following deployment, but no increase over time, or an increase in the health outcome over time. If possible, explain why the observed trend is observed.* ● Change observed: The eMTCT-R leads to a lower percentage of women delivering and on ART than facilities using the paper based register. Therefore, the eMTCT-R has a reduced effect on the intermediate health outcome. Results of the process evaluation need to be investigated to determine if the results were due to lack of implementation of a component of the project.

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
	• No change observed: There are no differences observed between the health outcome between facilities using the eMTCT-R and the paper based registers. Therefore, results of the process evaluation need to be investigated to determine if the results were due to lack of implementation of a component of the project.
☐ There is a criterion for selecting the data sources. It is clear what data collection methods will be used and why.	**Sample language:** This evaluation will leverage existing data sources to assess quantitative outcomes. Routinely reported data from the country's HMIS will be used to assess pre-deployment indicators and the eMTCT-R data will be used for assessing post-deployment indicators. Additionally, the routinely used ANC registries will be used to assess timeliness of ART pre-deployment. To collect qualitative data, key informant interviews will be conducted with eMTCT-R users and stakeholders.
☐ Procedures for selecting the sample is specified. It is clear where or from whom the data will be gathered.	**Tip:** For the research-oriented analysis, the sample size of the control facilities will be contingent on the expected "effect size". **Sample language:** To compare the HIV treatment initiation between pilot and control facilities, control facilities from the district will be sampled based on: • type of facility (public vs. private and level of care provided) and • health facility size (defined as the number of patients receiving HIV treatment or counseling per month) The sample size is contingent on the baseline rates of the outcomes of interest and the difference in outcomes that one expects to observe if the intervention is effective (also called the "effect size"). Control facilities will be sampled using a 1:3 ratio, therefore, for each pilot site, three control facilities will be selected. Using this 1:3 ratio helps increase

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
	the statistical power to detect differences in our outcomes of interest should those differences truly exist.
❑ The unit of analysis is specified and appropriate.	**Sample language:** The unit of analysis will depend on the specific evaluation question. The operational evaluation will use facility and respondent as units of analysis. The research-oriented evaluation will measure use the same units of analysis.
❑ The proposed sample size is justified and sufficient to meet the project objectives.	**Tip:** The sample size is contingent on the baseline rates of the outcomes of interest and the difference in outcomes that one expects to observe if the intervention is effective (also called the "effect size"). The sample size should be determined based on these parameters, keeping the type I and II errors consistent and rational.
Address ethical considerations and assurances	
❑ Ethical certifications of evaluators, data collectors, analysts and other staff in the evaluation are documented in an appendix.	**Sample language:** All evaluators are certified in human subjects' protection. They will train any transcribers in human subjects' protection to ensure confidentiality of information.
❑ Data security confidentiality assurances are described.	**Sample language:** All primary and secondary data sources will be de-identified during abstraction. To protect confidentiality when presenting results, information will be aggregated to a level that ensures that findings cannot be linked to specific facilities or specific individuals. All externally shared reports, manuscripts or presentations will follow these practices. The sponsoring institution (or lead evaluation organization) will retain the password protected data and information for three years after publications and will not use these beyond the scope of the evaluations.
❑ Procedures for informing participants about the evaluation and the methods for obtaining consent are described, where applicable.	**Tip:** Participants should be provided a participant information sheet that explains the evaluation's purpose, the intended activities, and how they will be involved; there consent to participate can be

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
	given either verbally or in writing.
❑ It is clear how participants' rights and information will be protected.	**Tip:** If information is collected directly from participants, they may be given a participant information sheet that includes a contact information for a member of the evaluation team, so that participants can contact this person with any questions or concerns about the procedures, participant rights, or other related issues.
❑ Ethical issues, particular to vulnerable populations if applicable, are adequately addressed (e.g., children, Key populations, prisoners, pregnant women).	**Tip:** If information is obtained directly from participants who have personal information contained within the eMTCT-R being evaluated, participants will be assured that their participation in the evaluation will not affect their ability to receive care.
Identify resources and articulate budget	
❑ Protocol includes a realistic budget and timeline for the evaluation organized by stage (protocol development, data collection and management, data analysis, evaluation report, and other dissemination modes).	**Tip:** Budget information is best displayed in a table or spreadsheet and a timeline is best in a table format. See Sample Protocol for example timeline. Funders may have a specific budget formats for which fund receipts should follow. See award specific guidelines for more details.
Construct data collection and management plans	
❑ Protocol includes a data collection plan defining: ❑ who will administer the data collection instruments, when and where; ❑ how data will be gathered; ❑ quality assurance procedures.	**Tip:** Be sure to include data security as part of the data collection and management plan in addition to describing who on the evaluation team will be responsible for pulling data from the eMTCT-R and anonymizing the data versus who will analyze the data, ideally these activities would not be performed by the same person.
❑ The content of the data collection instruments is relevant to the project objectives and is realistic, feasible,	**Tip:** The evaluation team and stakeholder groups should provide input as to whether the data collection instruments are appropriate for the

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
acceptable.	evaluation.

❑ Protocol includes a data management plan describing the areas listed below:
  ❑ data cleaning and organization;
  ❑ length of time data will be stored;
  ❑ special procedures for interview audio management and storage (including whether or not tapes will be translated and/or transcribed), if applicable.
	Sample language: Any data extracts containing aggregate patient health data from facilities or derived analytic datasets will be stored on password-protected project computers or secure cloud storage systems authorized by the sponsoring institution. Access permissions for storage locations will be provided to authorized personnel only.
	
	Data will be stored until the final analysis and reporting on the project are complete for three years and will be guided by the Ministry of Health on the method of eventual destruction of data including the shredding of any original paper-based information and systematic deletion of original data files from computers used by evaluation team members. The sponsoring institution will take responsibility for managing and storing the data to be used within this evaluation protocol.

Ensure appropriate evaluator qualifications and evaluation independence	
❑ Names and brief CVs of those conducting the evaluation are documented in an Appendix.	**Tip:** Funding institutions may have guidelines or templates for submitting evaluator team member CVs. For example, NIH has a biosketch format that fund recipients should follow.
❑ A conflict of interest statement signed by all members of evaluation team (PIs, Co-PIs, Implementing Partner-if applicable) is included.	**Tip:** A full sample conflict of interest statement is included in the Sample Protocol as an appendix. **Sample language for conflict of interest statement:** As an evaluator, I understand that I have a responsibility to maintain independence so that opinions, conclusions, judgments, and recommendations will be impartial and will be viewed as impartial by third parties. I certify that I have disclosed all relevant facts regarding real or potential conflicts of interest that could lead

Case Scenario #1: Strengthening case-based surveillance for prevention of mother-to-child HIV transmission – Evaluation of a tablet-based electronic PMTCT registry	
Standard and Criteria	**Tips and Sample Language**
	reasonable third parties with knowledge of the relevant facts and circumstances to conclude that I am able to maintain independence. I believe that I am capable of exercising objective and impartial judgment on all issues associated with conducting and reporting the work.
Disseminate results	
❑ It is clear how project findings and recommendations will be used to scale-up pilot programs, improve existing programs, and/or guide fiscal, program, or policy decision-making.	**Sample language:** Results will be disseminated to the different stakeholders including health facility managers, health facility leadership, district health leaders, and national (Ministry of Health) officials through policy briefs, reports, presentations, and mobile methods (teleconference and videoconference). Publication of results in academic and lay publications will be of value to the broader evaluation fraternity, particularly if additional scale up and evaluation were planned.

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[i] https://en.wikipedia.org/wiki/Quasi-experiment

Checklist for Scientific and Ethical Review: Case Scenario #2

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
Engage stakeholders	
❑ Stakeholders and their engagement in the planning and implementation of the evaluation (e.g., selecting evaluation questions, reviewing evaluation design, reviewing report) are described in the overview/background.	**Tip:** A table is a clear, concise way to outline the roles and priorities of the various stakeholders involved in an evaluation. See Table 1 in the case scenario. **Sample language:** The stakeholders for the economic evaluation are technology partners, health care workers, health care managers, the National Ministry of Health, and the funder of the evaluation. The stakeholders are involved throughout the evaluation and represent different priorities and goals for the evaluation. The technology partners helped develop the EMR system being evaluated. Healthcare workers and managers at typical intervention sites will provide feedback to ensure that evaluation procedures will be feasible. The Ministry of Health representatives help define evaluation questions, advise on data collection procedures, review data analysis plan and results, and lead the reporting and dissemination of evaluation findings. The funder will provide the monitoring of the evaluation progress to ensure good value for the resources invested in the intervention and the evaluation.
Clearly state evaluation questions, purpose, and objectives	
❑ The intent of the evaluation and justification are explained.	**Sample language:** Economic evaluation is the comparative analysis of alternative courses of action within the health sector in terms of both their costs and consequences. A value claim for EMRs is that they increase efficiency to provide high quality care at a reasonable cost. The intent of the evaluation is to assess whether the EMR meets this value claim and is affordable. This evaluation seeks to compare the costs and consequences of implementing an EMR at point of

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
	service delivery in one health facility vs. implementing a standard paper-based data collection and data management system. The results from the evaluation will help stakeholders to identify whether investment in EMR is affordable and cost-effective.
❑ Evaluation questions are specified.	**Sample language:** 1. What is the cost of owning and operating the new EMR system? 2. What is the cost of owning and operating the new EMR system compared to the costs of operating the existing paper record system? 3. What are the costs and consequences of owning and operating the new EMR system? 4. What is the financial benefit of owning and operating the new EMR system over a given, fixed period of time? 5. How would owning and operating the new EMR system affect the budget of the outpatient HIV clinic?
❑ There is a description of how evaluation results will be used and by whom.	**Tip:** This information can be presented in a table, especially if there are many stakeholders, deliverables, and uses for the findings. **Sample language:** The findings of this evaluation will be used to inform Ministry of Health and funders on: ● the cost of the EMR implementation, ● the consequences of the EMR implementation, ● the cost-effectiveness of the intervention.
Use appropriate evaluation design, methods, and analytical techniques	
❑ The type of evaluation is correctly specified (i.e., process, outcome, impact, economic).	**Tip:** Specify the type of evaluation early in the evaluation protocol under the section describing the evaluation approach. The specific data collection and analysis activities described in the protocol will follow from the type of evaluation. **Tip:** Clearly identify the economic evaluation type from among the partial and full economic evaluation types.

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
	Partial economic evaluation types • Cost description • Cost analysis • Cost-outcomes description • Return on investment analysis • Budget impact analysis Full economic evaluation types • Cost-effectiveness analysis • Cost minimization analysis • Cost consequences analysis • Cost utility analysis • Cost benefit analysis
❑ The type of design (e.g., experimental, quasi-experimental, non-experimental, qualitative, mixed design, etc.) and corresponding methods (e.g., survey, focus groups, interview, etc.) are specified.	**Tip:** Identify the perspective of the economic evaluation (payer, societal, etc.). Identify the method for enumerating costs (micro-costing or gross costing). **Tip:** For research-oriented, or full economic evaluations, indicate if the study will use a trial-based analysis method or a model-based analysis. **Sample language for cost analysis:** To perform a cost analysis of a new EMR, the costs of owning and operating the EMRS system will be compared to the paper-based record system. Given that the new EMR will replace the paper-based record system, a pre-post design is chosen. The cost analysis compares the monthly or annual cost of the paper-based record system before the implementation of the EMR system and then compares these costs to the monthly or annual cost of operating the EMR system. **Sample language for cost-effectiveness analysis:** For evaluating the EMR system setting, system-level outcomes, such as reductions in the total time spent per patient in the clinic, or reductions in the percentage of patients not reminded of the dates of their next visits, will be assessed. A decision-tree model will be used to estimate the likelihood that each event in a chain of events will occur under the paper-based record system, versus under the EMR system. The analysis will also report an incremental cost-

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
	effectiveness ratio which is the change in cost per unit change in the health outcome of interest comparing the EMR to the paper-based system.
❑ Design and methods are appropriate given the evaluation questions.	**Tip:** An evaluation team with diverse skill sets and backgrounds can help determine if the design and methods are appropriate for the evaluation questions. It is best to have several team members consider alternative designs and methods to ensure that the ones chosen fit the given interests, goals, and available resources.
❑ A clear data analysis plan to classify, interrelate, compare and display information is provided.	**Tip:** Costs will be reported in the currency unit of the country in which the evaluation takes place. The costs are sometimes converted to international dollars to costs can be compared across settings. Cost estimates need to be converted to a given year, using the appropriate, country-specific consumer price index. Analysts also need to consider the discount rate for purposes of estimating costs and outcomes that occur across multiple years. **Sample language for cost-effectiveness analysis:** In the case of a cost-effectiveness evaluation comparing a new EMR program (EMR) to the paper-based record system, we will use the percentage of ART patients receiving timely viral-load monitoring tests as out health-related outcome of interest. There are four possible outcomes: ● The EMR system leads to higher costs and lower effectiveness. The EMR system is said to be "dominated," and is not recommended for implementation. ● The EMR system leads to higher costs and greater effectiveness. The extent to which the increase in effectiveness is worth the increase in costs is subject to additional analysis. ● The EMR system leads to lower costs and reduced effectiveness. The extent to which the reduction in effectiveness is worth the additional cost savings is subject

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
	to additional analysis. The EMR system leads to lower costs and higher effectiveness. The EMR system is said to be "dominant" and is recommended for implementation.
❑ There is a criterion for selecting the data sources. It is clear what data collection methods will be used and why.	**Sample language:** There are three types of costs associated with EMR implementation that are considered in this economic evaluation: direct medical costs, direct non-medical costs, and indirect costs. In introducing a new EMR system, the main direct medical cost is the cost of additional clinical personnel time, as clinicians will need to spend time creating and updating medical records. This will be estimated through a time and motion study. Direct non-medical costs are those incurred by facilities (overhead costs and capital costs) or by patients (transportation and upkeep while seeking care). These will be estimated through a review of financial ledgers for all entities involved in the EMR implementation. Indirect costs are the costs of productivity lost as a result of care, or while seeking care. This cost category will apply mainly to patients due to additional patient waiting to allow clinical personnel to create and update medical records. These will be estimated through a time and motion study of patients. Data on health outcomes will be collected from patient health records at the comparison sites.
❑ Procedures for selecting the sample is specified. It is clear where or from whom the data will be gathered.	**Tip:** For cost analysis, all relevant costs are considered. Omitting costs will yield incomplete results from the economic evaluation. **Sample language:** Clinical outcome specific information will be extracted for all ART patients at the site where the EHR being evaluated and from all ART patients at the comparison site without the EHR. This represents a secondary data analysis that does not gather information directly from patients.

