Transitioning from paper to digital vaccination records: integration into clinic workflows, time utilization following workflow modifications, and impact on the timeliness of vaccinations

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Abstract

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Digital health interventions (DHI) have the potential to improve the management and utilization of health information to optimize healthcare worker performance and provision of care. Especially in Africa, where 25% of children remain un- or under-immunized, technologies that can help identify children due for a vaccination are particularly important for improving vaccination coverage. Low- and middle-income countries (LMICs) are beginning to introduce electronic immunization registries (EIRs) into their routine immunization services to better capture and store childhood vaccination information. Despite the increased introduction of EIRs in LMICs, few have been institutionalized at scale or evaluated to understand their impact on health systems and health-related outcomes. An improved understanding of the usability and effectiveness of these systems is needed to inform strategies for developing, deploying, and sustaining EIRs. We used qualitative data from semi-structured interviews with healthcare workers, time-and-motion observations of user workflows, and EIR data to study the effects of introducing an EIR on healthcare workers and vaccination-outcomes. The specific dissertation aims included: 1) describing the integration of an EIR into immunization clinic workflows in Kenya using realist methodology; 2) comparing time utilization of modified user workflows among immunization clinics in Kenya using an EIR; and, 3) assessing changes in on-time vaccination following the introduction of an EIR in Tanzania. We found that although EIRs were well accepted by users, there was often misalignment in goals and workflows between the system and reality which created challenges to EIR-use, increasing the time spent on data management activities, and ultimately, reducing the quality of EIR records, making them inadequate for measuring health-related outcomes at the population-level. Our research provided evidence on the importance of designing and deploying EIRs that closely align with user-workflows to increase the potential added value of these systems for improving provision of healthcare services and immunization coverage.

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Chapter 1: Introduction

BACKGROUND

Immunization programs strive to ensure that every child within their target population is adequately protected from vaccine preventable diseases (VPDs). Improving vaccination coverage is a multifactorial effort that requires keen insights and oversight of both the target population and health system. Accurate coverage data are needed by immunization clinic staff, program supervisors and managers, and national policy makers to identify un- and under-immunized children and to track progress towards immunization coverage goals [1,2]. Many immunization programs are challenged by inaccurate, untimely, and unspecific data for calculating vaccination coverage at national and sub-national levels [1-4]. Historically common administrative data sources in sub-Saharan Africa low-and middle-income countries (LMICs) have been paper-based immunization registries and tally sheets, aggregate monthly summaries, and home-based records; the paper-based monthly summaries are often entered into an electronic database for reporting of aggregated health system data, such as DHIS2[5]. This process of data entry often leads to data quality issues due to recording errors, redundant entries, and poor completeness and timeliness of reporting preventing immunization programs from making well-informed decisions that could help increase vaccination coverage [6,11,12].

Digital health interventions (DHIs) have become more prolific across health programs in LMICs in recent years[6]. Drivers for adopting DHI, particularly mobile technologies, include their wide acceptance, easy use, and large reach across populations [7]. As technology has become cheaper and more accessible, health programs are adopting DHI to improve the provision of and demand for health services. These interventions have substantial potential to alter how health information is managed and utilized to improve patient care and treatment, as well as data quality. The World Health Assembly recognized the importance of digital technologies to support health systems in 2018 and urged member states to assess and consider how DHIs could be optimized and integrated into existing health systems [7]. However, despite the increased availability of technology, in LMICs there has not been a corresponding increase in DHIs taken to regional or national scale, as many projects never move past the “proof-of-concept” phase and may have simply been deployed to demonstrate feasibility or were not built to sustain increasing patient volumes [8, 9].

Historically, few projects have reached scale due to lack of planning for resources or processes needed to scale-up, lack of interconnectedness between systems, lack of coordination between DHI projects, and lack of local technical capacity and multi-sectoral engagement [8]. Despite the increased deployment and use of DHIs, there have been few rigorous studies on the implementation, sustainability, and effectiveness of these interventions [7, 8]. Implementation science methods have become more relevant to the study of DHIs as more traditional, clinically-based research designs have been found to have limited applications for studying the integration and use of DHIs within existing systems [10, 11].

Electronic immunization registries (EIRs) routinely capture, store, and share patient-level, longitudinal health information in digitized records, allowing for improved data availability, quality, and accessibility [12, 13]. These DHI systems can improve immunization data quality by collecting more complete and accurate data through validation rules and warning prompts. These tools allow for more efficient capture and use of routinely reported individual level data as they enable vaccination data to be collected in a standardized, searchable format, so they can be assessed and aggregated in real-time. The use of DHIs amongst immunization programs has been promising for encouraging the uptake and adherence to routine vaccination schedules amongst children, however, more evidence is needed on their integration within existing healthcare settings and impact on health-related outcomes [14, 15].

This dissertation responds to the global call for more research on DHIs that evaluate effectiveness, costs, the enabling ecosystem, sustainability, effective pathways for data use, human transaction costs, and unintended consequences [8, 13, 16].

SPECIFIC AIMS

In chapter two of the dissertation, we describe the facilitators and barriers to EIR-usability in Kenya for a dual data-entry workflow, where both paper-records and the EIR are maintained simultaneously at the point-of-care. We use a realist evaluation to develop a middle-range theory to describe the underlying mechanisms of EIR-usability based on findings from semi-structured interviews and workflow observations. We use the middle-range theory to develop rules that future DHI implementers can follow to deploy systems that are well designed for users and improve the alignment between the system and reality.

In chapter three we compare time utilization following the introduction of workflow modifications in an effort to improve time efficiency. We used information collected from a time and motion study of EIR users in Kenya to assess the amount of time needed to provide services to children seen in the immunization clinic, identify how time utilization differed by facility size and length of experience using the EIR, and suggest workflow and EIR modifications needed to produce the largest time-savings.

To assess the impact of an EIR on vaccination timeliness, in chapter four we conduct an uncontrolled interrupted time-series analysis using EIR data from Tanzania. We hypothesized that the introduction of the EIR would lead to statistically significant changes in vaccination timeliness at 3, 6, and >6 months post-introduction. We highlight the complexities of using digitized individual-level routine health information system data for evaluation and research purposes.

Our results provide insights about the integration of an EIR into existing immunization clinic workflows through an understanding of EIR-usability, time utilization following workflow modifications, and whether timeliness of vaccinations improves. Findings illuminate how best to introduce an EIR into a workflow to promote consistent use and reduce the burden of the intervention on healthcare workers with the aim of providing evidence for how to build and deploy better EIRs that can impact health-related outcomes.

INNOVATION

An innovative feature of this dissertation is the combination of human-centered design (HCD) and implementation science research methodologies to assess qualitative and quantitative information on EIR-usability, by observing tasks, technology, individuals, organizational factors, and the physical environment [17-19]. The use of HCD research techniques is helpful for illuminating key pieces of the software that are not meeting user needs, while workflow observations provide additional insights needed to understand the system's effect on users while performing clinic activities. If we relied on only HCD methodology, we would miss key findings emerging from workflow observations that are important for understanding the mechanisms of data use and contextual factors effecting system sustainability. Both HCD and implementation science methods need to be used together, where HCD methods are used to study an intervention's acceptability in a lab-based setting while implementation science methods aim to understand if an intervention is effective in a healthcare delivery setting. These methods can be used together and iteratively, not simply during independent phases of project development.

This research contributes to the small, but growing, body of research that uses HCD and realist methodologies to describe the use of a DHI. Using realist research, we were able to build from findings in the empirical literature and develop a robust theory that explained the underlying processes that could affect EIR-usability and the influence of contextual factors. Had we simply summarized our qualitative findings thematically, we would have lost the opportunity to "practicalize" these findings in the form of rules for implementers. We incorporated HCD research into a realist evaluation that allowed us to develop meaningful findings about the underlying processes of EIR-usability that could be used by other DHI implementers to build sustainable systems.

Additionally, another innovative feature of this dissertation is that it leverages individual-level EIR data in a novel way to show the value and limitations of using this type of data for real-world evaluation purposes. Our study took advantage of the opportunity to use individual-level routine health information system data from the EIR to conduct a quasi-experimental analysis. We were able to showcase the utility and power of these data for answering an implementation science research question by developing appropriate performance metrics within the Tanzanian context that considered changes over time, clinician practices at the facility and district levels, and the cohort of children we expected to see most affected by the EIR's introduction. This research responds to the gap in DHI effectiveness studies and demonstrates the potential utility of using individual-level data from existing routine health information systems to gain insights about the impact of technology on health-related outcomes.

Chapter 2: Integration of a digital health intervention into immunization clinic workflows in Kenya: A qualitative realist evaluation of technology usability

ABSTRACT

Background: In an effort to increase vaccination coverage in low-resource settings, technological tools have been introduced to better track immunization records, improve data management practices, and provide improved access to vaccination coverage data for decision-making. Despite the potential for these electronic systems to improve provision of health services, few digital health interventions have been institutionalized at scale in low- and middle-income countries.