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
❑ The unit of analysis is specified and appropriate.	**Sample language:** The unit of analysis will depend on the specific type of economic evaluation. The cost analysis will report on a "per facility" cost of EHR implementation. The cost-effectiveness analysis will measure clinical outcomes in their "natural" units, namely "per patient with timely viral load test performed."
❑ The proposed sample size is justified and sufficient to meet the project objectives.	**Tip:** Sample size calculations are typically not included in economic evaluations.
Address ethical considerations and assurances	
❑ Ethical certifications of evaluators, data collectors, analysts and other staff in the evaluation are documented in an appendix.	**Sample language:** All evaluators are certified in human subjects' protection. They will train any transcribers in human subjects' protection to ensure confidentiality of information.
❑ Data security confidentiality assurances are described.	**Sample language:** All secondary data sources will be de-identified during abstraction. To protect confidentiality when presenting results, information will be aggregated to a level that ensures that findings cannot be linked to specific facilities or specific individuals. All externally shared reports, manuscripts or presentations will follow these practices. The sponsoring institution (or lead evaluation organization) will retain the password protected data and information for three years after publications and will not use these beyond the scope of the evaluations.
❑ Procedures for informing participants about the evaluation and the methods for obtaining consent are described, where applicable.	**Tip:** This is not typically applicable for economic evaluations.
❑ It is clear how participants' rights and information will be protected.	**Tip:** If information is collected directed from participants, they may be given a participant information sheet that includes a contact information for a member of the evaluation team, so that participants can contact this person with any

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
	questions or concerns about the procedures, participant rights, or other related issues.
❑ Ethical issues, particular to vulnerable populations if applicable, are adequately addressed (e.g., children, Key populations, prisoners, pregnant women).	**Tip:** If information is obtained directly from participants who have personal information contained within the specific EHR being evaluated, participants will be assured that their participation in the evaluation will not affect their ability to receive care. This is typically not an issue for economic evaluations.
Identify resources and articulate budget	
❑ Protocol includes a realistic budget and timeline for the evaluation organized by stage (protocol development, data collection and management, data analysis, evaluation report, and other dissemination modes).	**Tip:** Budget information is best displayed in a table or spreadsheet and a timeline is best in a table format. See Sample Protocol for example timeline. Funders may have a specific budget formats for which fund receipts should follow. See award specific guidelines for more details.
Construct data collection and management plans	
❑ Protocol includes a data collection plan defining: ❑ who will administer the data collection instruments, when and where; ❑ how data will be gathered; ❑ quality assurance procedures.	**Sample language:** Operational economic evaluations are ongoing given that costs are incurred continuously. For cost descriptions and cost-outcomes descriptions, data collection commences at initiation of the EMR system and continues until sufficient data have been collected and analyzed to ascertain the steady state costs of the EMR system. For the comparative analyses—cost analysis, return-on-investment analysis, and budget impact analysis—there is a need for a comparator. Given that the EMR system will completely replace the paper record system, a period of three to six months before the intervention is required, during which data are collected to ascertain the steady state cost of managing the paper record system.
❑ The content of the data collection instruments is relevant to the project objectives and is realistic, feasible, acceptable.	**Tip:** The evaluation team and stakeholder groups should provide input as to whether the data collection instruments are appropriate for the evaluation.

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**

❑ Protocol includes a data management plan describing the areas listed below:
  ❑ data cleaning and organization;
  ❑ length of time data will be stored;
  ❑ special procedures for interview audio management and storage (including whether or not tapes will be translated and/or transcribed), if applicable.
	Sample language: Any data extracts containing aggregate patient health data from facilities or derived analytic datasets will be stored on password-protected project computers or secure cloud storage systems authorized by the sponsoring institution. Access permissions for storage locations will be provided to authorized personnel only.
	
	Data will be stored until the final analysis and reporting on the project are complete for three years and will be guided by the Ministry of Health on the method of eventual destruction of data including the shredding of any original paper-based information and systematic deletion of original data files from computers used by evaluation team members. The sponsoring institution will take responsibility for managing and storing the data to be used within this evaluation protocol.

Ensure appropriate evaluator qualifications and evaluation independence	
❑ Names and brief CVs of those conducting the evaluation are documented in an Appendix.	**Tip:** Funding institutions may have guidelines or templates for submitting evaluator team member CVs. For example, NIH has a biosketch format that fund recipients should follow.
❑ A conflict of interest statement signed by all members of evaluation team (PIs, Co-PIs, Implementing Partner-if applicable) is included.	**Tip:** A full sample conflict of interest statement is included in the Sample Protocol as an appendix. **Sample language for conflict of interest statement:** As an evaluator, I understand that I have a responsibility to maintain independence so that opinions, conclusions, judgments, and recommendations will be impartial and will be viewed as impartial by third parties. I certify that I have disclosed all relevant facts regarding real or potential conflicts of interest that could lead reasonable third parties with knowledge of the relevant facts and circumstances to conclude that I am able to maintain independence. I believe that I am capable of exercising objective and impartial judgment on all issues associated with conducting and reporting

Case Scenario #2: Applied Health Economic Evaluation of an Electronic Medical Record (EMR) System in a Secondary Health Facility	
Standard and Criteria	**Tips and Sample Language**
	the work.
Disseminate results	
❑ It is clear how project findings and recommendations will be used to scale-up pilot programs, improve existing programs, and/or guide fiscal, program, or policy decision-making.	**Sample language:** Results will be disseminated to the different stakeholders including health facility managers, health facility leadership, district health leaders, and national (Ministry of Health) officials through policy briefs, reports, presentations, and mobile methods (teleconference and videoconference). Publication of results in academic and lay publications will be of value to the broader evaluation fraternity, particularly if additional scale up and evaluation were planned.

Practical Toolkit for
Health Information System
Evaluation

Appendix 3: Resources for Planning
HIS Evaluation

Working Draft: November 30, 2017

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Appendix 3A
Template for Stakeholder Matrix

Stakeholder Name and Brief Description	Level of Knowledge of the Issue	Interests in the HIS Intervention	Available Resources	Potential Roles in the Evaluation Process	Engagement Activities
	What is their specific expertise?	*What are the stakes from their perspective?*	*What material or technical resources do they bring to bear?*	*Sponsorship, planning, adapter, implementer, analysis, communication*	*What specific activities should they be involved in?*

Template for Checklist for Scientific and Ethical Review

Evaluation Title:	
Standard and Criteria	**Tips and Sample Language**
Engage stakeholders	
❑ Stakeholders and their engagement in the planning and implementation of the evaluation (e.g., selecting evaluation questions, reviewing evaluation design, reviewing report) are described in the overview/background.	
Clearly state evaluation questions, purpose, and objectives	
❑ The intent of the evaluation and justification are explained.	
❑ Evaluation questions are specified.	
❑ There is a description of how evaluation results will be used and by whom.	
Use appropriate evaluation design, methods, and analytical techniques	
❑ The type of evaluation is correctly specified (i.e., process, outcome, impact, economic).	
❑ The type of design (e.g., experimental, quasi-experimental, non-experimental, qualitative, mixed design, etc.) and corresponding methods (e.g., survey, focus groups, interview, etc.) are	

Evaluation Title:	
Standard and Criteria	**Tips and Sample Language**
specified.	
❑ Design and methods are appropriate given the evaluation questions.	
❑ A clear data analysis plan to classify, interrelate, compare and display information is provided.	
❑ There is a criterion for selecting the data sources. It is clear what data collection methods will be used and why.	
❑ Procedures for selecting the sample is specified. It is clear where or from whom the data will be gathered.	
❑ The unit of analysis is specified and appropriate.	
❑ The proposed sample size is justified and sufficient to meet the project objectives.	
Address ethical considerations and assurances	
❑ Ethical certifications of evaluators, data collectors, analysts and other staff in the evaluation are documented in an appendix.	
❑ Data security confidentiality assurances are described.	
❑ Procedures for informing participants about the evaluation and the methods for obtaining consent are described, where applicable.	

Evaluation Title:	
Standard and Criteria	**Tips and Sample Language**
❑ It is clear how participants' rights and information will be protected.	
❑ Ethical issues, particular to vulnerable populations if applicable, are adequately addressed (e.g., children, Key populations, prisoners, pregnant women).	
Identify resources and articulate budget	
❑ Protocol includes a realistic budget and timeline for the evaluation organized by stage (protocol development, data collection and management, data analysis, evaluation report, and other dissemination modes).	
Construct data collection and management plans	
❑ Protocol includes a data collection plan defining: ❑ who will administer the data collection instruments, when and where; ❑ how data will be gathered; ❑ quality assurance procedures.	
❑ The content of the data collection instruments is relevant to the project objectives and is realistic, feasible, acceptable.	

Evaluation Title:	
Standard and Criteria	**Tips and Sample Language**

❏ Protocol includes a data management plan describing the areas listed below:
  ❏ data cleaning and organization;
  ❏ length of time data will be stored;
  ❏ special procedures for interview audio management and storage (including whether or not tapes will be translated and/or transcribed), if applicable.	

Ensure appropriate evaluator qualifications and evaluation independence	
❏ Names and brief CVs of those conducting the evaluation are documented in an Appendix.	
❏ A conflict of interest statement signed by all members of evaluation team (PIs, Co-PIs, Implementing Partner-if applicable) is included.	
Disseminate results	
❏ It is clear how project findings and recommendations will be used to scale-up pilot programs, improve existing programs, and/or guide fiscal, program, or policy decision-making.	

Practical Toolkit for
Health Information System
Evaluation

Appendix 4: Resources for Data Collection

Working Draft: November 30, 2017

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Appendix 4A

Review of Software as a Service Systems for Data Collection in HIS Evaluation

Last Updated 28 Nov 2017

"Software as a service (SaaS) is a software distribution model in which a third-party provider hosts applications and makes them available to customers over the Internet."[1] The SaaS delivery model allows an organization to pay an annual or monthly subscription fee to use the company's online service, allowing for a much lower barrier to entry. SaaS services are ubiquitous in our day-to-day lives and the global healthcare industry is no different.

Organizations carrying out HIS evaluation have many choices when seeking to collect information from the health workforce. It's appropriate to clearly define the project's information needs for operational, monitoring and evaluation and research purposes. These information needs can be captured in a succinct set of functional requirements that should be used to evaluate systems to determine their fit.

SaaS is not the only model available to support an organization's information needs. Many point of service systems are owned and operated by the organizations who implement them. These models include varying types of ownership such as adopting and implementing open source systems, purchasing a vendor supported system and paying a one-time fee for downloading a product.

This document provides an example of an evaluation of numerous prominent SaaS systems to meet an organization's needs for a distributed data collection project. The document defines the information collection scenario, functional requirements, non-functional requirements and evaluates the candidate systems.

Data Collection Scenario

The data collection is focused on validating and updating a national master facility list (MFL). The project team already has access to a facility list with geographic information. An information collection team comprised of government and non-governmental organizations is responsible

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[1] http://searchcloudcomputing.techtarget.com/definition/Software-as-a-Service

for reviewing nearly 10,000 facilities, ensuring their information is up to date and adding any missing facilities that are known to the community.

The questionnaire will be administered along a geographic administrative hierarchy with team members at the provincial level responsible for all facilities in their catchment area. The team assumes that these individuals will wish to delegate a subset facilities to the district and local levels. Ultimately, the survey will be administered to the facility in-charge or any other person designated by them and will involve the interviewer visiting or calling the facility to acquire the necessary information.

The data will be collected using an electronic tool and submitted to a common server on a rolling basis. Enumerators will use their smartphones to download the electronic tool and key in responses to the questionnaire. In some cases, enumerators will need to be able to update facility records from a desktop computer. A central team will actively manage the data collection process to ensure high quality data is received in a timely manner.

The tool utilised will allow easy configuration of the questionnaire, support functionalities such as skip patterns, automatic collection of GPS coordinates and reading metadata such as the master facility list. The cost analysis is based on a survey that contains 100 fields and assumes we will need to collect approximately 12,000 forms during the project period.

Functional Requirements

The software system must be able to achieve the following core requirements:
- **Offline:** The system should allow for offline data collection on a smartphone.
- **Data Entry on PC:** The system should allow enumerators to enter data using a PC when they are calling facilities.
- **Import MFL:** Ability to import the current Master Facility List as an option field on the form and have a cascading dropdown provide appropriate filtering for users
- **Monitor Activity:** Ability to centrally store the information that is collected and monitor the use so I-TECH can provide feedback to enumerators
- **Report:** The system should be able to generate a list of completed sites and sites that still need to be surveyed by geographic area and enumerator. The system should also support basic analysis of the data e.g. frequency distributions
- **Export:** The system must be able to export the data in tabular way (XLS, CSV)
- **GPS:** The system should be able to collect GPS location during the process of gathering the data

The following requirements would be beneficial, but are not critical:
- **Enumerator Assignment:** Ability to assign an enumerator to collect a subset of facilities
- **Dashboards:** The system should allow data to be viewed on dashboards
- **DHIS2 API:** The system should have an API available for easy transfer of data to the MOH system-DHIS2.

Non-Functional Requirements

- **Cost:** We aim to minimize total cost of ownership for MOH and stakeholders
- The information must be stored in a secure system
- Enumerators should be able to be recognized in the system through some type of credentialing mechanism either logins or metadata
- The system should allow for user-friendly configuration
- The system should support skip patterns

Candidate Systems

This shortlist of candidate systems was derived from online research and experience. Our team discussed the pros and cons of hosting the information systems ourselves and we identified that the lowest cost option would be to implement a SaaS solution. Therefore, we chose not to pursue Open Data Kit, Epi Info and DHIS2.

Below is a list of candidate systems in alphabetical order:

CommCare (commcarehq.org)

Required:
- **Offline:** CommCare provides an offline mobile app that can be downloaded to the enumerator's smartphones.
- **Data Entry on PC:** This is available with the pro plan.
- **Import MFL:** Yes
- **Monitor Activity:** Yes, this is a standard feature
- **Report:** Yes
- **Export:** Yes
- **GPS:** Yes
- **Cost:** A minimum of $100/month (standard plan) if you choose not to have a web interface for data collection. If you do, the cost is $500/month (pro plan).

Optional:
- **Enumerator Assignment:** Yes, this would have to be done by creating case groups and assigning each facility to a particular case. Note that this feature requires a standard plan.
- **Dashboards:** Yes
- **DHIS2 API:** Requires a third party tool like MOTECH or OpenFN, which requires an additional cost.

Google Forms

Required:
- **Offline:** Not available. Google forms are not available for offline submission.
- **Data Entry on PC:** Primary mechanism for data collection.

- **Import MFL:** Not clearly supported. You can copy and paste them into the UI. The cascading dropdowns can be created using skip logic.
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes
- **Export:** Yes
- **GPS:** No
- **Cost:** Free if managed by an existing G Suite organisation or personal Google accounts. Alternatively, $5/user/month if you choose to set up a project-specific G Suite organisation.

   Optional:
- **Enumerator Assignment:** No
- **Dashboards:** No
- **DHIS2 API:** No

Google Sheets
   Required:
- **Offline:** Data collection is available in the Google Drive app, which will be synchronized when the smartphone becomes online again. Note that the user interface is a Spreadsheet, which may, or may not be the best mechanism for collecting the data.
- **Data Entry on PC:** Available
- **Import MFL:** Not clearly supported. You can copy and paste them into the UI. The cascading dropdowns can be created using skip logic.
- **Monitor Activity:** Yes, this is a standard feature of Google Apps.
- **Report:** Yes
- **Export:** Yes
- **GPS:** No
- **Cost:** Free if managed by an existing G Suite organisation or personal Google accounts. Alternatively, $5/user/month if you choose to set up a project-specific G Suite organisation.

   Optional:
- **Enumerator Assignment:** Not available as a feature. However, you could create one sheet per enumerator and compile the data at a later point.
- **Dashboards:** Not part of the core product, but could link to Google Charts
- **DHIS2 API:** No

Hoji.co.ke
   Required:
- **Offline:** Hoji provides the ability to collect data on a smartphone.
- **Data Entry on PC:** Not available.
- **Import MFL:** Yes
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes

- **Export:** Yes
- **GPS:** Yes
- **Cost:** The cost of Hoji is based on the number of fields submitted from the enumerator to the Hoji server. The organisation is responsible for purchasing a monthly package of credits. Each form that's submitted decrements from the total number of credits in the package. For example, if you purchase a Starter plan for 19,999 KES ($193 USD), you can submit up to 30,000 fields in a given calendar month. So, if your survey contains 100 fields, you can submit up to300 forms in that month (30,000/100). The Standard plan costs 49,999 KES ($483USD) and you can collect up to 100,000 fields or 1000 forms for a 100 field survey.

Optional:
- **Enumerator Assignment:** No
- **Dashboards:** Yes
- **DHIS2 API:** No

KoboToolbox (kobotoolbox.org)
Required:
- **Offline:** KoboToolbox provides the ability to collect data offline on a smartphone.
- **Data Entry on PC:** Available with or without internet connectivity. Able to sync from PCs when the internet becomes available again.
- **Import MFL:** Available
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes
- **Export:** Yes
- **GPS:** Yes
- **Cost:** Free

Optional:
- **Enumerator Assignment:** This isn't clearly evident based on the documentation. It is possible to create multiple users per project, but we are uncertain if you can assign a subset of facilities to a particular user.
- **Dashboards:** Yes
- **DHIS2 API:** No

MagPi (home.magpi.com)
Required:
- **Offline:** MagPi provides the ability to collect data offline on a smartphone.
- **Data Entry on PC:** Not Supported
- **Import MFL:** Available
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes
- **Export:** Yes
- **GPS:** Yes

- **Cost:** $500/month minimum for a pro account and $834/month for enterprise

    Optional:
- **Enumerator Assignment:** This appears to be possible with roles in the enterprise account, but the assignment is not clearly stated in the user documentation.
- **Dashboards:** Yes
- **DHIS2 API:** Available through a third party tool called OpenFN, that requires an additional cost.

Ona.io
    Required:
- **Offline:** Ona.io provides the ability to collect data offline on a smartphone.
- **Data Entry on PC:** Available with or without internet connectivity. Able to sync from PCs when the internet becomes available again.
- **Import MFL:** Available
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes
- **Export:** Yes
- **GPS:** Yes
- **Cost:** Public projects are free and private projects require a monthly fee. If chosen, we would want to use the Org Standard plan which costs $99/month.

    Optional:
- **Enumerator Assignment:** Available
- **Dashboards:** Yes
- **DHIS2 API:** Available through a third party tool called OpenFN, that requires an additional cost.

RedCap (redcap.iths.org/) - Assuming free access through ITHS consortium
    Required:
- **Offline:** The REDCap Mobile App provides the ability to collect data offline on a smartphone.
- **Data Entry on PC:** Available with internet connectivity.
- **Import MFL:** Available
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes
- **Export:** Yes
- **GPS:** Yes
- **Cost:** Free through the ITHS consortium.

    Optional:
- **Enumerator Assignment:** Available
- **Dashboards:** Yes
- **DHIS2 API:** No

SurveyCTO (www.surveycto.com)

Required:
- **Offline:** SurveyCTO provides the ability to collect data offline on a smartphone.
- **Data Entry on PC:** Available
- **Import MFL:** Available
- **Monitor Activity:** Yes, this is a standard feature.
- **Report:** Yes
- **Export:** Yes
- **GPS:** Yes
- **Cost:** The professional basics plan is appropriate for $99/month

Optional:
- **Enumerator Assignment:** Custom, enterprise level user access controls are noted as a feature in the professional plans, but this isn't clearly defined in any publicly available online documentation.
- **Dashboards:** Yes
- **DHIS2 API:** Available through a third party tool called OpenFN, that requires an additional cost.

Required Functionality	CommCare	Google Forms	Google Sheets	Hoji	Kobo Toolbox	MagPi	Ona	RedCap	Survey CTO
Offline	✔	✘	✔	✔	✔	✔	✔	✔	✔
Data Entry on PC	❗	✔	✔	✘	✔	✘	✔	✔	✔
Import MFL	✔	✘	✘	✔	✔	✔	✔	✔	✔
Monitor Activity	✔	✔	✔	✔	✔	✔	✔	✔	✔
Report	✔	✔	✔	✔	✔	✔	✔	✔	✔
Export	✔	✔	✔	✔	✔	✔	✔	✔	✔
GPS	✔	✘	✘	✔	✔	✔	✔	✔	✔
Monthly Cost	$100/ $500	Free	Free	$193/ $483	Free	$500/ $834	Free/ $99	Free	$99

Optional

	CommCare	Google Forms	Google Sheets	Hoji	Kobo Toolbox	MagPi	Ona	RedCap	Survey CTO
Enumerator Assignment	✔	✘	❗	✘	✘	✔	✔	✔	✔
Dashboards	✔	✘	❗	✔	✔	✔	✔	✔	✔
DHIS2 API	❗	✘	✘	✘	✘	❗	❗	✘	❗

✔ - Yes; ❗ - Conditional; ✘ - No

Disclaimer: This evaluation was performed independently based on publicly available information that was available at the time of writing. On two occasions, the author emailed hoji.co.ke for clarity where publicly available information was not clear. To the best of our knowledge, the information presented in this document is accurate. However, we assume no liability whatsoever for the accuracy and completeness of the information above. Any trademarks are the property of their respective owners. This document was not endorsed by and the authors are not affiliated with any organisations cited in this article.

How-To Guide: Configuring Tablets for Data Collection Without Centralized Management

Sample Tablet Setup Instructions

Some mobile deployment projects do not require central management using Enterprise Mobility Management services. However, organizations would like to enforce policies at the device level. This document provides steps required to setup each tablet for a pilot implementation that aims to scale regionally at 130 facilities.

Assumptions

- The organization is not going to deploy an Enterprise Mobility Management solution at this time
- Core workforce applications are available through the Google Play Store, not side-loaded. Side-loaded apps cannot be remotely updated and require a different configuration than what is noted in this document
- The deployment aims to reduce the likelihood that end users will access bandwidth intensive services online (Social Media, Video streaming, etc.)

Functional Requirements

The configuration solution must meet the following functions:
- **Remote Location and Wipe** - The solution must be able to remotely locate a device and wipe the data from it in the event that the mobile device is lost or stolen.
- **Prevent App Installs** - The solution must be able to prevent users from installing their own applications. This includes installing applications from the Google Play Store and sideloading them directly. This allows system administrators to maintain the deployment device and reduce the likelihood of abuse.
- **Restrict Social Media (Blacklist)** - The solution should be able to restrict access to social media through application downloads and web browsing. In the web browser, this is known as blacklisting websites. This will reduce the likelihood that end users will use the tablet for non-work purposes.

Record Keeping

Any large scale deployment needs to keep track of all assets that are deployed. These include physical assets as well as digital assets. Record keeping is critical for the success of these distributed deployments that do not have centralized management. For example, each device is able to be remotely located and wiped using the Google Account. This is available from a central location, only if the username and password are known for the Google account where the device is registered.

Physical Items

The deployment management should have a checklist for each physical item that is going to be given to the team member. Below is an example checklist:

The following physical items will be deployed for each tablet:
- Tablet - Android 6.0 Marshmallow
- Charging Cable
- Tablet Case
- Screen Protector
- SIM Card
- Security Cable
- Tablet Use Agreement

Tracking Accounts, Credentials and Assets

The central team should create a mechanism for tracking all tablets and credentials that are deployed by location. Here's a link to a sample spreadsheet that can aid in tracking devices.

As the organization performs the tablet setup process, they need to record numerous digital and physical assets:
- Photo of tablet warranty cards
- Storage of physical tablet warranty cards
- Photo of SIM Cards for record keeping
- Photo of IMEI and Serial Number from the device

Core Tablet Configuration Steps

Numerous applications need to be downloaded to deliver the functionality defined in the Functional Requirements Section. The team needs to create a Google Account for each device with a distinct username and password. This allows the account owner to remotely locate and wipe the device. Preventing app installs is done using Norton App lock, which prevents user access to the Google Play store and other applications that aren't necessary for work purposes. Blacklisting websites is a challenging process that requires sideloading an application named NetGuard and installing a hosts file that defines which sites the organization chooses to block.

Note that NetGuard requires a tablet that can run a local Virtual Private Network. Not all tablets come with this feature as part of their Android operating system and that the team should test these configuration steps before purchasing a lot of a particular device.

All installed and active apps on the device will automatically update from the Google Play store, even though Norton App lock blocks user access. For this reason, it's best to uninstall or disable applications that are not business critical, such as YouTube. The YouTube app is currently 92MB and updates regularly. If not disabled, app updates can drastically impact the mobile data usage of each tablet.

The remainder of the document defines the steps for a sample Samsung tablet configuration. The following steps need to be completed for each tablet:
1. Connect to WiFi
2. Update the device's operating system
3. Set date and time zone
4. Uninstall or disable unused applications
5. Create a Google Account for logging in to the Play Store
6. Update apps on the Play Store
7. Download and configure new apps
8. Add a lock screen PassCode

Step 1: Connect to Wi-Fi

We connect the device to the Wifi so all devices update over wifi, not over mobile data.
- Touch Settings
- Wi-Fi
- Choose a network and login

Step 2: Update the device's operating system

The first step is to ensure the mobile device has the latest Android security patches.
- Touch Settings
- About Tablet
- System Updates
- Update the device if it isn't up to date

Step 3: Set date and time zone

The tablet should be set to the time zone where it will be used:
- Touch Settings
- Date & Time
- Touch Automatic date & time then touch "Off" to disable this feature if out of the target time zone

- Touch Select time zone
- Choose time zone from the list

Step 4: Uninstall or disable unused applications

All applications that are installed on a tablet will get updates from the Google Play store. This uses precious bandwidth and can cause a bottleneck in the mobile app update process. Depending on the tablet configuration, some applications are not able to be uninstalled. They are only able to be disabled.

Steps:
- Touch Settings
- Apps
- Touch the application
- The left button will say either "Uninstall" or "Disable" touch it

Uninstall or disable these applications:
- YouTube
- Google Play Movies & TV
- Google Play Music

Step 5: Create a Google Account for logging in to the Play Store

We need to create a Google Account for the device so we are able to access the Google Play Store to download apps.
- Touch the Apps button
- Play Store
- A screen pops up to "Add your account." Touch "Or create a new account"
- Enter the owner's name, DOB and Gender
- Create a username and password
- Add the mobile number
- Agree to the privacy terms and create the account
- Toggle the feature to automatically back up device data to Google Drive
- Skip payment info
  (Google Play will open and the tablet will be configured to sync with a Google Account)

Step 6: Update apps on the Play Store

Many apps need to be updated the first time the Google Play Store is accessed. This step ensures all apps are updated before installing new apps.

- Touch the Apps button
- Play Store

- Touch the 3 line "hamburger" menu next to the Google Play search box then touch "My apps & games"
- If updates are available, touch the "update all" button

Step 7: Download and configure new apps

Now that the system is up to date, we need to download the new apps we will rely on for the end users. Search for and download each of the following applications:

- *Mobile Data Collection Tool* - The primary workforce application used on the device
    - Configuration: None
- WhatsApp - Used for communication with the support group
    - Configuration:
        - When you open WhatsApp, you need to create an account based on the tablet's mobile number
- (SideLoad) NetGuard - Used to filter web traffic to reduce abuse
    - Configuration:
        - Follow these instructions, but download the appropriate hosts file. (I-TECH_hosts file is available on our GitHub repository)
        - Once the hosts file is loaded in, you have to enable NetGuard
- Norton App Lock - Used to lock settings so users aren't able to access them
    - Configuration:
        - Walk through the steps to enable accessibility
        - Touch the three bar "hamburger" menu then "Activate Device Administrator" and create a pattern
        - Touch "Settings" in the same menu then touch the slider next to "Make pattern invisible"
        - Go back to the main screen and lock all apps that aren't needed
            - Google Play Store
            - Settings
            - Browser
            - (Samsung Specific Apps)
            - File Manager
            - Search
            - NetGuard
- Torch - Many users find the torch appropriate to download if it isn't already installed by Samsung

Step 8: Add a Lock Screen PassCode

We use a lock screen passcode to add a layer of security to the device during use and in the event that it's lost.

- Touch Settings
- Security

- Screen lock
- Choose a PIN or Password (Don't use a Pattern, these are easier to access)

Disclaimer: This evaluation was performed independently based on publicly available information that was available at the time of writing. To the best of our knowledge, the information presented in this document is accurate. However, we assume no liability whatsoever for the accuracy and completeness of the information above. Any trademarks are the property of their respective owners. This document was not endorsed by and the authors are not affiliated with any organisations cited in this article.

Appendix 4C

Compendium of Instruments for Data Collection [Sample]

Title of tool or instrument: RHIS Performance Diagnostic Tool
Authors: Anwer Aqil, Theo Lippeveld, and Dairiku Hozumi
Type of tool or instrument: HIS performance checklist
Description: This tool helps determine the overall level of routine HIS performance, looking separately at quality of data and use of information to identify weak areas. This diagnostic tool identifies strengths and weaknesses. The Performance Diagnostic Tool is the primary component of the PRISM toolset.
Citation/Source: Aqil, A., Lippeveld, T., & Hozumi, D. (2009). PRISM framework: a paradigm shift for designing, strengthening and evaluating routine health information systems. Health policy and planning, 24(3), 217-228.
Cited by: Cho, K. W., Kim, S. M., An, C. H., & Chae, Y. M. (2015). Diffusion of electronic medical record based public hospital information systems. Healthcare informatics research, 21(3), 175-183
Location: https://www.measureevaluation.org/resources/publications/ms-11-46-d. Downloadable PDF available. Tool begins on page 7 of the document. Additional PRISM tools are also located in this document

.