Objective: We aimed to describe how healthcare workers in Kenya had integrated an electronic immunization registry into their immunization clinic workflows and to use these findings to inform the development of a middle-range theory on the registry's usability.

Methods: Informed by realist methodology, we developed a middle-range theory to explain usability of the electronic immunization registry. We designed a qualitative study based on our theory to describe the barriers and facilitators influencing data entry and use. Qualitative data were collected through semi-structured interviews with users and workflow observations of immunization clinic sessions. Our findings were summarized by context-mechanism-outcome relationships formed after analyzing our key themes across interviews and workflow observations. Using these relationships we were able to identify common rules for future implementers to successfully introduce digital health tools.

Results: Across the 12 facilities included in our study, 18 healthcare workers were interviewed and 58 workflow sessions were observed. The common rules developed from our qualitative findings included: Rule 1- Ensure users complete training to build familiarity with the system, understand the value of the system and data, and know where to find support, Rule 2- Confirm the system captures all data needed for users to provide routine healthcare services and is easy to navigate, Rule 3- Identify workarounds for poor network, system performance, and too few staff or resources, and Rule 4- Make users aware of expected changes to their workflow, and how these changes might differ over time and by facility size/number of patients. Upon study completion, we revised the middle-range theory to reflect the importance of the goals and workflows of information systems aligning with reality.

Conclusion: We identified the major barriers and facilitators of usability and created a deeper understanding of the underlying mechanisms. We found that the electronic immunization registry had high acceptability amongst users, however, there were numerous barriers to using the system, even under ideal conditions. Implementers should consider users' workflows during design and implementation phases. Human centered design and human factors methods can assist during pilot stages to better align systems with users' needs and again after scale-up to ensure interventions are suitable for all user-settings.

INTRODUCTION

Around 25% of children in Africa remain under-immunized against vaccine preventable diseases[20]. Vaccinations have been shown to be one of the most effective public health interventions for reducing the burden of infectious diseases[21, 22]. In an effort to increase vaccination coverage in low-resource settings, technological tools have been introduced to better track un- or under-immunized children, communicate vaccination appointment reminders, improve data management practices, and provide improved access to immunization coverage data for program managers and decision-makers[23]. There has been an increased uptake of new data collection, management, and communication systems in low-resource healthcare settings as mobile phones, tablets, and laptops have become cheaper and more accessible. The potential of these interventions to improve health systems was recognized by the World Health Assembly in 2018 and in 2019 the World Health Organization provided recommendations on use of these systems for improving health outcomes based on available evidence[16, 24]. Despite this global call for use of electronic systems to improve provision of immunization services, few digital health interventions (DHI) have been institutionalized at scale in low- and middle-income countries (LMICs)[23, 25, 26].

DHI projects often fail to be effectively adopted by users or to demonstrate their potential value due to poor understanding of users' needs and the implementation context[27]. This poor fit between DHI and implementation settings can be overcome through the use of human-centered design (HCD), human factors and ergonomics, and implementation science approaches[28]. These approaches have become increasingly popular for international development and social innovation projects [29]. However, HCD approaches are often only used in the initial phases of designing and deploying a DHI; implementation science research approaches are needed to supplement this methodology to study whether these interventions are effective in practice after deployment. "HCD and implementation science share the common goal of improving the use of innovative and effective practices in real-world contexts"[30].

Traditional public health research and evaluation methodology focuses on hypothesis-driven questions and methods, while design-thinking research accommodates iteration, prototyping, and ambiguity[31].

We sought to use these methods to evaluate a DHI in a low-resource healthcare setting and consider how workflows and tasks might be influenced by contextual factors. The International Training and Education Center for Health (I-TECH) at the University of Washington built an electronic immunization registry (EIR) for the Kenya immunization program to manage data and better identify un- or under-immunized children. Our study aimed to identify how well health care workers (HCWs) had integrated the EIR into their immunization clinic workflows using qualitative HCD and implementation science research methodologies. In particular, we focused on understanding EIR-usability, including the design of the system as well as the capacity of HCWs to use data in the EIR for decision-making. We designed a realist evaluation within a mixed-methods workflow modification project to describe the barriers and facilitators influencing data entry and use following EIR introduction, specifically focusing on EIR-usability and acceptability. The overarching goal of the project was to assess and redesign immunization session workflows when the EIR was used at the point-of-care (POC). In this manuscript, we describe only the baseline qualitative observations, the baseline quantitative and modified workflow observations are presented in separate manuscripts.

Informed by existing theories of health-technology adoption, we developed a middle-range theory using realist research to more closely reflect the context in which the EIR was deployed and one that provided a more clear conception of the linkage between the technology and users' experiences. Realist research aims is to explain "how interventions work, for what populations, and under what circumstances"[32, 33]. Middle-range theories characterize configurations of contexts, mechanisms, and outcomes to construct hypotheses about social phenomena[34]. We felt this methodology would provide a more dynamic and meaningful interpretation of our qualitative data. Our study objectives were to:

- Understand EIR-acceptability and users' perceptions of facilitators and barriers to EIR-use,

- Develop and test a middle-range theory on EIR-usability using findings from our study, and
- Create rules about EIR design and deployment for future DHI implementers.

The development of the middle-range theory allowed us to build off of the findings of other empirical studies, and then use our own findings to revise the theory to better outline the underlying mechanisms and contextual factors affecting usability.

METHODS

Methods are reported according to the Consolidated criteria for Reporting Qualitative research (COREQ) checklist [35].

Study Setting

Siaya County is located in Western Kenya along Lake Victoria with a population of 993,183 people as of 2019, with most living in a rural environment[36]. According to the most recent Demographic and Health Survey in 2014, 78% of children in Siaya County were fully vaccinated[37]. At the time of this study, multiple DHI projects were being deployed across the county, and some HCWs included in our study were involved in other projects.

Intervention Description

The EIR was introduced to all immunizing facilities in Siaya County, Kenya starting in 2018. A tablet-based EIR application was designed and developed using open-source software (OpenSRP/OpenMRS) adapted for the Kenyan healthcare setting to reflect the country's immunization program schedule, closely reflecting the standard paper-based reporting forms used by HCWs during immunization sessions. It was designed as a tablet-based POC system with online/offline functionality connected to a central data repository. Information on a child registered in the EIR could be viewed and edited from any tablet when the system was online. The EIR collected child demographic and contact information along with their vaccination records, receipt of Vitamin A and insecticide-treated nets (ITNs), as well as height and weight information for growth monitoring. The EIR was not interoperable with the national DHIS2 routine health information system at the time of this study.

The EIR was rolled out to all 161 immunizing facilities throughout the county through several phases of training. It was first piloted in Gem sub-county in early 2018 at 10 health facilities. This was followed by introduction to an additional 10 facilities in the same sub-county in late 2018. The software was tested and upgraded before being scaled-up in early 2019 to the remaining 141 immunizing health facilities. A cascade-training approach was used, led by the Ministry of Health (MOH) and I-TECH Kenya, where 1-2 staff from each facility were trained. Each facility received one tablet immediately following training. A WhatsApp group was established and maintained by the MOH and I-TECH to create a peer-support network for users and allow for remote troubleshooting.

It should be noted that prior to data collection for this study, the EIR software was upgraded which, anecdotally, solved some of the known software bugs, but slowed the system's performance and caused it to sometimes shut down unexpectedly.

Implementation and data-entry

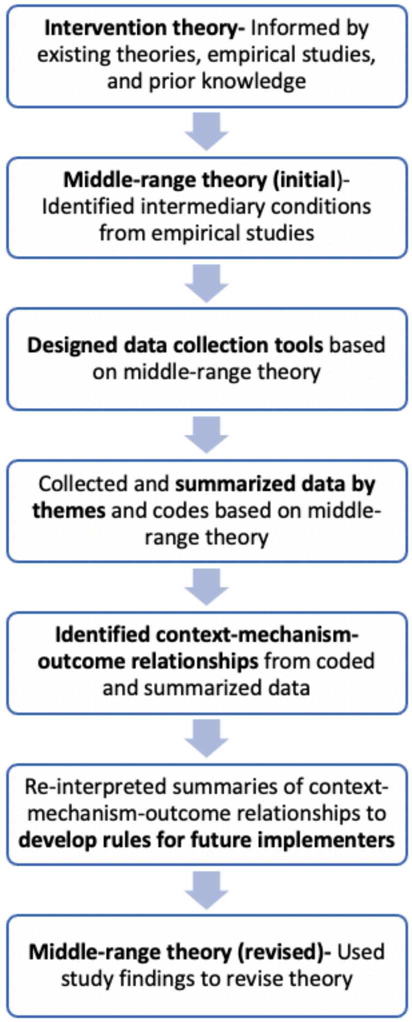
At each immunizing-facility, upon completion of training and receipt of a tablet, HCWs were expected to begin using the EIR immediately, first by entering information from the facility's paper-based immunization registry for the preceding twelve months and then prospectively entering vaccination data for every child seen for services thereafter. Following MOH guidance, HCWs using the EIR completed dual-data entry, inputting patient information into paper-based tools and the EIR either concurrently at the POC or retrospectively to simultaneously maintain records, at the end of a clinic session. All facilities were required to maintain up-to-date paper records throughout the study period.

Research Design

For our realist evaluation, we first developed an intervention theory on EIR-usability to explain how an EIR could theoretically improve the use of data for decision-making. We defined usability as the technology's "quality of use", considered "the degree to which a product or system can be used by specific users to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk and satisfaction in specific contexts of use"[38]. We were interested in understanding the relationship between data accessibility and use, rather than the EIR's impact on health-related outcomes.

Using prior knowledge of health technology evaluations and informed by existing theories of health-technology adoption, we drafted the intervention theory and then used findings from a targeted search of empirical studies to revise the theory[33] (Figure 2.1). We considered the FITT framework, which describes evaluating the fit between individual, task, and technology for improved user-adoption, and the Smith and Carayon ergonomics balance theory of job design for stress reduction, which expands from FITT to include physical environment and organizational conditions[39, 40]. We iterated on the intervention theory, continuously updating the theory based on findings from the literature. To illustrate how the intervention theory may vary by different conditions, we created a middle-range theory; we used findings from empirical studies and evaluations to identify variations in the conditions and considered how our study's findings on EIR-usability were reflected by the intervention theory and which intermediary conditions could impact usability.

Figure 2.1 Overview of theory development and data synthesis



Data Collection

Facilities were purposively selected from a sampling frame that included all public facilities in Siaya County performing POC data entry and administering vaccines on a daily basis. Based on this list we chose 12 facilities based on size and length of experience using the EIR and considered the accessibility of the facility for data collection. We hypothesized that smaller facilities would experience more challenges using the EIR over paper-based tools, compared to larger facilities and that large facilities would require additional resources to sustain use of the EIR. Facility size was determined by the number of children in the facility's catchment area, using the categories of small, medium, and large, based on the 33rd and 66th quantiles of the sampling frame. Length of experience using the EIR was categorized as <3 months and ≥3 months. One to two HCWs at each facility most familiar with the EIR were selected for interviews, usually they had been formally trained on the EIR, but some learned on-the-job. Sub-county health records information officers (SCHRIOs) overseeing EIR deployment among the selected facilities were also interviewed on their perceptions of facilitators and barriers among the staff they supervised. We determined that if data saturation was not reached by the time data collection was completed at all 12 facilities, we would institute a stopping criterion of two facilities (per category) until we reached saturation based on the types of challenges observed during workflow observations[41].

Qualitative data were collected through semi-structured interviews with users and direct workflow observations of immunization clinic sessions; data collection tools were driven by the initial middle-range theory. Direct observation is a standard method in human factors research and considered to be a useful technique when studying how technology changes user workflows and tasks[19, 42, 43]. In July 2019, two researchers with previous experience collecting qualitative data (SD and RW), trained four local data collectors on how to conduct semi-structured interviews and workflow observations. Data collectors had previous experience conducting surveys and had no prior relationships with the interviewees. Interviews were conducted in-person following observation of an immunization session. The facility visits were facilitated by the SCHRIOs, who introduced the data collectors to the facility staff and were sometimes present at the facility during the interviews.

The standardized semi-structured interviews included open-ended response questions and questions with Likert scale responses (scale 1-5) to indicate level of agreement about EIR-usability based on Nielsen's expanded usability heuristics (data collection tools included in the Supplementary Materials)[44]. Responses were marked on paper forms and data collectors took notes on open-ended interview questions and workflow observations in real-time. Interview responses were recorded on paper and later input into a spreadsheet for cleaning and analysis.

To document user workflows, data collectors used a standardized tool to observe and document the workflow of HCWs providing services to children seen in the immunization clinic for vaccinations or growth monitoring. Data collectors were instructed to stand in the immunization room and observe an entire session, usually conducted in the morning, until at least five children had been observed. Each facility's workflow was documented, including the sequence of activities, characteristics of the child being seen, and the number of staff working during the immunization session. Interruptions and/or other environmental observations were noted. Data were collected on paper forms and later entered into an online GoogleForm©.

Data Analysis

We calculated the frequencies of facility and interviewee characteristics. For the workflow observations and Likert scale responses, we used descriptive statistics to summarize the number of workflows by type, order of activities, and frequency of activities. For the qualitative data, the researchers wrote memos on key usability-observations for each interview following data collection. The memos along with the initial middle-range theory were used to develop themes and codes to summarize the open-ended questions. A code list was created and then piloted using three interviews. For every response, the coder had to choose the most appropriate theme and at least one code; some codes were further classified into sub-codes. SD and RW used Atlas ti© to independently code each interview, then reviewed discrepancies, and came to a consensus. Codes were updated following the initial round of review, but only for those concerning usability, as more specificity was needed (see Appendix Table 2.A for codes and definitions). All data were managed and summarized in Microsoft Excel©.

Synthesis of Rules

To better understand EIR-usability, we summarized our findings by context-mechanism-outcome relationships formed after analyzing our key themes across interviews and facility memos. Context was considered as the conditions in a given setting that could influence the mechanism-outcome relationships, either positively or negatively. We considered mechanisms to indicate underlying processes needed to generate our outcomes. As indicated by our study objective, our outcomes of interest were users' acceptance of the EIR when used at the POC alongside paper-based tools and usability of the EIR data.

We summarized the coded data by the context-mechanism-outcome configurations and then re-read and re-interpreted the data looking for patterns, common themes, and negative evidence to identify emergent rules that could be used by future implementers in low-resources settings to successfully introduce a DHI. Proposed rules were discussed and agreed upon with other research team members. We continued to iterate upon the rules, guided by the summaries, until the rules were able to appropriately capture our findings. These rules were reviewed by RW to ensure they aligned with the study findings and then used to describe the final results and how they related to the middle-range theory. Respondents did not provide feedback on findings.

Ethics

This study was determined as non-human subjects research by University of Washington Institutional Review Board and received human subjects ethics approval from AMREF Health Africa- Kenya and the U.S. Centers for Disease Control and Prevention as it was considered part of routine program evaluation. The interview team received consent from all participants to complete the semi-structured interviews. SD, RW, and JS led the design, implementation, and interpretation of findings for this study. SD advised on the design and implementation of the EIR.

RESULTS

Facility and Healthcare Worker Characteristics

Of the 12 facilities purposively sampled, 6 (50%) facilities had <3 months of experience using the EIR and four (33%) facilities fell into each facility size category (Table 2.1). Ten facilities (83%) were public, the remaining two were faith-based (17%). Ten (83%) facilities administered vaccinations daily. All 12 (100%) facilities had electricity, however only two (17%) had a backup power supply. Of the 19 interviewees, 14 (74%) had been working at the facility for 1-5 years, 10 (53%) had ≥3 months of experience using the system, and 12 (63%) were nurses.

Table 2.1 Facility and Healthcare Worker Characteristics

Facility Characteristics	Facilities, n=12	Healthcare Worker Characteristics	Healthcare Workers, n=19
Length of time using the EIR		**Years working at facility**	
<3 months	6 (50%)	<1 year	1 (5%)
≥3 months	6 (50%)	1-5 years	14 (74%)
Facility type		6-10 years	1 (5%)
Dispensary	4 (33%)	>10 years	2 (11%)
Health centre	6 (50%)	Missing	1 (5%)
County referral hospital	2 (17%)	**Time spent using EIR**	
Facility size		1-3 months	8 (42%)
Small	4 (33%)	>3 months	10 (53%)
Medium	4 (33%)	Missing	1 (5%)
Large	4 (33%)	**Staff cadre**	
Facility ownership		Nurse	12 (63%)
Faith-based	2 (17%)	Nurse in-charge	3 (16%)
Public	10 (83%)	Lab technician	1 (5%)
Vaccines administered daily		Missing	3 (16%)
Yes	10 (83%)		
Facility has electricity			
Yes	12 (100%)		
Facility has backup power			
Yes	2 (17%)		
Staffing			
Average number of nurses stationed in the immunization clinic	2.6		