Title of tool or instrument: e-Health Readiness assessment tools
Authors: Shariq Khoja, Richard E. Scott, Ann L. Casebeer, M. Mohsin, A.F.M. Ishaq, and Salman Gilani
Type of tool or instrument: Readiness assessment tool
Description: Two e-health readiness assessment tools for application in healthcare institutions of developing countries: one for managers, and one for healthcare providers. There are four categories of readiness described in each tool: core readiness, technological readiness, learning readiness, and societal readiness.
Citation/Source: Khoja, S., Scott, R. E., Casebeer, A. L., Mohsin, M., Ishaq, A. F. M., & Gilani, S. (2007). e-Health readiness assessment tools for healthcare institutions in developing countries. Telemedicine and e-Health, 13(4), 425-432.
Cited by: Khoja, S., Scott, R. E., Casebeer, A. L., Mohsin, M., Ishaq, A. F. M., & Gilani, S. (2007). e-Health readiness assessment tools for healthcare institutions in developing countries. Telemedicine and e-Health, 13(4), 425-432
Location: https://www.researchgate.net/publication/5992662_e-Health_Readiness_Assessment_Tools_for_Healthcare_Institutions_in_Developing_Countries. Items for the tools are described in Tables 1-5.

Title of tool or instrument: EMR Monitoring and Evaluation sheet
Author: Samuel Kang'a, Nancy Puttkammer, Steven Wanyee, Davies Kimanga, Jason Madrano, Veronica Muthee, Patrick Odawo, Anjali Sharma, Tom Oluoch, Katherine Robinson, James Kwach, and William B. Lober
Type of tool or instrument: M&E Survey
Description: Tool to measure EMR use, acceptability and reliability and improvement in patient care, record keeping, and reporting.
Citation/Source: Standards and Guidelines for Electronic Medical Record Systems in Kenya. Ministry of Public Health and Sanitation and the Ministry of Medical Services of Kenya.
Cited by: Kang'a et al (2017). A national standards-based assessment on functionality of electronic medical records systems used in Kenyan public-Sector health facilities. International journal of medical informatics, 97, 68-75.
Location:https://www.ghdonline.org/uploads/Standards_and_Guidelines_for_Electronic_Medical_Record_Systems.pdf. Annex H in the PDF document.

[Document to be completed]

Practical Toolkit for
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Appendix 5: Literature Reviews and Annotated Bibliographies

Working Draft: November 30, 2017

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Appendix 5B

Annotated Bibliography of HIS Theories

HIS Evaluation Theories

Search Strategy

All Pubmed Title/Abstract returned by a query that specified one HIS term and one evaluation term:

   [HIS terms] + [Theory terms]

Abstracts were reviewed for inclusion based on relevance to information systems and HIS domains; included articles were summarized, if articles cited other studies not found in the initial review, but were deemed relevant, they were included.

HIS Terms
- eHealth
- electronic health record
- electronic medical record
- health data system
- health informatics
- health information system
- health information technology
- laboratory information system
- mHealth
- pharmacy information system
- telemedicine

Theory Terms
- Framework
- Culture
- Literature review
- Model
- Principles
- Synthesis
- Systematic review
- Theoretical
- Theory

1. Ammenwerth E, Iller C, Mahler C. IT-adoption and the interaction of task, technology and individuals: a fit framework and a case study. BMC Med Inform Decis Mak. 2006 Jan 9;6:3. doi:10.1186/1472-6947-6-3.

   Summary: FITT framework—fit between individuals, task and technology, taking into account the process-oriented character of an IT introduction. Views information systems as technical systems embedded in social-organizational environments. Socio-organizational settings may differ and lead to different adoption processes of the same IT system. Helps to better analyze the socio-organizational-technical factors that influence IT adoption.
   Example uses: Describing adoption of a nursing documentation system in a hospital.
   Unique aspects: Other models concentrate on individual attributes of the users and of technology, this model is based on the idea that IT adoption in a clinical environment depends on the fit between the attributes of the users (e.g., computer anxiety, motivation), of the attributes of the technology (e.g., usability, functionality, performance), and of the attributes of the clinical tasks and processes.

2. Anderson JG. Evaluation in health informatics: social network analysis. Comput Biol Med. 2002 May;32(3):179-93.

   Summary: Used to analyze the relationships among entities such as people, departments, and organizations. Based on the premise that individuals are influenced by direct and indirect exposure to other person's attitudes and behavior; by access to resources through the network; and by the individual's location in the interpersonal network. There are four elements of an evaluation design, namely, the units that comprise the network, the type of relations among the units, the properties of the relation, and the level of analysis.
   Example uses: Can be used to identify individual roles in the social network such as leaders and isolates. One example is to identify the structure of the referral and consultation networks that link physicians in a group practice; and to study the effect of the physicians' location in the network on their use of the hospital information system. Another examples is the introduction of a computer-based health appraisal system, analyzing frequency of communications between staff.
   Unique aspects: Distinguishing characteristic of this approach is that it uses information about relations between individuals and organizational units and their attributes to understand individual and organizational behavior.

3. Aqil A, Lippeveld T, Hozumi D. PRISM framework: a paradigm shift for designing, strengthening and evaluating routine health information systems. Health Policy Plan. 2009 May;24(3):217-28. doi:10.1093/heapol/czp010.

   Summary: Performance of Routine Information System Management framework. States that RHIS performance is affected by RHIS processes, which in turn are affected by technical, behavioural and organizational determinants. Delineates the direct and indirect relationships of the determinants on RHIS performance and measures their relative importance. Considers behavioural, organizational and technical determinants. Tools include: RHIS performance diagnostic tool, RHIS overview tool, RHIS management assessment tool, and the organizational and behavioural assessment tool.
   Example uses: Measures: (a) RHIS performance; (b) status of RHIS processes; (c) the promotion of a culture of information; (d) supervision quality; and (e) technical determinants. Identifies redundancies, workload, fragmentation and level of integration. Measures the level and role of behavioural factors such as motivation, confidence levels, demand for data, task competence and problem-solving skills, while organizational variables include promotion of a culture of information and rewards.
   Unique aspects: Focuses on RHIS performance management; considers RHIS to be a system with a defined performance and describes organizational, technical, and behavioural determinants and processes that influence its performance. Draws attention to neglected RHIS processes, such as checking data quality, displaying of information and giving feedback, and makes them part of the accepted norms.

4. Davis FD, Bagozzi RP, Warshaw PR. User acceptance of computer technology: a comparison of two theoretical models. Manage Sci. 1989 Aug;35(8): 982-1003. doi:10.1287/mnsc.35.8.982.

Summary: Technology acceptance model (TAM). Use of theory of reasoned action (TRA) to specify the causal linkages between two key beliefs: perceived usefulness and perceived ease of use, and users' attitudes, intentions and actual computer adoption behavior. Analyzes why users adopt or reject a system.
Example uses: Measures usage, behavioral intention, and attitude about the use of a software system.
Unique aspects: Predicts and explains user acceptance and rejection of computer-based technology. Only usable for voluntary use of IT systems, additional factors should be included in this model, such as extrinsic motivation, user experiences with the system, and characteristics of the task to be supported by IT.

5. DeLone WH, McLean ER. The DeLone and McLean model of information systems success: a ten-year update. J. Manage Inf Syst. 2003 Apr;19(4):9-30.

    Summary: Interactive model for conceptualizing and operationalizing information system success, "IS success model". Interrelated dimensions, "systems quality" measures technical success; "information quality" measures semantic success; and "use, user satisfaction, individual impacts," and "organizational impacts" measure effectiveness success. Recently added "service quality" as a dimension.
    Example uses: Measuring goodness-of-fit based on survey data from users of IS. E-commerce system.
    Unique aspects: IS success is multidimensional and interdependent construct, therefore it is necessary to study the interrelationships among, or to control for, those dimensions. Uses a causal success model, including both process and variance models. Not specific to health systems. Other authors have stated (Ammenwerth), that this model has an isolated focus on IT quality and system quality, indicating that only the system's quality itself determines the overall impact, does not help explain why the same IT system can be adopted in a different way.

6. Dixon DR. The behavioral side of information technology. Int J Med Inform. 1999 Dec;53(1-3):117-23.

    Summary: Information Technology Adoption Model (ITAM). Implementation and evaluation are intertwined. Looks at the individual user and predicts adoption of an information technology. Can illustrate areas where evaluation can be carried out and implementation strategies refined and introduced. Perceived usefulness and perceived ease of use are not dependent on the system design features, but on this fit of the user and system design features. (Ammenwerth)
    Example uses: Adoption of IT used to enable and enhance guideline and pharmaceutical adoption.
    Unique aspects: Focuses on individual change and adoption behavior. Uses "notion of fit"; it is not individual attributes which are important, but the quality of the fit. Points missed by the Davis model, such as extrinsic motivation or task characteristics, are not included. (Ammenwerth)

7. Eivazzadeh S, Anderberg P, Larsson TC, Fricke SA, Berglund J. Evaluating health information systems using ontologies. JMIR Med Inform. 2016 Jun 16;4(2):e20. doi:10.2196/medinform.5185.

Summary: Unified eValuation Ontology. Organizes, unifies, and aggregates the quality attributes of several health information systems into a tree-style ontology structure. Identifies what to evaluate in a health information system.

Example uses: Evaluating 7 cloud-based eHealth applications deployed across the EU.

Unique aspects: Systematic, context sensitive, and relevant across a heterogeneous set of health information systems. Focuses on how to form local ontology. Formal and computable way of capturing knowledge in a domain by specifying the domain's key concepts and interconnecting them by a predefined set of relations. Considers case-specific internal requirements and offers the possibility of further investigations for other indications related to evaluation of the subject systems.

8. Venkatesh V, Davis FD. A theoretical extension of the technology acceptance model: four longitudinal field studies. Manage Sci. 2000;46(2):186-204.

   Summary: Technology acceptance model—TAM2. Incorporates additional theoretical constructs spanning social influence processes and cognitive instrumental processes. Constructs: social influence processes—subjective norm, voluntariness and compliance with social influence, internalization of social influence, images and social influence, changes in social influence with experience; cognitive instrumental processes—job relevance, output quality, result demonstrability, perceived ease of use, changes in cognitive instrumental influences with experience.

   Unique aspects: Extends TAM to address causal antecedents of one of its two belief constructs, perceived usefulness.

9. Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. MIS Q. 2003;27(3):425-78.

   Summary: Unified Theory of Acceptance and Use of Technology. Goal is to understand usage as the key dependent variable. Determinants: performance expectancy, effort expectancy, attitude toward using technology, social influence, facilitating conditions, self-efficacy, anxiety, and behavioral intention to use the system.

   Unique aspects: Integrates the fragmented theory and research on individual acceptance of information technology into a unified theoretical model that captures the essential elements of eight previously established models. Provides a refined view of how the determinants of intention and behavior evolve over time.

10. Yusof MM, Kuljis J, Papazafeiropoulou A, Stergioulas LK. An evaluation framework for health information systems: human, organization and technology-fit factors (HOT-Fit). Int J Med Inform. 2008 Jun;77(6):386-98. doi:10.1016/j.ijmedinf.2007.08.011.

    Summary: Incorporates comprehensive dimensions and measures of HIS and provides a technological, human, and organizational fit. Framework, human, organization and technology-fit (HOT-fit) is capable of being useful in conducting a thorough evaluation study. Assist with unfolding and understanding the perceived complexity of HIS evaluation. Eight interrelated dimensions of HIS success: system quality, information quality, service quality, system use, user satisfaction,

organizational structure, organizational environment, and net benefits. The framework could be used to evaluate the performance, effectiveness and impact of HIS or IT in healthcare settings.

Example use: Imaging system in a primary care organization.

Unique aspects: Makes use of the IS Success Model and the IT-Organization Fit Model. Framework can be applied in a flexible way, taking into account different contexts and purposes, stakeholders' point of views, phases in system development life cycle, and evaluation methods. Structured debating tool that stakeholders can access in order to know their own system health better.

Appendix 5C

Annotated Bibliography of HIS Evaluation Best Practices

HIS Evaluation Best Practices and Methods

Search Strategy
All Pubmed Title/Abstract returned by a query that specified one HIS term and one evaluation term:

      [HIS terms] + [Theory terms]

Abstracts were reviewed for inclusion based on relevance to information systems and HIS domains; included articles were summarized, if articles cited other studies not found in the initial review, but were deemed relevant, they were included.

HIS Terms	*Theory Terms*
• eHealth	• Framework
• electronic health record	• Culture
• electronic medical record	• Literature review
• health data system	• Model
• health informatics	• Principles
• health information system	• Synthesis
• health information technology	• Systematic review
• laboratory information system	• Theoretical
• mHealth	• Theory
• pharmacy information system	
• telemedicine	

1. Andargolia A, Scheepers H, Rajendran D, Sohal A. Health information systems evaluation frameworks: A systematic review. Int J Med Inform. 2017;97:195-209.

    Summary: Various studies have proposed frameworks to reduce the complexity in the assessment of health information systems (HIS). The authors carried out a systematic literature review on HIS evaluation studies to identify the currently available HIS evaluation frameworks. For each study, the paper analyzed the 'who' (which stakeholders are involved, who defines the evaluation goals and processes), 'what' (what innovation, what context), 'how' (how to select suitable measures), 'when' (when in the lifecycle of a project), and 'why' (which goals or purposes) of the evaluation processes used. Most studies addressed some, but not all, of the five main questions, and the critical role of context was also largely neglected in these studies.
    Unique aspects: This paper reviews a wide range of eHealth evaluation frameworks, including general frameworks, frameworks focused on the HIS lifecycle, social relationships focused

frameworks, and behavioral focused frameworks. This paper could be used to understand the range of HIS evaluation frameworks which have been published. It highlights considerations for the planning of HIS evaluations.

2. Boland MR, Rusanov A, So Y, Lopez-Jimenez C, Busacca L, Steinman RC, et al. From expert-derived user needs to user-perceived ease of use and usefulness: a two-phase mixed-methods evaluation framework. J Biomed Inform. 2014 Dec;52:141-50. doi:10.1016/j.jbi.2013.12.004.

Summary: Two-phase mixed-methods evaluation framework. Bridges the gap between co-evolving user needs and technology designs during iterative prototyping. Phase I, a usability expert collects user needs and compares the intervention with related systems by aligning system functions with derived user needs for each system. Phase 2 involves the system's end-users to collect quantitative and qualitative data. Enables validation of expert-derived user needs, elicitation of unanticipated users' needs, collection of users' perceptions of the system. The authors evaluated the prototypes of a novel clinical research decision support system called Integrated Model for Patient Care and Clinical Trials (IMPACT), which is designed to provide decision support for scheduling research visits, using this framework.
Unique aspects: Relevant for early prototype evaluations for emerging HIT interventions, when users are unclear about their needs and when a baseline is lacking. Prevents end-users from being adversely affected by a system requiring critical improvements.

3. Grant A, Plante I, Leblanc F. The TEAM methodology for the evaluation of information systems in biomedicine. Comput Biol Med. 2002 May;32(3):195-207.

Summary: Total Evaluation and Acceptance Model (TEAM) methodology. Based on three dimensional framework- role, time, and structure. Role identifies four main categories—designer, specialist user, end user, and stakeholder. Time identifies four main phases. Structure distinguishes strategic, tactical or organization and operational levels. A good evaluation methodology should: 1) focus on a variety of concerns, 2) use multiple methods, 3) be modifiable, 4) be longitudinal, 5) be summative and formative.
Unique aspects: Insistence on a global rather than partial approach to the evaluation; dynamic nature of an information system which is continually in modification. Comprehensible, comprehensive, and flexible.