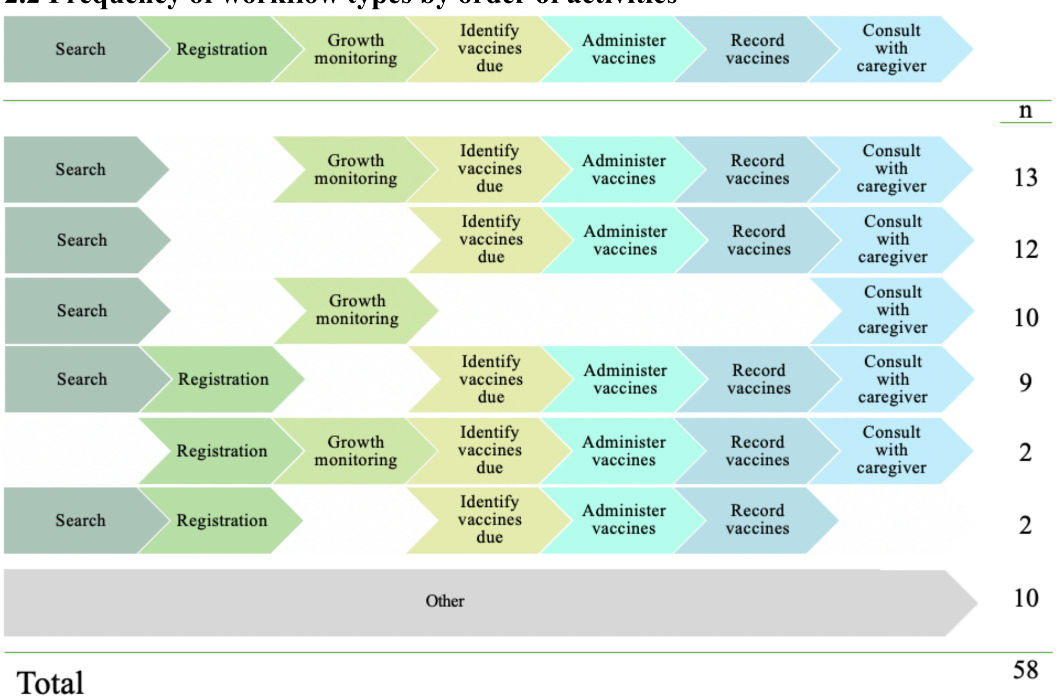
Workflow Summaries

There were no workflow observations documented at one facility due to no children presenting for services. Of the 58 workflow observations completed at 11 facilities, there were 42 (72%) where the

HCW alternated between inputting information into the EIR and the paper-based tools for each activity at the POC, while for five observations (9%) the HCW only used paper-based tools and later entered data into the EIR, and for 11 observations (19%) only paper-based tools were used. When the EIR was not used at the POC, it was due to issues with system performance.

Of the 58 workflows observed, no vaccines were administered during 12 (21%) of the observations (Figure 2.2). Generally, the workflows included a similar order of activities; the most common workflow (22%) was observed amongst children returning to the facility, having already been registered in the EIR, where the HCW searched for their record, conducted growth monitoring, identified vaccines due, administered and recorded the vaccines, and then provided a consult with the caregiver. Workflows varied by whether the child needed to be registered, needed growth monitoring, was due to receive vaccinations, and whether or not a consult with the caregiver was provided.

Figure 2.2 Frequency of workflow types by order of activities



Users' agreement with the ease of use of the EIR at the POC was assessed using standard heuristics as presented in Table 2.2. Generally, there was a high level of agreement (≥ 75%) with EIR usability, however, users disagreed on the EIR being well integrated into their workflow, with 32% disagreeing on having a good workflow when completing dual data-entry and 42% disagreeing on having enough staff to adequately use the EIR during an immunization clinic.

Table 2.2 User agreement on usability of an electronic immunization registry at the point-of-care

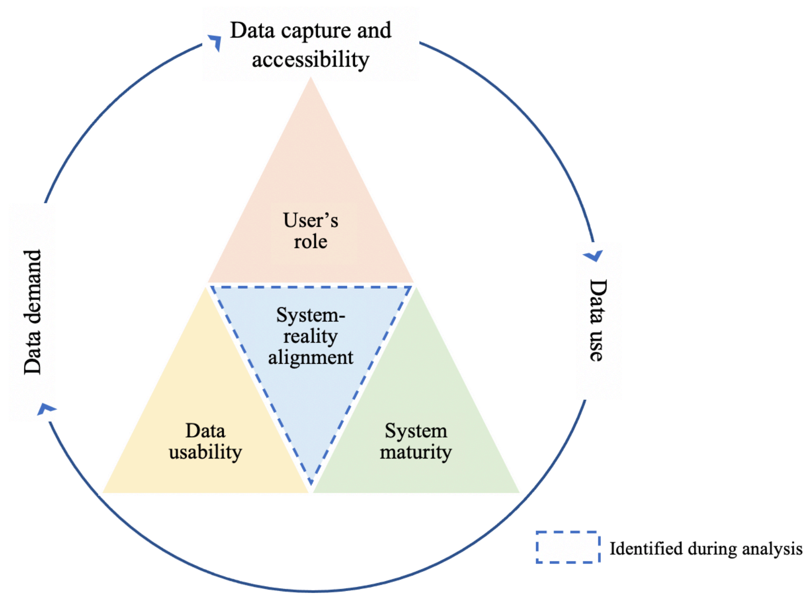
Usability Category	#	Usability Statements	Median (Min-Max)	All Facilities: Disagree or Strongly Disagree	Neither agree nor disagree	Agree or Strongly Agree
				% of Participants		
Visibility of system status	1	You feel the system provides enough feedback/messages to you as it processes information, you understand what the system is doing.	4 (2 - 5)	1 (5%)	0 (0%)	18 (95%)
Match between system and real world	2	You feel that the EIR captures the correct information during a nutrition and immunization session.	5 (2 - 5)	3 (16%)	0 (0%)	16 (84%)
User Control/Error Prevention	3	You feel you have the ability to undo and redo actions when entering child information.	4 (1 - 5)	1 (5%)	0 (0%)	18 (95%)
	4	If you make an error when using the EIR, you feel it is easy to correct the mistake and that the system helps you prevent making mistakes.	4 (1 - 5)	2 (11%)	0 (0%)	17 (89%)
	5	It is easy to move from one screen page/menu to the next	5 (2 - 5)	1 (5%)	0 (0%)	18 (95%)
	6	You can easily update/edit all the child registration details	5 (2 - 5)	1 (5%)	1 (5%)	17 (89%)
Aesthetic and minimalist design	7	You feel there is not too much information in the EIR, and that all of the information is needed.	4 (1 - 5)	2 (11%)	1 (5%)	16 (84%)
Flexibility and efficiency of use	8	You feel the system is flexible enough to allow you to complete frequent actions easily.	4 (2 - 5)	1 (5%)	0 (0%)	18 (95%)
	9	I find the EIR easy to use.	5 (4 - 5)	0 (0%)	0 (0%)	19 (100%)
Help and documentation	10	You feel it is easy to find help when you need it.	4 (2 - 5)	3 (16%)	1 (5%)	15 (79%)
Help users recognize, diagnose, and recover from errors	11	You feel that the error messages the EIR generates help to indicate a problem and suggest how to solve it.	4 (2 - 5)	2 (11%)	3 (16%)	14 (74%)
Integration into real-time workflow	12	The EIR provides the information I need to easily vaccinate children.	5 (4 - 5)	0 (0%)	0 (0%)	19 (100%)
	13	I have enough time to vaccinate all patients attending an immunization clinic.	4 (2 - 5)	1 (5%)	0 (0%)	18 (95%)
	14	The clinic workflow is good when using the EIR and paper tools at the point-of-care.	4 (2 - 5)	6 (32%)	1 (5%)	12 (63%)
	15	We have enough tablets for our clinic to use the EIR.	4 (1 - 5)	3 (16%)	0 (0%)	16 (84%)
	16	We have enough staff to adequately use the EIR during our immunization clinic.	4 (1 - 5)	8 (42%)	1 (5%)	10 (53%)
	17	The system was functioning well most of the time when you needed to use it.	4 (1 - 5)	4 (21%)	1 (5%)	14 (74%)
	18	System downtime was minimal.	4 (2 - 5)	1 (5%)	1 (5%)	17 (89%)
	19	I trust that the data in the EIR is stored securely and will not be lost.	4 (1 - 5)	1 (5%)	0 (0%)	18 (95%)
	20	I trust the data in the EIR are of good quality.	5 (2 - 5)	1 (5%)	1 (5%)	17 (89%)
Satisfaction	21	I would recommend the system for use by other users/health facilities	5 (4 - 5)	0 (0%)	0 (0%)	19 (100%)
	22	Overall, I am satisfied with the EIR.	4 (4 - 5)	0 (0%)	0 (0%)	19 (100%)
	23	The EIR improves the quality of patient care.	4 (4 - 5)	0 (0%)	0 (0%)	19 (100%)
	24	I feel I received adequate training on how to use the EIR appropriately for my clinic.	4 (2 - 5)	4 (21%)	1 (5%)	14 (74%)
	25	I know where to find the EIR user guides and help functions.	4 (1 - 5)	4 (21%)	0 (0%)	15 (79%)
	26	I feel I receive adequate supervisory support for using the EIR in my clinic.	4 (1 - 5)	3 (16%)	1 (5%)	15 (79%)

Middle-Range Theory

Our final intervention theory illustrated EIR usability as a cyclical relationship between data demand, data capture and accessibility, and data used for decision-making, which covers activities such as identifying clients due for vaccination, scheduling future visits, and retrieving clients' contact information (Appendix Figure 2.A). Poor data demand, accessibility, and use have been observed due to weaknesses at the individual, organization, and infrastructure levels, leading EIRs to serve little utility for decision-making [16]. We included these levels as components of the enabling environment for our intervention theory. At the individual level, we considered how EIR usability was dependent on a user's capacity and/or personal motivation. As described by self-determination theory, feelings of competence and a sense of autonomy can enhance intrinsic motivation for a worker to perform a task[45]. EIR-users are likely to internalize their use and demand for data as they find more interest, meaningfulness, and satisfaction with activities. Individuals who perceive their work as meaningful are more committed to their organization, more engaged, and more productive[46]. For the organization level, we considered the impact a program's culture, policies, and hierarchy may have on EIR-use; if culture and policies do not accommodate new technology, use is likely to remain low. For infrastructure, including available resources, we considered how EIRs require technical infrastructure that is routinely maintained and upgraded, as well as sufficient staffing levels and program funding to support users and maintain equipment. The use of an EIR alone will not improve immunization coverage, other environmental enablers mediate the impact of EIR usability on coverage.

For our middle-range theory we expanded the intervention theory and added the intermediary conditions of system maturity, user's role, and data usability based on empirical study findings, including our own (Figure 2.3). System maturity refers to, "the extent to which digital technologies are used as enablers to deliver a high-quality health service", and dictates system fidelity, the accessibility and usability of the EIR data, and how data are used for healthcare decision-making[47]. Data usability refers to, the "degree to which data are of sufficient quality (accuracy), completeness, timeliness to allow for effective decision making"[48]. Existing literature suggests that as HCWs use data more and use the full range of EIR-functionality, they can improve the quality of data by identifying inconsistencies and may start to demand more high-quality data, which improves their trust in the data, and therefore reinforces data use[13, 49]. The role of the user refers to their specific job tasks, responsibilities, and expectations in a given position and setting; for instance, if the user were required to use the EIR, but the EIR did not provide information needed to perform a job task, this would be poor use of the EIR given the user's role. Note that the conditions are not mutual exclusive and there is much overlap between them when framing their effect on EIR-usability.

Figure 2.3 Middle-Range Theory of EIR-Usability for Improving Immunization Coverage



System maturity - "the extent to which digital technologies are used as enablers to deliver a high-quality health service", and dictates system fidelity, the accessibility and usability of the EIR data, and how data are used for healthcare decision-making.

Data usability - "degree to which data are of sufficient quality (accuracy), completeness, timeliness to allow for effective decision making".

User's role- specific job tasks, responsibilities, and expectations in a given position and setting.

System-reality alignment- the congruence between the system, the user's needs, and real-time workflow.

Enabling environmental factors (not pictured): Factors influencing EIR-usability include the existing **infrastructure and resources**, such as the technical infrastructure, system maintenance and upgrades, staffing, and program funding, as well as an **individual's characteristics** such as competency, satisfaction, and motivation, all of which can be further influenced by **organizational structure** which would include the program's culture, policies and guidance, and organizational hierarchy and responsibilities.

Based on our study findings, described below, we revised the middle-range theory to better reflect the importance of information systems aligning with reality and included this as an additional intermediary condition. Alignment refers to the congruence between the system's design and functionality, the user's information needs, and real-time workflow. This definition covers whether the system is simple enough to navigate at the POC, collects all information routinely used, and allows for data to be easily accessible to perform routine tasks. This helped to clearly emphasize the importance of the EIR accommodating the other intermediaries to support the cycle of data demand, data capture and accessibility, and data use. We carried through the inclusion of the enabling environment from the intervention theory as we found that factors such as high user workloads, untrained staff, or poor internet connectivity could greatly influence EIR-usability. Using this theory, we captured how EIRs can improve the capacity of users to effectively serve patients, however, poor alignment between the system and reality could decrease the system's usability, and ultimately effectiveness.

Context-Mechanism-Outcome Configurations and Rules

Our analysis identified workflow flexibility, software design, system performance and network reliability, and self-efficacy as mechanisms that reflected the intermediary conditions of our middle-range theory. Context characteristics related to the enabling environmental factors of our theory and included: staffing levels, number of patients, training, and routine use of the EIR. Our outcomes of interest, EIR acceptability and data accessibility, were selected *a priori* and reflected by the existing cyclical EIR-usability relationship; we did not find any new outcomes to emerge during analysis. The addition of system-reality alignment to the middle-range theory was considered the key condition needed to tie together the context-mechanism-outcome configurations and was used to guide the crafting of rules for future DHI implementers (Table 2.3).

Table 2.3 Linkages between EIR usability rules and the middle-range theory

Enabling Environment- Contextual Factors	Intermediary Conditions- Mechanisms	EIR-Usability- Outcomes	Rules to improve alignment between system and reality
Training • Receiving adequate training allows users to operate the entirety of the EIR's functionality; without adequate training, users lack the knowledge of how to use the EIR effectively *Routine use* • The EIR is used frequently at the POC, helping to improve the user's comfort with the system; without routine use, the user has to relearn the system at each use *Number of patients* • Having many patients waiting to receive services can put added pressure on users to provide services quickly, while having few patients eases their workload *Staffing levels* • Having few staff increases pressure on users to provide services quickly and to multi-task, while having adequate staffing levels allows for work to be equally divided and better organized	*Data usability: Software design* • Users felt that the EIR **data were meaningful, important, and useful** *User's role: Self-efficacy* • Users noted that after having extended experience using the EIR, the system was **easier to use, and their workflow improved** • Some facilities **did not have training manuals** available and users voiced the need for refresher and on-the-job training	*EIR acceptability* • Training allowed users to feel they could **satisfactorily use and understand the EIR**, using the EIR was not seen as a challenge; untrained staff were dissatisfied with the system • Amongst users that didn't use the EIR regularly, they **trusted paper records more** • At one small facility, users felt that the **system took more time and effort when used at the POC**, and patients viewed the EIR as a **luxury and a poor use of staff time**	*Rule 1: Ensure users complete training to build familiarity with the system, understand the value of the system and data, and know where to find support*
	System-reality alignment: Workflow flexibility • **Not all activities were conducted for each child** seen at a facility, not all were measured for growth monitoring or given Vitamin A, while occasionally family planning consultations were provided *Data usability: Software design* • Users positively spoke of the **accessibility and searchability** of the information • Error messages generated by the system suggested **did not help to solve problems** • The system sometimes **incorrectly classified** children as defaulters; users **disagreed on whether too much or just enough information was required** by the system	*EIR acceptability* • Users felt that the system included all of the information needed to **successfully conduct an immunization session** • Some users felt that the EIR should **include information beyond immunizations**, like more comprehensive data capture for nutrition services *Data accessibility* • Good accessibility of data **allowed users to quickly find and use information for patient care**	*Rule 2: Confirm the system captures all data needed for users to provide routine healthcare services and is easy to navigate*
	System-reality alignment: Workflow flexibility • Users liked that the EIR was flexible, they felt the system had eased their workload because it was **more efficient to use than paper and reduced the burden of paperwork** • Users felt more time was needed to conduct **dual data-entry and that activities were more tedious and took more effort**, especially when there were many patients waiting to be seen *User's role: Self-efficacy* • Dual data-entry could be **mentally demanding, hectic, time-consuming, frustrating, and confusing** • Users at larger facilities felt that when there were **few patients waiting, the EIR was helpful.**	*EIR acceptability* • User **frustration increased** when there was a **large workload** • **More trained staff were needed** in some facilities to more efficiently register new patients and provide more support for EIR-use	*Rule 3: Make users aware of expected changes to their workflow, and how these changes might differ over time and by facility size/number of patients*
	System maturity: System performance and network reliability • When the **internet was working, the EIR was easy to use**, however, when the network was slow, this caused problems with synchronization and searching for records *System reality-alignment: Workflow flexibility* • Some facilities had **too few staff to perform dual data-entry** • Users at large facilities had more staff to attend to patients, they felt they **needed more tablets** to use the EIR effectively	*EIR acceptability* • Users felt additional time pressure if the **EIR poorly performed** and a facility had many patients waiting • At small and large facilities having low manpower **caused time pressure and frustration when using the EIR at POC** and some facilities relied on non-immunization clinic staff, such as students and receptionists, to help enter records into the system • Some users found it **easier and faster to look up and record information in the paper tools**, rather than logging into the system, **because it took so long for the system to respond**	*Rule 4: Identify workarounds for poor network, system performance, and too few staff or resources*

Rule 1: Ensure users complete training to build familiarity with the system, understand the value of the system and data, and know where to find support

Users' perceptions and experience with training influenced their feelings about EIR usability and alignment between the system, their workflows, and capacity. For instance, untrained staff were often dissatisfied with the system, indicating a lack of self-efficacy. Training allowed users to feel they could satisfactorily use and understand the EIR. Users felt confident after completing training and using the EIR was not seen as a challenge. One user only trusted the data they personally had entered into the system because the other HCWs in their facility had not been trained and therefore could not be trusted to enter data correctly. Working with untrained staff caused dissatisfaction with the system among some users. Training time was believed to be too limited and some users felt it was hard to retain all the information provided, further decreasing self-efficacy, although 74% (n=14) of users believed that they received adequate training. However, the SCHRIOs felt the transition to the EIR occurred too quickly, and that users needed longer training. We observed several staff using the EIR who had received on-the-job training (OJT), while other staff that had been formally trained were working in other areas of the facility at the time of observation.