4. Gray K, Sockolow P. Conceptual models in health informatics research: a literature review and suggestions for development. JMIR Med Inform. 2016 Feb 24;4(1):e7. doi:10.2196/medinform.5021.

Summary: Integrative conceptual model. Seven-step methodology—1) acknowledging the limitation of health science and information science conceptual models; 2) giving a rationale for one's choice of an integrative conceptual model; 3) explicating a conceptual model verbally and graphically; 4)

seeking feedback about a conceptual model from stakeholders in both the health science and information science domains; 5) aligning a conceptual model with an appropriate research plan; 6) adapting a conceptual model in response to new knowledge over time; and 7) disseminating conceptual models in scholarly and scientific forums.

Unique aspects: Can use conceptual models in improve practice by anticipating unintended consequences before they emerge during system implementation, access important opportunities for innovation in order to researchers to be more effective and have a greater impact. Provides representative selection of examples of conceptual modeling.

5. Jayasuriya R. Managing information systems for health services in a developing country: a case study using a contextualist framework. Int J Inf Manage. 1999 Oct;19(5):335-49. doi:10.1016/S 0268-4012(99)00031-6.

   Summary: Contextualist framework. Need to analyze and understand organization, environmental, and cultural issues in adopting models and procedures used elsewhere when managing information systems in developing countries. Analysis of the context of the system, can be differentiated into an 'inner' context (ongoing strategy, structure, culture, management, and politics) and 'outer' context (national economic, political, and social). The author presents this framework applied to a computerized information system for health services in the Philippines.
   Unique aspects: Historically there has been insufficient identification of factors that need to be considered in managing IS. Requires a historical understanding of the context, content, and process because change evolves over time and issues of the present are results of its previous history.

6. Kazanjian A, Green CJ. Beyond effectiveness: the evaluation of information systems using a comprehensive health technology assessment framework. Comput Biol Med. 2002 May;32(3):165-77.

   Summary: Comprehensive Health Technology Assessment Framework. Aims to provide an empirical, evidence-based foundation for decision-making. Dimensions are 1) population at risk, 2) population impact, 3) economic concerns, 4) social context, and 5) technology assessment information.
   Unique aspects: Multidisciplinary approach. Most suitable for decision makers who need to compare the impact of information system technologies within a framework that is inclusive of all competing health technologies. Can be used for policy and decision-making as well as produce useful questions for developers.

7. Khoja S, Durrani H, Scott RE, Sajwani A, Piryani U. Conceptual framework for development of comprehensive e-health evaluation tool. Telemed J E Health. 2013 Jan;19(1):48-53. doi:10.1089/tmj.2012.0073.

   Summary: Developed a matrix of evaluation themes and stages of e-health programs based on a literature review. The matrix presents a conceptual framework for developing an e-health evaluation tool to examine and measure different factors that play a definite role in the success of e-

health programs during each stage of the e-health life cycle. Tool developed is the Kjoha-Durrani-Scott Framework for e-Health evaluation.

Unique aspects: Builds on existing theories of health and technology evaluation and covers a range of areas affected or influenced by e-health interventions. Tools have been developed for each box (theme and life-cycle stage) of the matrix. Relevant themes were assessed by experts and the framework was completed through discussion with a number of e-health researchers and evaluators.

8. Luzi D, Pecoraro F, Tamburis O. Economic evaluation of health IT. Stud Health Technol Inform. 2016; 222:165-80.

   Summary: Focuses on the classification of costs and outcomes as well as on type of economic analysis to be performed. Based on HTA guidelines. Considers perspective, research method, type of assessment, type of study, comparator, and time horizon.
   Unique aspects: Aims to enrich the line of inquiry into economic evaluation approaches for the adoption and implementation of health IT.

9. Shaw, Nicola T. 'CHEATS': a generic information communication technology (ICT) evaluation framework. Comput Biol Med. 2002 May;32(3):209-20.

   Summary: CHEATS—generic framework for the evaluation of information communication technologies. Utilizes both qualitative and quantitative methods. Multidisciplinary approach is essential when evaluating new and emerging technologies. Six aspects for evaluating ICTs: clinical, human and organizational, educational, administrative, technical, and social.
   Unique aspects: Comprehensive framework from which aspects can be drawn and parts utilized. Lists different aspects that should be considered so evaluation deficiencies can be recognized and areas acknowledged where outcomes are unknown, unclear, or impossible to ascertain.

10. Sockolow PS, Crawford PR, Lehmann HP. Health services research evaluation principles. broadening a general framework for evaluating health information technology. Methods Inf Med. 2012;51(2):122-30. doi:10.3414/ME10-01-0066.

    Summary: Health Information Technology Research-based Evaluation Framework (HITREF). HIT evaluation framework that uses HSR principles to address identified shortcomings in available HIT evaluation frameworks. New criterion of evaluation include: functionality, diffusion, user satisfaction, barriers or facilitators to adoption, patient satisfaction with care, selection or development, implementation and training, and unintended consequences/benefits.
    Unique aspects: The commitment to evidence is a strength of this framework.

11. Westbrook JI, Braithwaite J, Iedema R, Coiera EW. Evaluating the impact of information communication technologies on complex organizational systems: a multi-disciplinary, multi-method framework. Stud Health Technol Inform. 2004;107(Pt2):1323-27.

Summary: Seeks to address the complexity and political fragmentation of human practice and their roles in determining the use and outcomes of ICT implementations. Incorporates a range of methods: surveys, interviews, focus groups, ethnography, work-task analysis, work sampling, web-log analysis, critical incident technique, results mapping, and clinical outcome indicator data analysis. Uses a socio-technical standpoint.
Unique aspects: Aim is for the final framework to be generic and generalizable for use beyond the health sector.

12. Yusof MM, Arifin A. Towards an evaluation framework for laboratory information systems. J Infect Public Health. 2016 Dec;9(6):766-73. doi:10.1016/j.jiph.2016.08.014.

Summary: Total testing process (TTP)-LIS framework. Analyzes factors related to human, organization and technology- such as the ease of system use and learning, system flexibility, relevant information, user attitude, planning, strategy, management and communication between doctor and laboratory staff. Combination of factors and dimensions in the HOT-fit and TTP models resulted in a comprehensive laboratory test process flow and HIS evaluations dimensions.
Unique aspects: Aims to provide better illustration of systematic, coordinated, and optimized laboratory testing process and LIS flow as well to facilitate a rigorous error evaluation.

Additional Resources

Clarke K, O'Moore R, Smeets R, Talmon J, Brender J, McNair, et al. A methodology for evaluation of knowledge-based systems in medicine. Artif Intell Med. 1994 Apr;6(2):107-21.

Cresswell K. Evaluation of implementation of health IT. Stud Health Technol Inform. 2016;222:206-19.

Effken JA. Different lenses, improved outcomes: a new approach to the analysis and design of healthcare information systems. Int J Med Inform. 2002 Apr;65(1):59-74.

Kushniruk A. Evaluation in the design of health information systems: application of approaches emerging from usability engineering. Comput Biol Med. 2002 May;32(3):141-49.

Appendix 5D

Annotated Bibliography of Other Resources for HIS Evaluation

Guides, Toolkits, and Other Resources

1. World Health Organization eHealth Evaluation Guide

    [Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment](). Geneva: World Health Organization; 2016. (Licence: CC BY-NC-SA 3.0 IGO.)

    Summary: This resource on Monitoring and Evaluating Digital Health Interventions provides step-wise guidance to improve the quality and value of monitoring and evaluation (M&E) efforts in the context of digital health interventions. This Guide is intended for implementers and researchers of digital health activities, as well as policy-makers seeking to understand the various stages and opportunities for systematically monitoring implementation fidelity and for evaluating the impact of digital health interventions. This comprehensive guide covers M&E planning, articulating value claims, designing monitoring tools and processes, study design for evaluation, and data quality assessment.
    Example uses: This is an excellent comprehensive resource for planning HIS evaluation. It illustrates each section with examples from eHealth and mHealth evaluations, and includes many links and references for further information on each topic.
    Unique aspects: The guide includes sample logic models and results frameworks from digital health projects, as well as step-by-step instructions for data mapping and data quality assessment.

2. PANACeA eHealth Evaluation Tool [Website]()

    Khoja S, Durrani H, Scott RE, Sajwani A, Piryani U. [Conceptual framework for development of comprehensive e-health evaluation tool](). Telemed J E Health. 2013;19(1):48-53.

    Summary: The "KDS framework", as it is known, builds on existing theories of health and technology evaluation and presents a conceptual framework for developing an eHealth evaluation tool to examine and measure different factors that play a definite role in the success of eHealth programs. The tool contains questions regarding health, technology, economic, readiness and change management, social and cultural, ethical, and policy outcomes of an eHealth program measured at various stages of any eHealth program/project, including: 1) development; 2) implementation; 3) integration; and 4) sustained operation. The tool is also further divided into categories to be filled by

Managers, Staff and Clients. The authors argue that success of eHealth systems and interventions should consider assessment across all domains.

Example uses: The KDS framework and survey tool was used in evaluation of five information and communication technology (ICT) projects undertaken as part of the PAN-Asian Collaboration For Evidence-based eHealth Adoption and Application (PANACeA), with support from the International Development Research Center (IDRC).

Unique aspects: The KDS framework and survey tool enables stakeholders with different perspectives to indicate the degree to which they feel an HIS system has met expectations across the seven identified domains. It allows triangulation of perspectives among different stakeholders.

3. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance
   Guidelines

   Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., et al. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *The BMJ*, *350*, h1258. http://doi.org/10.1136/bmj.h1258

   Summary: The Medical Research Council of the United Kingdom (MRC) Process Evaluation Framework discusses process evaluation themes of implementation, mechanism and context. Specifically:
   - Implementation addresses "what is implemented, and how?"
   - Mechanism addresses "how does the delivered intervention produce change?"
   - Context addresses "how does context affect implementation and outcomes?"

   Example uses: The MRC framework presents concepts in process evaluation of complex interventions which can easily be adapted to HIS evaluations.

   Unique aspects: The framework clarifies the relationship of process and outcome evaluation in complex health interventions, and discusses the purpose of process evaluation by stage of the intervention implementation. During a pilot stage, process evaluation can help with understanding feasibility and with identifying improvements to optimize implementation and outcomes. During later stages of program implementation, when effectiveness is of greater interest, then process evaluation can build confidence in the conclusions by assessing what was actually delivered (quantity, quality). Process evaluation can also be used to assess generalizability and the effects of context on intervention outcomes.

4. Consolidated Framework for Implementation Research (CFIR) Website

   Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50. PMCID: PMC2736161.

   Summary: Many health-related interventions which are found to be effective in research studies fail to translate into meaningful improvements for patients when they are scaled up across diverse settings. Many implementation theories have been published to help promote effective implementation. When these theories are compared, they demonstrate both overlap and gaps. The Consolidated Framework for Implementation Research (CFIR) offers an overarching implementation

theory about what works where and why across multiple contexts. To identify the constructs in CFIR, the authors reviewed published theories of implementation of complex health interventions, and combined constructs across published theories that had different labels but were redundant or overlapping in definition, and parsed apart constructs that conflated underlying concepts. The CFIR is composed of five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation.

Example Uses: The CFIR provides a pragmatic structure for thinking about measurement of the complex, interacting, multi-level, and dynamic realities of implementation in the real world. While not specific to HIS implementation, many of the concepts in the CFIR framework are readily applicable to inquiry about HIS projects.

Unique aspects: A web-based tool offers resources for measurement of CFIR constructs. The items in the CFIR tool can be used within surveys or questionnaires when studying HIS implementation.

5. The MAPS toolkit: mhealth assessment and planning for scale. Geneva: World Health Organization; 2015.

Summary: The MAPS Toolkit is designed to help mHealth (mobile health) implementers to successfully and sustainably scale-up their innovations. Developed by the World Health Organization (WHO), in partnership with the United Nations Foundation and the Johns Hopkins University Global mHealth Initiative, the MAPS Toolkit is a self-assessment tool that guides mHealth projects through a continuous process of thorough assessment, careful planning, and targeted improvements. It lays out six overarching thematic areas for consideration and action planning for scaling up and sustaining mHealth deployments. These six areas are: Groundwork, Partnerships, Financial Health, Technology and Architecture, Operations, and Monitoring and Evaluation. Each of the six areas contains a self-administered questionnaire and scorecard that enable mHealth project teams to objectively measure their progress in relation to their vision for scaling up and ensuring sustainability. Each axes also includes tips and lessons from the field – all informed by the experiences of pioneering mHealth projects.

Example uses: The MAPS Toolkit outlines high-level considerations for planning Monitoring and Evaluation strategies for eHealth and mHealth projects.

Unique aspects: The scorecard on Monitoring and Evaluation addresses the availability of tools and processes for monitoring implementation, the allocation of resources to support evaluation, the definition of value claims to shape the evaluation goals, the availability of data sources, and the appropriate involvement of stakeholders, among other considerations.

6. Agency for Healthcare Research and Quality (AHRQ) Health IT Evaluation Toolkit

Cusack CM, Byrne C, Hook JM, McGowan J, Poon EG, Zafar A. Health Information Technology Evaluation Toolkit: 2009 Update (Prepared for the AHRQ National Resource Center for Health Information Technology under Contract No. 290-04-0016.) AHRQ Publication No. 09-0083-EF. Rockville, MD: Agency for Healthcare Research and Quality. June 2009.

Summary: The US Agency for Health Care Research and Quality (AHRQ) has created a planning guide for evaluation of health IT systems and projects, as well as a website with practical resources for evaluation of digital health interventions. The guide includes the following sections:

- Section I: This section gives an overview of the process of planning a HIS evaluation;
- Section II: This section gives examples of measures that can be used in HIS evaluations, such as clinical outcome measures, clinical process measures, and provider attitude measures. It provides methodologic notes on using each specific measure and provides links to further resources;
- Section III: This section presents examples of implementation projects with suggested evaluation methodologies for each. They include two barcode medication implementation projects, a telemedicine project, a computerized provider order entry (CPOE) implementation, and a picture archiving and communication systems (PACS) project.

The website also includes quick reference guides on topics such as measuring impact of health IT on nurses' time use, or measuring the frequency of alerts and reminders which result in direct action. The "Health IT Survey Compendium" portion of website includes an extensive compendium of surveys that have been used in HIS evaluation, which is searchable by survey type (i.e. focus group guide, interview guide, or questionnaire) and by domain of focus (e.g. functionality, satisfaction, usability).

Example uses: This survey instruments available in the "Health IT Survey Compendium" can be adapted for use in HIS evaluations in global settings.

Unique aspects: The AHRQ toolkit provides a wealth of guidance as well as links to exemplary studies and specific measurement tools. While the examples and resources are primarily drawn from US and Canadian settings, they are adaptable to resource-limited global settings.