In terms of software design, the EIR data was seen as meaningful, important, and useful by users, with 89% (n=17) of users feeling they were of good quality. The system was perceived as a safe and confidential data source, 95% (n=18) of users trusted that the data stored in the EIR were secure. They trusted the data because it could not be tampered with and liked that the system rejected incorrect information and that mistakes could be corrected later. Users felt that the EIR had a positive impact on data quality because the records were backed-up. Amongst users that did not use the EIR regularly, they trusted paper records more, as they were seen as more reliable. At one small facility, a HCW felt patients viewed the EIR as a luxury and a poor use of staff time.

Some facilities did not have training manuals available and users voiced the need for refresher and OJT; 21% (n=4) of users interviewed did not know where to find user guides. In terms of staffing, some facilities had IT staff available to help maintain the EIR, while others required SCHRIOs to assist or used WhatsApp groups for assistance; 79% (n=15) of users agreed that it was easy for them to find help, however getting assistance immediately was not easy for all facilities, and not all facilities received supervision visits. Additionally, SCHRIOs believed there was a gap in the support structure; further supported by our observation that 16% of users believed they did not receive adequate supervisory support.

Rule 2: Confirm the system captures all data needed for users to provide routine healthcare services and is easy to navigate

All users were satisfied with the EIR, agreed that it improved patient care, and would recommend the system to other users/health facilities (Table 2.2). EIR users believed that the system included all of the essential information needed to successfully conduct an immunization session. However, there were important differences observed for each child seen for services, where some were coming in for immunizations while others were being seen for a well-child visit; this required flexibility in user-workflows and software designed to accommodate differing visit-types. We observed that not all activities were conducted for each child seen at a facility; for instance, not all were measured for growth monitoring or given Vitamin A, while occasionally family planning consultations were provided to the caregiver. Some users suggested that the EIR should include information beyond immunizations, like more comprehensive data capture for nutrition services and tetanus toxoid vaccine, which is only a recommended vaccine for adults and not included in standard childhood vaccination clinics.

There were several EIR software updates needed to make it a more user-friendly design. Users noted that the recommended childhood vaccine schedule was not presented correctly in the EIR due to software bugs along with the need for Vitamin A and insecticide treated net schedules to be updated. The system sometimes incorrectly classified children as defaulters because of the software bugs, which caused some users to trust the paper records over the EIR. Users disagreed on whether too much or just enough information was required by the system. Also, the name of a child's father should have been included in the registration form, and several other fields should be made optional because caregivers cannot always provide this information at the time of registration. Additionally, some defaulters were displayed incorrectly, some users could not capture those children living outside the county, and it was sometimes difficult for users to update a child's registration information.

Users positively spoke of the efficiency of the system for storing patient information as well as the accessibility and searchability of the information. Others noted they felt less time pressure to perform tasks when using the system because they trusted the data inputted and found the system easy to navigate, especially when it became routine and they used it every day. Some users felt the EIR was easier to use than paper tools and made their work less burdensome, 100% (n=19) of users agreed that the system was easy to use. However, we did observe users that still relied on paper wall calendars to identify a child's next vaccination date, rather than use the automatically generated date from the EIR. Despite the challenges, the SCHRIOs also felt the EIR was easy to use and were satisfied with the system. They observed that HCWs were not hesitant to use the EIR and were impressed by the system.

In terms of system functionality, it was mentioned that error messages could be unclear or difficult to understand, 11% (n=2) of users did not feel that the error messages generated by the system suggested how to solve problems. We observed that when the EIR was lagging, some users had difficulty understanding if all information had been saved, as the EIR did not give notification. Amongst all users interviewed, 95% (n=18) agreed that the system provided enough feedback, 84% (n=16) agreed the EIR captured the correct information, 89% (n=17) believed errors could be prevented and information easily updated, and 95% (n=18) agreed that it is easy to navigate through the system. The clinical decision support features reminded users of which services or vaccines were due for a particular patient, in addition to quickly identifying which patients were defaulters. The EIR generated the monthly report of the total number of children vaccinated, which allowed for easy summation of data and for users to understand trends in the data. Users liked that the tablet was more portable than paper records and that the system guided the user on what to do next during a patient visit and they could easily move within the system. Users felt that updating information in the system was easy. Some users noted that using the EIR to search for children registered outside of the facility could be difficult because it required data syncing which could be slow or not possible if there was no internet connectivity, but did like this system feature.

Rule 3: Make users aware of expected changes to their workflow, and how these changes might differ over time and by facility size/number of patients

We heard mixed feelings about dual data-entry during a clinic session. Some users felt it could be mentally demanding, hectic, time-consuming, frustrating, and confusing, subsequently hampering their self-efficacy to use the system at the POC. We observed that some users waited until an immunization session was completed before entering information into the EIR in an effort to reduce their workload. Since beginning to use the EIR, some users felt that their workload had increased, but that their duties had not changed. Several users preferred using paper records because they could more quickly record information. However, in terms of workflow flexibility, other users liked that the EIR was flexible, they felt the system had eased their workload because it was more efficient to use than paper, reduced the burden of paperwork because they could copy information from the EIR into the paper tools, and helped when completing paper records. Users noted that after having extended experience using the EIR the system was easier to use and their workflow improved. Numerous users mentioned they would prefer to only use the EIR.

Users felt more time was needed to conduct dual data-entry and that activities were more tedious and took more effort, especially when there were many patients waiting to be seen. Although 95% (n=18) of users interviewed agreed that they had enough time to vaccinate all patients attending an immunization clinic, only 63% (n=12) agreed that they had a good workflow when they completed dual data-entry at the POC. During busy clinic sessions, some facilities would only enter information into paper records at the POC and then enter information into the EIR after the session. It was mentioned that frustration increased during these types of sessions. At small and large facilities having low staffing levels, likely alongside high patient volumes, caused time pressure and frustration when using the EIR at POC. When the immunization clinic was busy, users at small facilities felt more pressure and stress when performing dual data-entry at POC, especially when there were staff shortages. While users at larger facilities felt that when they had few patients waiting, the EIR was helpful. Additionally, users voiced that having to complete retrospective data entry took a long time, especially at large facilities. Pressure to perform activities quickly was compounded when the EIR performed poorly and a facility had many patients waiting. We did observe several sessions where a patient consult was not completed, possibly due to lack of time.

Rule 4: Identify workarounds for poor network, system performance, and too few staff or resources

Almost all staff interviewed mentioned an external challenge they faced to successfully use the EIR. Users explained that when the internet was working, the EIR was easy to use, however, when the network was slow, this caused problems with synchronization and searching for records. Users felt additional time pressure to perform tasks when there was poor network connectivity. We observed some users multi-tasking while the EIR was hanging. Sometimes the system failed to respond completely, and information could not be entered or updated. However, 74% (n=14) of users agreed that the system functioned most of the time when it was needed and 89% (n=17) said system downtime was minimal, they felt that performing dual data-entry was acceptable if the EIR was working well. Using the system required more effort when there was poor network connectivity, as connectivity was needed to login and perform advanced record searches. When the EIR suffered from poor performance which caused hanging and sometimes failure to save data or low availability of network which preventing synching and information could not be entered or updated, users felt frustrated. Some users found it easier and faster to look up and record information in the paper tools, rather than logging into the system, because it took so long or the system to respond. The SCHRIOs believed that some facilities struggled transitioning to the EIR because of network connectivity, high patient volume, and staff shortages. They felt that the facilities needed back-up power, improved network connectivity, adequate staffing, more tablets for large facilities, and access to the EIR data.

In terms of workflow flexibility, users at all facility sizes felt that more staff needed to be trained on the system to ensure coverage when trained staff were unavailable and for completing real-time data-entry. Some facilities had too few staff to perform dual data-entry, sometimes relying on non-immunization clinic staff, such as students and receptionists, to help enter records into the system. Half (53%, n=10) of users indicated having enough staff to adequately use the EIR during an immunization session. Although users at large facilities had more staff to attend to patients, they felt they needed more tablets to use the EIR effectively, this was also mentioned by 16% (n=3) of all users. It was noted that more trained staff were needed in some facilities to efficiently register new patients and provide more support for EIR-use. Staff only used the EIR and paper-tools concurrently when there were few clients. To accommodate low staffing levels, we observed data clerks or community health volunteers receive OJT in order to help complete the EIR records while the nurse would fill in the paper-based tools. One facility had developed a workaround so that the reception staff entered information into the EIR, however these staff were not compensated for their assistance and viewed the tasks as outside their job duties.