7. Agarwal S, LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C, et al. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ. 2016;352:i1174. doi:10.1136/bmj.i1174.

Summary: A major obstacle to widespread adoption of mobile health (mHealth) innovations at scale has been the absence of guidelines from normative bodies. This is based in a lack of quality reporting to provide an evidence-base on mHealth work which is being done around the world. The mERA checklist seeks to standardize the reporting of mHealth findings and to promote the expansion of the evidence base by:

- supplementing existing reporting standards to provide a concrete checklist of criteria specific to reporting on digital innovations; and
- elaborating on the existing criteria to support high-quality methodological reporting of evidence.

The reporting checklist aims for better comparisons between research findings, and the ability to combine experiences across different settings to advocate for innovations which can improve patient experiences around the globe.

Example uses: mERA should be used at the study planning stage, as well as at the stage of reporting results.

Unique aspects: This checklist is similar in purpose to other sets of normative guidelines for publication, such as the CONSORT guidelines, but it is contextualized for mHealth.

8. Talmon J, Ammenwerth E, Brender J, de Keizer N, Nykanen P, Rigby M. STARE-HI—Statement on reporting of evaluation studies in Health Informatics. Int J Med Inform. 2009;78(1):1-9.

    Summary: This paper presents guidelines for publication of evaluation studies of Health Informatics applications. The STARE-HI principles cover topics to be addressed in papers describing evaluations of Health Informatics interventions. These principles include formulation of title and abstract, of introduction (e.g. scientific background, study objectives), study context (e.g. organizational setting, system details), methods (e.g. study design, outcome measures), results (e.g. study findings, unexpected observations) and discussion and conclusion of an IT evaluation paper. When manuscripts adhere to these aspects, readers will be better positioned to place the studies in a proper context and judge their validity and generalisability. The STARE-HI guidelines contribute to quality of published quantitative and qualitative evaluation studies in health informatics.
    Example uses: STARE-HI should be used at the study planning stage, as well as at the stage of reporting results.
    Unique aspects: This checklist is similar in purpose to other sets of normative guidelines for publication, such as the CONSORT guidelines, but it is contextualized for health informatics.

9. Labrique AB, Vasudevan L, Kochi E, Fabricant R, Mehl G. mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. Glob Health Sci Pract. 2013 Aug;1(2):160-71. doi:10.9745/GHSP-D-13-00031.

    Summary: mHealth and ICT Framework. Constructed around standard health system goals and places intended users and beneficiaries in central focus, against the context of the proposed mHealth service package. Two key components: 1. a place to depict the specifics of the mHealth intervention and 2. a visual depiction of mHealth implementation through the concept of "touch points" or points of contact. Define 12 common mHealth applications and the health system constraints they address—1. Client education and behavior change communication, 2. Sensors and point-of-care diagnostics, 3. Registries/vital events tracking, 4. Data collection and reporting, 5. Electronic health records, 6. Electronic decision support, 7. Provider-to -provider communication, 8. Provider work planning and scheduling, 9. Provider training and education, 10. Human resources management, 11. Supply chain management, 12. Financial transactions and incentives.
    Example use: Application of component parts of the framework within the RMNCH continuum, establishes "when" during the reproductive life cycle the mHealth project will focus. Identifies the beneficiary targets of the mHealth strategy, as well as the intended users of the system. Identifies which interventions the mHealth strategy will target.
    Unique aspects: Helps individual projects articulate their mHealth strategies and facilitates identification of gaps in innovation, solutions, and implementation activity.

Appendix 5E

Annotated Bibliography of Exemplary HIS Evaluation Studies

Global Health Information System Framework: Exemplary Studies

1. Amoroso CL, et al. Using electronic medical records for HIV care in rural Rwanda. Stud Health Technol Inform. 2010;160(Pt 1):337-341.

Abstract: Partners In Health (PIH) implemented an electronic medical record (EMR) system in Rwanda in 2005 to support and improve HIV and TB patient care. The system holds detailed patient records, accessible to clinicians through printed reports or directly via a computer in the consultation rooms. Ongoing assessment of data quality and clinical data use has led multiple interventions to be put in place. One such evaluation cycle led to the implementation of a system which identified 15 previously undiagnosed pediatric patients with HIV. Another cycle led to an EMR intervention which helped to decrease the proportion of completed critical CD4 lab results that did not reach clinicians by 34.2% (p = .002). Additionally an automated data quality improvement system reduced known errors by 92% by providing local data officers a tool and training to allow them to easily access and correct data errors. Electronic systems can be used to support care in rural resource-poor settings, and frequent assessment of data quality and clinical use of data can be used to support that goal.

Purpose of Evaluation	Document the process of identifying areas within the EMR program requiring improvement; describe the results of implementing interventions to improve the quality of patient data, and increase usage of the clinical data.
Type of Information System	EMR
Geographic Setting	Rwanda
Business Setting	Rural health centers
Stage of Life Cycle	Demonstration/initial deployment (middle)
Study Design	Descriptive cases study
Application of Quantitative Methods	EMR data quality metrics; comparison of laboratory registers and EMR data on CD4 results; usage audit metrics; counts of HIV-exposed children tested.
Application of Qualitative Methods	Process analysis
Method of Participant Selection	Convenience sample

Relevant Domains	Health; Business Process
Assessment of System Inputs	None noted
Assessment of Relevant Processes	System usage
Assessment of Outputs or Outcomes	Number of HIV-exposed children tested based on automated report, data quality, data availability.
Intent to Use Evaluation Results	Establishing a cycle of audit and quality improvement in the EMR program will allow for faster progress towards having the most effective and useful system possible.
Reference to Published Theories, Frameworks, or Tools	None noted
Key Conclusions	Cycles of user-guided improvement can lead to measureable improvement in clinical processes.
Notes	Demonstrates QI done in a systematic way.

2. Cho I, et al. Design and implementation of a standards-based interoperable clinical decision support architecture in the context of the Korean EHR. Int J Med Inform. 2010;79(9):611-622.

Abstract: BACKGROUND: In 2000 the Korean government initiated efforts to secure healthcare accessibility and efficiency anytime and anywhere via the nationwide healthcare information system by the end of 2010. According to the master plan, electronic health record (EHR) research and development projects were designed in 2005. One subproject was the design and implementation of standards-based interoperable clinical decision support (CDS) capabilities in the context of the EHR system. OBJECTIVE: The purpose of this study was to describe the challenges, process, and outcomes of defining and implementing a national CDS architecture to stimulate and motivate the widespread adoption of CDS services in Korea. METHODS: CDS requirements and design principles were established by conducting a selective literature review and a survey of clinicians, managers, and hospital and industrial health information technology engineers regarding issues related to CDS architectures. The previous relevant works of the American Medical Informatics Association, the Healthcare Information and Management Systems Society, and Health Level Seven were used to validate the scope and themes of the service architecture. The Arden Syntax, Standards-Based Sharable Active Guideline Environment, First DataBank, and SEBASTIAN approaches were used to assess the coverage of the application architecture thus defined. A CDS prototype of an outpatient hypertension management system was implemented and assessed in a simulated experimental setting to evaluate the feasibility of the proposed architecture. RESULTS: Four CDS service features were identified: knowledge application, knowledge management, audit and evaluation, and CDS and knowledge governance. Five core components of CDS application architecture were also identified: knowledge-execution component, knowledge-authoring component, data-interface component, knowledge repository, and service-interface component. The coverage and characteristics of the architecture identified herein were found to be comparable with those described previously. Two scenarios of deployment architecture were identified in the context of Korean healthcare. The preliminary feasibility test revealed that the architecture exhibited good performance and made it

easy to integrate patient data. **CONCLUSION**: We have described the efforts that have been made to realize CDS service features, core components, application, and deployment architectures in the context of the Korean EHR. These outcomes showed the potential to contribute to the adoption of CDS at the national level.

Purpose of Evaluation	Describe the challenges, process, and outcomes of defining and implementing a national CDS architecture to stimulate and motivate the widespread adoption of CDS services in Korea; specific goals; define CDS architecture for EHR; develop shareable and reusable knowledge base; and identify core components of a CDS module.
Type of Information System	CDS features of EHR
Geographic Setting	South Korea
Business Setting	Simulated experimental setting
Stage of Life Cycle	Design and development
Study Design	Experimental simulation
Application of Quantitative Methods	Surveyed symposium attendees to estimate knowledge and experience with CDS; experimental simulation measured concordance of physician recs with CDS recommendations.
Application of Qualitative Methods	Surveyed symposium attendees to gain understanding of expectations for CDS, open-ended elicitation of requirements.
Method of Participant Selection	None noted
Relevant Domains	Technology
Assessment of System Inputs	Needs assessment for CDS; identification of desirable features.
Assessment of Relevant Processes	None noted
Assessment of Outputs of Outcomes	CDS performance compared to physician judgment.
Intent to Use Evaluation Results	Template for development of CDS in Korean EHRs.
Reference to Published Theories, Frameworks, or Tools	None noted
Key Conclusions	CDS development often not tied to organizational goals; study produced specific recommendations for Korean context.
Notes	

3. Cho KW, et al. Diffusion of electronic medical record based public hospital information systems. Healthc Inform Res. 2015;21(3):175-183.

Abstract: **OBJECTIVES**: This study was conducted to evaluate the adoption behavior of a newly developed Electronic Medical Record (EMR)-based information system (IS) at three public hospitals in Korea with a focus on doctors and nurses. **METHODS**: User satisfaction scores from four performance layers were analyzed before and two times after the newly develop system was introduced to evaluate the adoption process of the IS with Rogers' diffusion theory. **RESULTS**: The 'intention to use' scores, the most important indicator for determining whether or not to adopt the IS in Rogers' confirmation stage for doctors, were very high in the third survey (4.21). In addition, the scores for 'reduced medication errors', which is the key indicator for evaluating the success of the IS, increased in the third survey for both doctors and nurses. The factors influencing 'intention to use' with a high odds ratio (>1.5) were the 'frequency of attendance of user training sessions', 'mandatory use of system', 'reduced medication errors', and 'reduced medical record documentation time' for both doctors and nurses. **CONCLUSIONS**: These findings show that the new EMR-based IS was well accepted by doctors. Both doctors and nurses also positively considered the effects of the new IS on their clinical environments.

Purpose of Evaluation	Evaluate the adoption behavior of a newly developed EMR-based IS at three public hospitals in Korea, with a focus on doctors and nurses.
Type of Information System	EMR
Geographic Setting	South Korea
Business Setting	Public hospitals
Stage of Life Cycle	Initial deployment
Study Design	Before-and-after comparison study
Application of Quantitative Methods	Likert-like scale of 1–5? For KPIs
Application of Qualitative Methods	None noted
Method of Participant Selection	Unspecified
Relevant Domains	Human, Technology, Economic, Business Process
Assessment of System Inputs	None noted
Assessment of Relevant Processes	System usage, information sharing, knowledge management, system management.
Assessment of Outputs of Outcomes	System quality, information quality, perceived ease of use, security and authentication, business process efficiency, business transaction quality, work performance of user.
Intent to Use Evaluation Results	Findings can be used to improve system for rollout to other hospital.
Reference to Published Theories, Frameworks, or Tools	Delone and McLean IS success model; Performance Reference Model (developed by the Office for Management of Budget in the US; input, process, business, performance, each with KPIs); Rogers diffusion of innovation theory.
Key Conclusions	The 'intention to use' scores were very high in final survey. In addition, the scores for 'reduced medication errors', which is

	the key indicator for evaluating the success of the IS, increased in the third survey for both doctors and nurses. The factors influencing 'intention to use' with a high odds ratio (>1.5) were the 'frequency of attendance of user training sessions', 'mandatory use of system', 'reduced medication errors', and 'reduced medical record documentation time' for both doctors and nurses.
Notes	None noted

4. Durrani H, et al. Health needs and eHealth readiness assessment of health care organizations in Kabul and Bamyan, Afghanistan. East Mediterr Health J. 2012;18(6):663-670.

Abstract: This study assessed the need and readiness of health care institutions in Kabul and Bamyan, Afghanistan for successful implementation of information and communication technology in health care (eHealth). A mixed methods design was adopted at 2 institutions in the Aga Khan Development Network in Afghanistan: the French Medical Institute for Children in Kabul and Bamyan Provincial Hospital, Bamyan. Information for the needs assessment was obtained from interviews and focus groups and eHealth readiness was assessed using a validated survey tool. The needs of institutions in the Aga Khan Development Network in Afghanistan were categorized as follows: provision of care needs; learning needs; and information management needs. eHealth readiness on average was lower in Bamyan compared with Kabul in all areas of the readiness assessment. Other institutions in Afghanistan may benefit from adopting the model of needs and readiness assessment used for Aga Khan Development Network institutions.

5. Gimbel S, et al. An assessment of routine primary care health information system data quality in Sofala Province, Mozambique. Popul Health Metr. 2011;9:12.

Abstract: BACKGROUND: Primary health care is recognized as a main driver of equitable health service delivery. For it to function optimally, routine health information systems (HIS) are necessary to ensure adequate provision of health care and the development of appropriate health policies. Concerns about the quality of routine administrative data have undermined their use in resource-limited settings. This evaluation was designed to describe the availability, reliability, and validity of a sample of primary health care HIS data from nine health facilities across three districts in Sofala Province, Mozambique. HIS data were also compared with results from large community-based surveys. **METHODOLOGY**: We used a methodology similar to the Global Fund to Fight AIDS, Tuberculosis and Malaria data verification bottom-up audit to assess primary health care HIS data availability and reliability. The quality of HIS data was validated by comparing three key indicators (antenatal care, institutional birth, and third diptheria, pertussis, and tetanus [DPT] immunization) with population-level surveys over time. **RESULTS AND DISCUSSION**: The data concordance from facility clinical registries to monthly facility reports on five key indicators—the number of first antenatal care visits, institutional births, third DPT immunization, HIV testing, and outpatient consults—was good (80%). When two sites were excluded from the analysis, the concordance was markedly better (92%). Of monthly facility reports for immunization and maternity services, 98%

were available in paper form at district health departments and 98% of immunization and maternity services monthly facility reports matched the Ministry of Health electronic database. Population-level health survey and HIS data were strongly correlated (R = 0.73), for institutional birth, first antenatal care visit, and third DPT immunization. **CONCLUSIONS**: Our results suggest that in this setting, HIS data are both reliable and consistent, supporting their use in primary health care program monitoring and evaluation. Simple, rapid tools can be used to evaluate routine data and facilitate the rapid identification of problem areas.

6. Gider Ö, et al. Evaluation of electronic prescription implications in Turkey: an investigation of the perceptions of physicians. Worldviews Evid Based Nurs. 2015;12(2):88-97.

Abstract: **BACKGROUND**: Electronic prescribing (e-prescribing) is an evolving area of healthcare information technology that aims to support physician decision-making by capturing, reviewing, and issuing medical prescriptions with high potential for improving the quality and safety of the process. **PURPOSE**: To describe physician perception of e-prescription use in healthcare organizations that work with social security and to evaluate their infrastructures for MEDULA (an information system for billing and other health informatics) in healthcare organizations in Turkey. **METHODS**: A cross-sectional survey design was used for this study. A convenience sample of physicians in eight general hospitals and in two oral and dental health centers of the Ministry of Health in Turkey were surveyed. **RESULTS**: Survey response rate was 47% (248/425). The majority of physicians (62%) support e-prescribing but have not used an electronic signature for prescriptions (78.2%). Almost half of them believe that e-prescriptions would positively contribute to patient safety (43%) **LINKING EVIDENCE TO ACTION**: Our study provides a first look at the perceptions of physicians regarding the implications of e-prescriptions, which became mandatory on January 15, 2013, in Turkey. Advocates of e-prescribing have suggested that additional efforts are needed to strengthen clinical decision systems. Physicians and nurses are better able to adopt e-prescribing systems and to view them positively if they recognize the limitations of paper-based prescribing and understand the utility of electronic systems in addressing some of these limitations. This study represents a starting point for government and related organizations to improve their knowledge on how well the implied benefits of e-prescriptions are realized in their acquisition, appraisal, and use in health policy decision-making and health systems.

7. Hahn D, et al. Where is information quality lost at clinical level? A mixed-method study on information systems and data quality in three urban Kenyan ANC clinics. Glob Health Action. 2013;6(1):21424.

Abstract: **BACKGROUND**: Well-working health information systems are considered vital with the quality of health data ranked of highest importance for decision making at patient care and policy levels. In particular, health facilities play an important role, since they are not only the entry point for the national health information system but also use health data (and primarily) for patient care. **DESIGN**: A multiple case study was carried out between March and August 2012 at the antenatal care (ANC) clinics of two private and one public Kenyan hospital to describe clinical information systems and assess the quality of information. The following methods were developed and employed in an iterative process: workplace walkthroughs, structured and in-depth interviews with

staff members, and a quantitative assessment of data quality (completeness and accurate transmission of clinical information and reports in ANC). Views of staff and management on the quality of employed information systems, data quality, and influencing factors were captured qualitatively. **RESULTS**: Staff rated the quality of information higher in the private hospitals employing computers than in the public hospital, which relies on paper forms. Several potential threats to data quality were reported. Limitations in data quality were common at all study sites including wrong test results, missing registers, and inconsistencies in reports. Feedback was seldom on content or quality of reports and usage of data beyond individual patient care was low. **CONCLUSIONS**: We argue that the limited data quality has to be seen in the broader perspective of the information systems in which it is produced and used. The combination of different methods has proven to be useful for this. To improve the effectiveness and capabilities of these systems, combined measures are needed which include technical and organizational aspects (e.g., regular feedback to health workers) and individual skills and motivation.

8. Hochgesang M, et al. [Scaling-up health information systems to improve HIV treatment: An assessment of initial patient monitoring systems in Mozambique](). Int J Med Inform. 2017;97:322-330.

Abstract: **INTRODUCTION**: The rapid scale-up of HIV care and treatment in resource-limited countries requires concurrent, rapid development of health information systems to support quality service delivery. Mozambique, a country with an 11.5% prevalence of HIV, has developed nation-wide patient monitoring systems (PMS) with standardized reporting tools, utilized by all HIV treatment providers in paper or electronic form. Evaluation of the initial implementation of PMS can inform and strengthen future development as the country moves towards a harmonized, sustainable health information system. **OBJECTIVE**: This assessment was conducted in order to 1) characterize data collection and reporting processes and PMS resources available and 2) provide evidence-based recommendations for harmonization and sustainability of PMS. **METHODS**: This baseline assessment of PMS was conducted with eight non-governmental organizations that supported the Ministry of Health to provide 90% of HIV care and treatment in Mozambique. The study team conducted structured and semi-structured surveys at 18 health facilities located in all 11 provinces. Seventy-nine staff were interviewed. Deductive a priori analytic categories guided analysis. **RESULTS**: Health facilities have implemented paper and electronic monitoring systems with varying success. Where in use, robust electronic PMS facilitate facility-level reporting of required indicators; improve ability to identify patients lost to follow-up; and support facility and patient management. Challenges to implementation of monitoring systems include a lack of national guidelines and norms for patient level HIS, variable system implementation and functionality, and limited human and infrastructure resources to maximize system functionality and information use. **CONCLUSIONS**: This initial assessment supports the need for national guidelines to harmonize, expand, and strengthen HIV-related health information systems. Recommendations may benefit other countries with similar epidemiologic and resource-constrained environments seeking to improve PMS implementation.

9. Kang'a S, et al. A national standards-based assessment on functionality of electronic medical records systems used in Kenyan public-sector health facilities. Int J Med Inform. 2017;97:68-75.

Abstract: **BACKGROUND**: Variations in the functionality, content and form of electronic medical record systems (EMRs) challenge national roll-out of these systems as part of a national strategy to monitor HIV response. To enforce the EMRs minimum requirements for delivery of quality HIV services, the Kenya Ministry of Health (MoH) developed EMRs standards and guidelines. The standards guided the recommendation of EMRs that met a preset threshold for national roll-out. **METHODS**: Using a standards-based checklist, six review teams formed by the MoH EMRs Technical Working Group rated a total of 17 unique EMRs in 28 heath facilities selected by individual owners for their optimal EMR implementation. EMRs with an aggregate score of >/=60% against checklist criteria were identified by the MoH as suitable for upgrading and rollout to Kenyan public health facilities. **RESULTS**: In Kenya, existing EMRs scored highly in health information and reporting (mean score=71.8%), followed by security, system features, core clinical information, and order entry criteria (mean score=58.1%-55.9%), and lowest against clinical decision support (mean score=17.6%) and interoperability criteria (mean score=14.3%). Four EMRs met the 60.0% threshold: OpenMRS, IQ-Care, C-PAD and Funsoft. On the basis of the review, the MoH provided EMRs upgrade plans to owners of all the 17 systems reviewed. **CONCLUSION**: The standards-based review in Kenya represents an effort to determine level of conformance to the EMRs standards and prioritize EMRs for enhancement and rollout. The results support concentrated use of resources towards development of the four recommended EMRs. Further review should be conducted to determine the effect of the EMR-specific upgrade plans on the other 13 EMRs that participated in the review exercise.

10. Kihuba E, et al. Assessing the ability of health information systems in hospitals to support evidence-informed decisions in Kenya. Glob Health Action. 2014;7:24859.

Abstract: BACKGROUND: Hospital management information systems (HMIS) is a key component of national health information systems (HIS), and actions required of hospital management to support information generation in Kenya are articulated in specific policy documents. We conducted an evaluation of core functions of data generation and reporting within hospitals in Kenya to facilitate interpretation of national reports and to provide guidance on key areas requiring improvement to support data use in decision making. **DESIGN**: The survey was a cross-sectional, cluster sample study conducted in 22 hospitals in Kenya. The statistical analysis was descriptive with adjustment for clustering. **RESULTS**: Most of the HMIS departments complied with formal guidance to develop departmental plans. However, only a few (3/22) had carried out a data quality audit in the 12 months prior to the survey. On average 3% (range 1-8%) of the total hospital income was allocated to the HMIS departments. About half of the records officer positions were filled and about half (13/22) of hospitals had implemented some form of electronic health record largely focused on improving patient billing and not linked to the district HIS. Completeness of manual patient registers varied, being 90% (95% CI 80.1-99.3%), 75.8% (95% CI 68.7-82.8%), and 58% (95% CI 50.4-65.1%) in maternal child health clinic, maternity, and pediatric wards, respectively. Vital events notification rates were low with 25.7, 42.6, and 71.3% of neonatal deaths, infant deaths, and live births

recorded, respectively. Routine hospital reports suggested slight over-reporting of live births and under-reporting of fresh stillbirths and neonatal deaths. **CONCLUSIONS**: Study findings indicate that the HMIS does not deliver quality data. Significant constraints exist in data quality assurance, supervisory support, data infrastructure in respect to information and communications technology application, human resources, financial resources, and integration.

11. Landis-Lewis Z, et al. Barriers to using eHealth data for clinical performance feedback in Malawi: A case study. Int J Med Inform. 2015;84(10):868-875.

Abstract: **INTRODUCTION**: Sub-optimal performance of healthcare providers in low-income countries is a critical and persistent global problem. The use of electronic health information technology (eHealth) in these settings is creating large-scale opportunities to automate performance measurement and provision of feedback to individual healthcare providers, to support clinical learning and behavior change. An electronic medical record system (EMR) deployed in 66 antiretroviral therapy clinics in Malawi collects data that supervisors use to provide quarterly, clinic-level performance feedback. Understanding barriers to provision of eHealth-based performance feedback for individual healthcare providers in this setting could present a relatively low-cost opportunity to significantly improve the quality of care. **OBJECTIVE**: The aims of this study were to identify and describe barriers to using EMR data for individualized audit and feedback for healthcare providers in Malawi and to consider how to design technology to overcome these barriers. **METHODS**: We conducted a qualitative study using interviews, observations, and informant feedback in eight public hospitals in Malawi where an EMR system is used. We interviewed 32 healthcare providers and conducted seven hours of observation of system use. **RESULTS**: We identified four key barriers to the use of EMR data for clinical performance feedback: provider rotations, disruptions to care processes, user acceptance of eHealth, and performance indicator lifespan. Each of these factors varied across sites and affected the quality of EMR data that could be used for the purpose of generating performance feedback for individual healthcare providers. **CONCLUSION**: Using routinely collected eHealth data to generate individualized performance feedback shows potential at large-scale for improving clinical performance in low-resource settings. However, technology used for this purpose must accommodate ongoing changes in barriers to eHealth data use. Understanding the clinical setting as a complex adaptive system (CAS) may enable designers of technology to effectively model change processes to mitigate these barriers.

12. Ma S, et al. Effectiveness of implementation of electronic malaria information system as the national malaria surveillance system in Thailand. JMIR Public Health Surveill. 2016;2(1):e20.

Abstract: **BACKGROUND**: In moving toward malaria elimination, one strategy is to implement an active surveillance system for effective case management. Thailand has developed and implemented the electronic Malaria Information System (eMIS) capturing individualized electronic records of suspected or confirmed malaria cases. **OBJECTIVE**: The main purpose of this study was to determine how well the eMIS improves the quality of Thailand's malaria surveillance system. In particular, the focus of the study was to evaluate the effectiveness of the eMIS in terms of the system users' perception and the system outcomes (i.e., quality of data) regarding the management of malaria patients. **METHODS**: A mixed-methods technique was used with the framework based on

system effectiveness attributes: data quality, timeliness, simplicity, acceptability, flexibility, stability, and usefulness. Three methods were utilized: data records review, survey of system users, and in-depth interviews with key stakeholders. From the two highest endemic provinces, paper forms matching electronic records of 4455 noninfected and 784 malaria-infected cases were reviewed. Web-based anonymous questionnaires were distributed to all 129 eMIS data entry staff throughout Thailand, and semistructured interviews were conducted with 12 management-level officers. **RESULTS**: The eMIS is well accepted by system users at both management and operational levels. The data quality has enabled malaria personnel to perform more effective prevention and control activities. There is evidence of practices resulting in inconsistencies and logical errors in data reporting. Critical data elements were mostly completed, except for a few related to certain dates and area classifications. Timeliness in reporting a case to the system was acceptable with a delay of 3–4 days. The evaluation of quantitative and qualitative data confirmed that the eMIS has high levels of simplicity, acceptability, stability, and flexibility. **CONCLUSIONS**: Overall, the system implemented has achieved its objective. The results of the study suggested that the eMIS helps improve the quality of Thailand's malaria surveillance system. As the national malaria surveillance system, the eMIS's functionalities have provided the malaria staff working at the point of care with close-to-real-time case management data quality, covering case detection, case investigation, drug compliance, and follow-up visits. Such features has led to an improvement in the quality of the malaria control program; the government officials now have quicker access to both individual and aggregated data to promptly react to possible outbreak. The eMIS thus plays one of the key roles in moving toward the national goal of malaria elimination by the next decade.

13. Ndira SP, et al. [Assessment of data quality of and staff satisfaction with an electronic health record system in a developing country (Uganda): a qualitative and quantitative comparative study](#). Methods Inf Med. 2008;47(6):489-498.

Abstract: **OBJECTIVES**: To assess if electronic health record systems in developing countries can improve on timeliness, availability and accuracy of routine health reports and staff satisfaction after introducing the electronic system, compared to the paper-based alternative. **METHODS**: The research was conducted with hospital staff of Tororo District Hospital in Uganda. A comparative intervention study with qualitative and quantitative methods was used to compare the paper-based (pre-test) to the electronic system (post-test) focusing on accuracy, availability and timeliness of monthly routine reports about mothers visiting the hospital; and staff satisfaction with the electronic system as outcome measures. **RESULTS**: Timeliness: pre-test 13 of 19 months delivered to the district timely, delivery dates for six months could not be established; post-test 100%. **AVAILABILITY**: pre-test 79% of reports were present at the district health office; post-test 100%. Accuracy: pre-test 73.2% of selected reports could be independently confirmed as correct; post-test 71.2%. Difficulties were encountered in finding enough mothers through direct follow up to inquire on accuracy of information recorded about them. Staff interviews showed that the electronic system is appreciated by the majority of the hospital staff. Remaining obstacles include staff workload, power shortages, network breakdowns and parallel data entry (paper-based and electronic). **CONCLUSION**: While timeliness and availability improved, improvement of accuracy could not be established. Better approaches to ascertaining accuracy have to be devised, e.g.,

evaluation of intended use. For success, organizational, managerial, and social challenges must be addressed beyond technical aspects.

14. Nicol E, et al. Human factors affecting the quality of routinely collected data in South Africa. Stud Health Technol Inform. 2013;192:788-792.

Abstract: Evaluations that have looked at the people aspect of the health information system in South Africa have only focused on the availability of human resources and not on competence or other behavioural factors. Using the Performance of Routine Information System Management (PRISM) tool that assumes relationships between technical, behavioural and organizational determinants of the routine information processes and performance, this paper highlights some behavioural factors affecting the quality of routinely collected data in South Africa. In the context of monitoring maternal and child health programmes, data were collected from 161 health information personnel in 58 health facilities and 2 district offices from 2 conveniently sampled health districts. A self-administered questionnaire was used to assess confidence and competence levels of routine health information system (RHIS) tasks, problem solving anddata quality checking skills, and motivation. The findings suggest that 64% of the respondents have poor numerical skills and limited statistical and data quality checking skills. While the average confidence levels at performing RHIS tasks is 69%, only 22% actually displayed competence above 50%. Personnel appear to be reasonably motivated but there is considerable deficiency in their competency to interpret and use data. This may undermine the quality and utility of the RHIS.

15. Nicol E, et al. Assessing the quality of routine data for the prevention of mother-to-child transmission of HIV: An analytical observational study in two health districts with high HIV prevalence in South Africa. Int J Med Inform. 2016;95:60-70.