DISCUSSION

Findings

Our study identified the major barriers and facilitators to EIR-usability and created a deeper understanding of the underlying mechanisms and outcomes affecting users. We found that generally the EIR was well accepted, however, users faced numerous challenges to using the system, even under ideal conditions. The EIR incorrectly displayed key fields due to software bugs and numerous facilities could not easily access the system or synch records due to poor system performance. Additionally, the introduction of the EIR imposed new obstacles for the users, often exacerbated by contextual factors such as whether the facility had enough staff, lack of routine use of the system, adequacy of training, and number of patients waiting. These contextual factors were incorporated to our context-mechanism-outcome relationships and reflected by the enabling environment in our middle-range theory.

Users tended to have greater satisfaction with the EIR when it more closely aligned to their workflow, what we have termed as system-reality alignment, and vocalized their preference for removing paper-based tools and only performing paperless data entry. We confirmed that our initial middle-range theory describing EIR-usability was upheld, but our study highlighted the importance of system-reality alignment as a necessary intermediary condition. This finding has been described as the "design-reality gap", the success or failure of a DHI is dependent on the size of the gap which reflects the tension between designing systems for the present versus the future[50]. DHIs should serve as mechanisms to improve healthcare provision and data use, however they need to adapt to the realities of the users and their enabling environment to be viable data management tools.

Software design

As identified by our need to include system-reality alignment in our middle-range theory, we found that DHI design should not be dictated by a specific disease or health program and that the initial design process for the EIR was inadequate. Because immunization information had been prioritized for the EIR's design, some growth monitoring and nutrition information was not well captured despite it being part of a general well-child visit where HCWs have to provide different types of services to children. This was partly due to the adaptation of the software from an existing implementation of the system and immunization-focused stakeholders involved with the implementation process. Although the use of "global goods" such as OpenSRP can be monetarily beneficial for low-resource settings because they are technically free to use, they still need to be evaluated and significantly updated and upgraded to a fit a new setting before they can be effectively used[51]. Additionally, trade-offs have to be made between system flexibility and with accommodating user needs and data quality, as well as building program-specific versus more comprehensive systems[52]. HCD researchers and designers are faced with both understanding current practices as well as understanding how those practices may change in the future, and their methods should reflect this tension[53]. We can echo the voices of others, calling for implementers to place greater importance on continuous system adaptation and improvement of sociotechnical systems[18, 54, 55]. As workflows will need to be adapted over time as technology, human capacity, and healthcare needs change, efforts for adapting workflows could be particularly helpful, along with continuing to sensitize patients on the importance and expected changes following system introduction. Future studies could consider whether our middle-range theory is upheld as a DHI matures.

DHI and the Evaluation Lifecycle

When deploying a DHI, implementers should consider users' workflows during both the design and deployment phases. It is important to ensure that workflows which may vary by site and user are considered during the design phase. Especially in areas with poor access to electricity or internet, robust evaluations of a geography's connectivity should be conducted prior to introduction and the DHI should be designed not on an ideal connectivity scenario, but based on reality. For this study, the I-TECH team had surveyed each facility for internet access and electricity outages, but had not considered collecting more detailed information on the strength of the internet connection which would have been important information during the design phase to ensure the EIR could be used without interruption in low-connectivity areas.

Implementers should rigorously pilot test the DHI to ensure that the benefits of the system continue to outweigh any software performance issues. It would be helpful if implementation teams decided at the onset of DHI deployment what they considered adequate performance metrics, prior to scale-up. Having a metric for determining if the DHI is performing well can help inform whether facilities are ready to move to paperless data entry. Qualitative HCD studies can assist during pilot stages by ensuring that system-usability and user acceptability are captured in time to make changes to the system, while implementation science methods can be used after introduction and during scale-up to assess intervention effectiveness; if usability problems are identified after scale-up, HCD methods can again be used to better understand lack of DHI adoption.

Using HCD methods to understand the fit between users and technology we were able to distill our findings into four rules that considered the importance of a user's workflow and the enabling environment. Since the 1980s, health technology focused researchers have invoked socio-technical approaches to move conceptual understanding beyond simple cause and effect relationships in order to explain complex relationships. However, HCD methods are not routinely used in global health as the field has traditionally focused on medical/therapeutic interventions. The utility and benefit of HCD in global health is being more broadly recognized as a component of a public health professional's toolkit; however as of early 2019, few studies have been published that use HCD methods[56, 57].

The perceived benefit of HCD is that it provides a structured approach to "systematize innovation in public health" and that design thinking methodologies can provide new approaches to problem-solving in complex health systems, where more traditional methods may fail[56, 58]. There has been a continued emphasis on the importance of interactions between human behavior, organizational procedures, policies, and cultures when introducing an automated system and how new technologies need to be studied within these contexts[59]. Using HCD and implementation science methods together, we were able to observe and capture these interactions through our qualitative analysis. There is symmetry in the ideal approach to designing and implementing DHI alongside HCD/implementation science methodologies; as DHI are flexible systems that need to adapt to changes over time, their deployment and maintenance should be coupled with iterative evaluations over their lifespan that can continue to assess why changes are needed and how best to adapt the system. We encourage future evaluators to explore these methodologies and make them part of standard DHI evaluation practices.

Study Strengths

This is the first study to our knowledge that combines HCD and realism for understanding the integration of a DHI into user workflows. Using realist research we were able to build from findings in the empirical literature and develop a robust middle-range theory that explained the underlying processes that could affect EIR-usability and the influence of contextual factors. Had we simply summarized our qualitative findings by themes and codes, we would have lost the opportunity to "practicalize" these findings in the form of rules for implementers. The use of HCD research techniques for our study was helpful for illuminating key pieces of the software that were not meeting user needs, while the workflow observations provided additional insights needed to understand the system's effect on clinic activities. If we had relied on only HCD methodology that prioritized assessing acceptability we would have missed some key findings emerging from the interviews that were important for understanding the mechanisms of data use and contextual factors needed for project sustainability. Potential errors and failures can be best understood by observed system operations and these failures can only be identified when the system is operating in its real environment. Surprisingly we found that the use of dual data entry at facilities, rather than paperless alone, provided users with a side-by-side comparison of the two types of systems, which we think allowed them to make more specific and clear comments about facilitators and barriers, and allowed us to understand where key pieces of information/usability gaps were in the EIR compared to paper tools.

Limitations

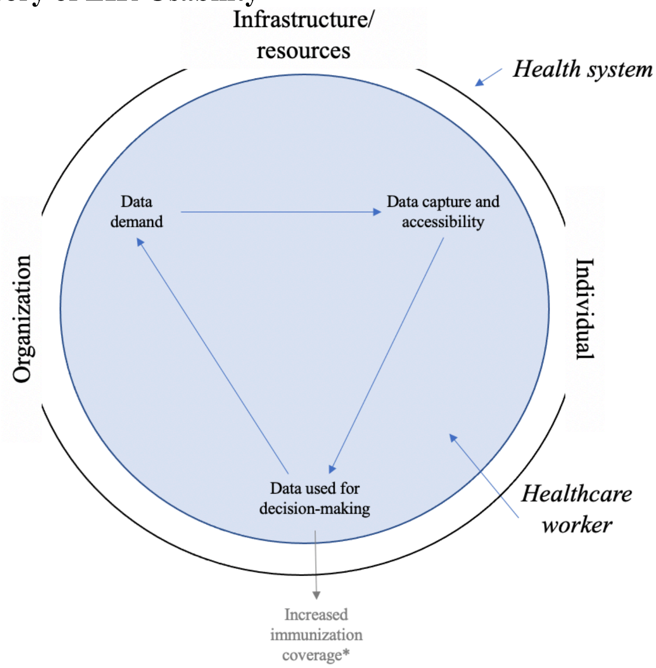
We faced several limitations during this study including the limited generalizability of our findings due to the purposive sampling approach and biases due to the Hawethorne effect where HCWs may have changed their behavior because they were being observed. Also, the EIR's software was upgraded immediately before study initiation and although, both our team and the implementation team did not expect the EIR's performance to change due to this upgrade, we observed and heard through interviews that the upgrade greatly impacted system performance. Therefore, our results reflect the findings of an unreliable system and are not representative of EIR-usability in a setting where the system is working as intended.

CONCLUSION

We identified the major barriers and facilitators of EIR-usability and created a deeper understanding of the underlying processes influencing usability through our middle-range theory and rules for future implementers. We found that generally the EIR had high acceptability amongst users, however, there were numerous barriers to using the system, even under ideal conditions. Implementers should consider users' workflows during the design and implementation phases, and ensure they are evaluating how workflows may vary by site and user, in order to find alignment between the system and reality. HCD and human factors research can assist during a digital intervention's pilot stages in time to make system changes, in addition to being used after scale-up to ensure interventions are acceptable in all user-settings.