Abstract: **BACKGROUND**: The prevention of mother-to-child transmission of HIV (PMTCT) is a key maternal and child-health intervention in the context of the HIV/AIDS pandemic in South Africa. Accordingly, the PMTCT programmes have been incorporated in the routine District Health Management Information System (DHMIS) which collects monthly facility-based data to support the management of public-health services. To date, there has been no comprehensive evaluation of the PMTCT information system. **OBJECTIVES**: This study seeks to evaluate the quality of output indicators for monitoring PMTCT interventions in two health districts with high HIV prevalence. METHODS: An analytical observational study was undertaken based on the Performance of Routine Information System Management (PRISM) framework and tools, including an assessment of the routine PMTCT data for quality in terms of accuracy and completeness. Data were collected from 57 public health facilities for six pre-defined PMTCT data elements by comparing the source registers with the routine monthly report (RMR), and the RMR with the DMHIS for January and April 2012. This was supplemented by the analysis of the monthly data reported routinely in the DMHIS for the period 2009-2012. Descriptive statistics, analysis of variance (ANOVA) and Bland Altman analysis were conducted using STATA(R) Version 13. **RESULTS**: Although completeness was relatively high at 91% (95% CI: 78-100%) at facility level and 96% (95% CI: 92-100%) at district level, the study revealed considerable data quality concerns for the PMTCT information with an average accuracy between the register and RMR of 51% (95% CI: 44-58%) and between the RMR and DHMIS database

of 84% (95% CI: 78-91%). We observed differences in the data accuracy by organisational authority. The poor quality of the data was attributed partly to insufficient competencies of health information personnel. **CONCLUSIONS**: The study suggests that the primary point of departure for accurate data transfer is during the collation process. Institutional capacity to improve data quality at the facility level and ensure core competencies for routine health information system (RHIS)-related tasks are needed. Further exploration of the possible factors that may influence data accuracy, such as supervision, RHIS processes, training and leadership are needed. In particular understanding is needed about how individual actions can bring about changes in institutional routines.

16. Oluoch T, et al. [Better adherence to pre-antiretroviral therapy guidelines after implementing an electronic medical record system in rural Kenyan HIV clinics: a multicenter pre-post study](). Int J Infect Dis. 2015;33:109-113.

Abstract: **INTRODUCTION**: The monitoring of pre-antiretroviral therapy (pre-ART) is a key indicator of HIV quality of care. This study investigated the association of an electronic medical record system (EMR) with adherence to pre-ART guidelines in rural HIV clinics in Kenya. **METHODS**: A retrospective study was carried out to assess the quality of pre-ART care using three indicators: (1) the performance of a baseline CD4 test, (2) time from enrollment in care to first CD4 test, and (3) time from baseline CD4 to second CD4 test. A comparison of these indicators was made pre and post the introduction of an EMR system in 17 rural HIV clinics. **RESULTS**: A total of 18523 patients were receiving pre-ART care, of whom 38.8% in the paper group had had at least one CD4 test compared to 53.4% in the EMR group (p<0.001). The adjusted odds of performing a CD4 test in clinics using an EMR was 1.59 (95% confidence interval 1.49–1.69). The median time from enrolment into HIV care to first CD4 test was 1.40 months (interquartile range (IQR) 0.47–4.87) for paper vs. 0.93 months (IQR 0.43–3.37) for EMR. The median time from baseline to first CD4 follow-up was 7.5 months (IQR 5.97–10.73) for paper and 6.53 months (IQR 5.57–7.87) for EMR. **CONCLUSION**: The use of the EMR system was associated with better compliance to HIV guidelines for pre-ART care. EMRs have a potential positive impact on quality of care for HIV patients in resource-constrained settings.

17. Puttkammer N, et al. [An assessment of data quality in a multi-site electronic medical record system in Haiti](). Int J Med Inform. 2016;86:104-116.

Abstract: **OBJECTIVES**: Strong data quality (DQ) is a precursor to strong data use. In resource limited settings, routine DQ assessment (DQA) within electronic medical record (EMR) systems can be resource-intensive using manual methods such as audit and chart review; automated queries offer an efficient alternative. This DQA focused on Haiti's national EMR—iSante—and included longitudinal data for over 100,000 persons living with HIV (PLHIV) enrolled in HIV care and treatment services at 95 health care facilities (HCF). **METHODS**: This mixed-methods evaluation used a qualitative Delphi process to identify DQ priorities among local stakeholders, followed by a quantitative DQA on these priority areas. The quantitative DQA examined 13 indicators of completeness, accuracy, and timeliness of retrospective data collected from 2005 to 2013. We described levels of DQ for each indicator over time, and examined the consistency of within-HCF performance and associations between DQ and HCF and EMR system characteristics. **RESULTS**: Over all iSante data, age was incomplete in <1% of cases, while height, pregnancy status, TB status, and

ART eligibility were more incomplete (approximately 20–40%). Suspicious data flags were present for <3% of cases of male sex, ART dispenses, CD4 values, and visit dates, but for 26% of cases of age. Discontinuation forms were available for about half of all patients without visits for 180 or more days, and >60% of encounter forms were entered late. For most indicators, DQ tended to improve over time. DQ was highly variable across HCF, and within HCFs DQ was variable across indicators. In adjusted analyses, HCF and system factors with generally favorable and statistically significant associations with DQ were University hospital category, private sector governance, presence of local iSante server, greater HCF experience with the EMR, greater maturity of the EMR itself, and having more system users but fewer new users. In qualitative feedback, local stakeholders emphasized lack of stable power supply as a key challenge to data quality and use of the iSante EMR. **CONCLUSIONS**: Variable performance on key DQ indicators across HCF suggests that excellent DQ is achievable in Haiti, but further effort is needed to systematize and routinize DQ approaches within HCFs. A dynamic, interactive "DQ dashboard" within iSante could bring transparency and motivate improvement. While the results of the study are specific to Haiti's iSante data system, the study's methods and thematic lessons learned holdgeneralized relevance for other large-scale EMR systems in resource-limited countries.

18. Saleh S, et al. Readiness of healthcare providers for eHealth: the case from primary healthcare centers in Lebanon. BMC Health Serv Res. 2016;16(1):644.

Abstract: **BACKGROUND**: eHealth can positively impact the efficiency and quality of healthcare services. Its potential benefits extend to the patient, healthcare provider, and organization. Primary healthcare (PHC) settings may particularly benefit from eHealth. In these settings, healthcare provider readiness is key to successful eHealth implementation. Accordingly, it is necessary to explore the potential readiness of providers to use eHealth tools. Therefore, the purpose of this study was to assess the readiness of healthcare providers working in PHC centers in Lebanon to use eHealth tools. **METHODS**: A self-administered questionnaire was used to assess participants' socio-demographics, computer use, literacy, and access, and participants' readiness for eHealth implementation (appropriateness, management support, change efficacy, personal beneficence). The study included primary healthcare providers (physicians, nurses, other providers) working in 22 PHC centers distributed across Lebanon. Descriptive and bivariate analyses (ANOVA, independent t-test, Kruskal Wallis, Tamhane's T2) were used to compare participant characteristics to the level of readiness for the implementation of eHealth. **RESULTS**: Of the 541 questionnaires, 213 were completed (response rate: 39.4 %). The majority of participants were physicians (46.9 %), and nurses (26.8 %). Most physicians (54.0 %), nurses (61.4 %), and other providers (50.9 %) felt comfortable using computers, and had access to computers at their PHC center (physicians: 77.0 %, nurses: 87.7 %, others: 92.5 %). Frequency of computer use varied. The study found a significant difference for personal beneficence, management support, and change efficacy among different healthcare providers, and relative to participants' level of comfort using computers. There was a significant difference by level of comfort using computers and appropriateness. A significant difference was also found between those with access to computers in relation to personal beneficence and change efficacy; and between frequency of computer use and change efficacy. **CONCLUSION**: The implementation of eHealth cannot be achieved without the readiness of healthcare providers. This study demonstrates that the majority of healthcare providers at PHC centers across Lebanon are

ready for eHealth implementation. The findings of this study can be considered by decision makers to enhance and scale-up the use of eHealth in PHC centers nationally. Efforts should be directed towards capacity building for healthcare providers.

19. Tilahun B, Fritz F. Comprehensive evaluation of electronic medical record system use and user satisfaction at five low-resource setting hospitals in Ethiopia. JMIR Med Inform. 2015;3(2):e22.

Abstract: **BACKGROUND**: Electronic medical record (EMR) systems are increasingly being implemented in hospitals of developing countries to improve patient care and clinical service. However, only limited evaluation studies are available concerning the level of adoption and determinant factors of success in those settings. **OBJECTIVE**: The objective of this study was to assess the usage pattern, user satisfaction level, and determinants of health professional's satisfaction towards a comprehensive EMR system implemented in Ethiopia where parallel documentation using the EMR and the paper-based medical records is in practice. **METHODS**: A quantitative, cross-sectional study design was used to assess the usage pattern, user satisfaction level, and determinant factors of an EMR system implemented in Ethiopia based on the DeLone and McLean model of information system success. Descriptive statistical methods were applied to analyze the data and a binary logistic regression model was used to identify determinant factors. **RESULTS**: Health professionals (N=422) from five hospitals were approached and 406 responded to the survey (96.2% response rate). Out of the respondents, 76.1% (309/406) started to use the system immediately after implementation and user training, but only 31.7% (98/309) of the professionals reported using the EMR during the study (after 3 years of implementation). Of the 12 core EMR functions, 3 were never used by most respondents, and they were also unaware of 4 of the core EMR functions. It was found that 61.4% (190/309) of the health professionals reported over all dissatisfaction with the EMR (median=4, interquartile range (IQR)=1) on a 5-level Likert scale. Physicians were more dissatisfied (median=5, IQR=1) when compared to nurses (median=4, IQR=1) and the health management information system (HMIS) staff (median=2, IQR=1). Of all the participants, 64.4% (199/309) believed that the EMR had no positive impact on the quality of care. The participants indicated an agreement with the system and information quality (median=2, IQR=0.5) but strongly disagreed with the service quality (median=5, IQR=1). The logistic regression showed a strong correlation between system use and dissatisfaction (OR 7.99, 95% CI 5.62-9.10) and service quality and satisfaction (OR 8.23, 95% CI 3.23-17.01). **CONCLUSIONS**: Health professionals' use of the EMR is low and they are generally dissatisfied with the service of the implemented system. The results of this study show that this dissatisfaction is caused mainly and strongly by the poor service quality, the current practice of double documentation (EMR and paper-based), and partial departmental use of the system in the hospitals. Thus, future interventions to improve the current use or future deployment projects should focus on improving the service quality such as power infrastructure, user support, trainings, and more computers in the wards. After service quality improvement, other departments (especially inter-dependent departments) should be motivated and supported to use the EMR to avoid the dependency deadlock.

20. Were MC, et al. Creation and evaluation of EMR-based paper clinical summaries to support HIV-care in Uganda, Africa. Int J Med Inform. 2010;79(2):90-96.

Abstract: **PURPOSE**: Getting the right information to providers can improve quality of care. We set out to provide patient-specific Electronic Medical Record (EMR)-based clinical summaries for providers taking care of HIV-positive adult patients in the resource-limited setting of Mbarara, Uganda. **METHODS**: We evaluated the impact of implementing these clinical summaries using time-motion techniques and provider surveys. **RESULTS**: After implementation of EMR-based clinical summaries, providers spent more time in direct care of patients (2.9 min vs. 2.3 min, p<0.001), and the length of patient visits was reduced by 11.5 min. Survey respondents indicated that clinical summaries improved care, reduced mistakes, and were generally accurate. Current antiretroviral medication, patient identifying information, adherence information, current medication, and current medical problems were among the highest-rated elements of the summary. **CONCLUSIONS**: By taking advantage of data stored in EMRs, efficiency and quality of care can be improved through clinical summaries, even in settings with limited resources.

21. Xu W, et al. [Analysis and evaluation of the electronic health record standard in China: a comparison with the American national standard ASTM E 1384](#). Int J Med Inform. 2011;80(8):555-561.

Abstract: **OBJECTIVE**: To analyze and evaluate the newly issued Electronic Health Record (EHR) Architecture and Data Standard of China (Chinese EHR Standard) and identify areas of improvement for future revisions. **DESIGN**: We compared the Chinese EHR Standard with the standard of the American Society for Testing and Materials Standard Practice for Content and Structure of Electronic Health Records in the United States (ASTM E 1384 Standard). METHODS: The comparison comprised two steps: (1) comparing the conformance of the two standards to the international standard: Health Informatics-Requirements for an Electronic Health Record Architecture (ISO/TS 18308), and showing how the architectures of the two standards satisfy or deviate from the ISO requirements and (2) comparing the detailed data structures between the two standards. **RESULTS**: Of the 124 requirement items in ISO/TS 18308, the Chinese EHR Standard and the ASTM E 1384 Standard conformed to 77 (62.1%) and 111 (89.5%), respectively. The Chinese EHR Standard conformed to 34 of 50 Structure requirements (68.0%), 22 of 24 Process requirements (91.7%), and 21 of 50 Other requirements (42.0%). The ASTM E 1384 Standard conformed to 49 of 50 Structure requirements (98.0%), 23 of 24 Process requirements (95.8%), and 39 of 40 Other requirements (78.0%). **CONCLUSIONS**: Further development of the Chinese EHR Standard should focus on supporting privacy and security mechanism, diverse data types, more generic and extensible lower level data structures, and relational attributes for data elements.

22. Yourkavitch J, et al. [How do we know? An assessment of integrated community case management data quality in four districts of Malawi](#). Health Policy Plan. 2016;31(9):1162-1171.

Abstract: The World Health Organization contracted annual data quality assessments of Rapid Access Expansion (RAcE) projects to review integrated community case management (iCCM) data quality and the monitoring and evaluation (M&E) system for iCCM, and to suggest ways to improve data quality. The first RAcE data quality assessment was conducted in Malawi in January 2014 and we present findings pertaining to data from the health management information system at the

community, facility and other sub-national levels because RAcE grantees rely on that for most of their monitoring data. We randomly selected 10 health facilities (10% of eligible facilities) from the four RAcE project districts, and collected quantitative data with an adapted and comprehensive tool that included an assessment of Malawi's M&E system for iCCM data and a data verification exercise that traced selected indicators through the reporting system. We rated the iCCM M&E system across five function areas based on interviews and observations, and calculated verification ratios for each data reporting level. We also conducted key informant interviews with Health Surveillance Assistants and facility, district and central Ministry of Health staff. Scores show a high-functioning M&E system for iCCM with some deficiencies in data management processes. The system lacks quality controls, including data entry verification, a protocol for addressing errors, and written procedures for data collection, entry, analysis and management. Data availability was generally high except for supervision data. The data verification process identified gaps in completeness and consistency, particularly in Health Surveillance Assistants' record keeping. Staff at all levels would like more training in data management. This data quality assessment illuminates where an otherwise strong M&E system for iCCM fails to ensure some aspects of data quality. Prioritizing data management with documented protocols, additional training and approaches to create efficient supervision practices may improve iCCM data quality.