APPENDIX

Figure 2.A Intervention Theory of EIR-Usability



*Immunization coverage was not part of our realist evaluation

Table 2.A Code Dictionary

Choose 1	*Choose at least 1*		
Theme	**Code**	**Sub-code**	**Definition**
Strength Weakness Recommendations Quote	Infrastructure and Resources	Connectivity	Refers to internet/network connection and power/electricity.
		Resources	Refers to staffing, equipment and stock.
		Support	Refers to supervisory and technical support provided by MOH or partner organizations.
		Clinic Environment	Refers to clinic's organization, noise levels, and cleanliness.
	Organization and Governance		Refers to MOH's leadership and guidance on use of the EIR.
	Training		Refers to formal training session upon roll-out of the EIR, need for refresher training, or if HCW isn't trained or doesn't remember how to perform a particular task.
	Workflow		Refers to HCWs perrforming simultaneous activities, organization of activities, alterations to workflow used for different scenarios, interruptions, dual data entry, time to complete activities, and patients waiting.
	Data Quality and Use	Perceptions	Refers to trusting the data, individual motivations and trust in the EIR. It could be coded alongside usability if it's referring to how KIP improves data quality.
		Completeness of information	Refers to the number of records entered into the EIR and the type/amount of information included in the system, but not due to system malfunction. It could be coded alongside usability if it is related to design, i.e., missing key pieces of information.
	Unexpected Observations		Refers to unique uses of the EIR.
	HCW Self-Efficacy		Refers to HCW confidence in the ability to exert control over one's own motivation, behavior, and social environment, also frustration.
	Usability	System support	Refers to how the system notifies of errors and guides users.
		Clinical decision support	Refers to how users can view defaulters and when a child is due immunizations.
		Match between system and real world	Refers to whether information used in the clinic routinely is missing, design issue or workflow issue, and portability of the tablet.
		User interface	Refers to user's ability to navigate within the system and updating/editing records.
		Performance	Refers to the EIR hanging, freezing, or shutting off, etc.
	Acceptability		Refers to how satsified the HCW is with KIP and their attitudes about the sytem.

Chapter 3: Time utilization among immunization clinics using an electronic immunization registry: A time and motion study of modified user workflows

ABSTRACT

Background: Digital health interventions (DHIs) have the potential to improve the provision of healthcare services through digitized data collection and management. Low- and middle-income countries (LMICs) are beginning to introduce electronic immunization registries (EIRs) into their routine immunization services to better capture and store childhood vaccination information. Especially in Africa, where 25% of children remain un- or under-immunized, technologies that can help identify children due for a vaccination are particularly important for improving vaccination coverage. However, an improved understanding of the effectiveness of these systems is needed to develop and deploy sustainable EIRs in LMICs.

Objective: We conducted an interventional pre-post study which sought to improve time efficiency through workflow modifications in Kenyan immunization clinics. Our aim was to describe how activity times differed after introducing workflow modifications that could potentially reduce the time needed to perform routine data entry activities. Our intent was to demonstrate changes in efficiency when moving from the existing dual-data entry workflow to a future paperless workflow by health facility size and length of experience.

Methods: We tested how three workflow modifications would affect time utilization amongst healthcare workers using the EIR at the point-of-care compared to baseline immunization clinic workflows. Our outcome of interest was the time taken to complete each task and immunization clinic session, comparing the time between the baseline and modified workflows. We used a standardized tool to observe and document the immunization clinic workflow. To estimate differences in time utilization, we used bivariate analyses and fit multivariate linear mixed-effects models.

Results: Our study found that for healthcare workers using an EIR, the introduction of modified workflows decreased the amount of time needed to provide services to children seen in the immunization clinic. With a baseline mean time of 10 minutes spent per child, this decreased by about 3 minutes when the preparation modification was introduced and almost 5 minutes for the paperless and combined modifications. Our initial hypothesis that there would be differences seen at baseline by size of facility and length of experience was confirmed. Results pertaining to the EIR's performance and ability to connect to the internet were particularly insightful about potential causes of delays.

Conclusion: We were able to conduct a fairly quick clinical simulation exercise introducing modified workflows and estimating their impact on time utilization in immunization clinics using an EIR. We found that the paperless workflow provided the largest time savings when delivering services, although this was threatened by poor EIR performance and internet connectivity. This study demonstrated that not only should DHI be built and adapted for particular use-cases, but that existing user workflows also need to adapt to new technology.

INTRODUCTION

Digital health interventions (DHIs) have the potential to improve the provision of healthcare services. Through digitized data collection and management, these interventions can improve the accessibility and use of patient information, support clinical decisions, and improve communication between patients and clinicians. In 2018 the World Health Assembly recognized the importance of DHI for reaching the Sustainable Development Goals and recommended that these interventions be used to strengthen health systems[7, 24, 60]. Despite global support for these types of technologies, there is mixed evidence on their empirical benefits, cost-effectiveness, and scalability [54, 55, 61, 62].

Low- and middle-income countries (LMICs) are beginning to introduce electronic immunization registries (EIRs) into their routine immunization services to better capture and store childhood vaccination information. EIRs are computerized tools used to collect population-based vaccination data about residents within a specific geographic area. They allow for monitoring vaccination coverage by provider, vaccine, dose, age, target group, and geographical area, and facilitate the monitoring of individuals receiving immunizations, in addition to improving the efficiency of routine data management activities [25, 63, 64]. Especially in geographies such as Africa, where 25% of children remain un- or under-immunized, technologies that facilitate the identification children due for a vaccination are particularly important for improving vaccination coverage and ultimately morbidity and mortality due to vaccine-preventable diseases[20]. However, an improved understanding of efficiencies created by EIRs is needed to design and deploy sustainable systems in LMICs. Efficiency of use is one aspect of optimal fit between a user’s tasks and a new technology; finding the optimal fit can lead to improved acceptability and satisfaction of the technology, as well as contribute to high fidelity of technology’s use, allowing for potential improvements in health outcomes to be realized.

We conducted an interventional pre-post study which sought to improve efficiency of use of an EIR in immunization clinics through three modifications made to user workflows. We were interested in understanding factors influencing the time spent per activity and quantifying the added value of moving from a dual data-entry workflow, where patient information is entered into both paper-based tools and the EIR, to a completely digital workflow. We used the dual data-entry workflow as our baseline, rather than a paper-based workflow, because this was a crucial transition stage introduced by the government as part of the EIR implementation plan and lasted much longer than anticipated, making it important to study its impact on efficiency. Although DHI are built to improve efficiencies, these efficiencies are not always realized, therefore it is important to describe time utilization and study how to optimize workflows[65].

The International Training and Education Center for Health (I-TECH) at the University of Washington built an EIR for the Kenya Expanded Programme for Immunization (KEPI) to track children's vaccination histories and identify un- or under-immunized children. We saw the opportunity to assess the efficiency of an EIR in the workflows of healthcare workers (HCWs) in different types of facilities and how the fit between technology and tasks could be improved. More attention is being given to the use of iterative methods for implementing and redesigning DHI for better adaption and sustainability in their given settings[27]. We used an experimental approach to modify workflows to improve efficiencies through human-centered design (HCD) and ergonomics methods.

HCD has become increasingly popular in the global digital health community, as it uses rapid ideation and iteration mixed-methods approaches to build technology that fits users' needs and preferences[57, 61]. HCD approaches can provide formative research needed to optimize an intervention and can help increase intervention adoption[31]. Ergonomic and human factors research are considered two of the main methods used to evaluate work systems and implement solutions in an effort to decrease workloads and increase patient safety[66]. Direct observation is a standard method in human factors research and considered to be a useful technique when studying how technology changes user workflows and tasks[19, 42, 43]. We used observational time-and-motion methods to assess the time spent by HCWs on routine activities when using an EIR and to observe challenges with usability. Our aim was to describe how activity times differed after introducing three workflow modifications that could potentially reduce the time needed to perform routine data entry activities and simulate a completely digital workflow.

METHODS

We followed the Suggested Time and Motion Procedures (STAMP) to report our study methods[67]. These procedures aim to improve the consistency of reporting time-and-motion research in health informatics.

Study Design

We designed a quantitative study within a mixed-methods workflow modification project. A non-randomized factorial observational study was conducted to test how three workflow modifications would affect time utilization amongst HCWs using the EIR at the point-of-care (POC) compared to baseline immunization clinic workflows. Our intent was to demonstrate changes in efficiency when moving from the existing dual-data entry workflow to the intended future paperless workflow. Time utilization was considered from the patient perspective, from the start to end of their time spent interfacing with a HCW during an immunization session. We hypothesized that time spent by HCWs performing routine activities would be reduced following introduction of the workflow modifications and that time spent on routine activities would differ by health facility size and length of experience using the EIR. We considered various existing health information system evaluation frameworks as well as the availability of data during the study design phase. The frameworks included the FITT framework which describes evaluating the fit between individual, task, and technology for improved user-adoption and the Smith and Carayon ergonomics balance theory of job design for stress reduction, which expands from FITT to include physical environment and organizational conditions[39, 40]. Our study was informed by these frameworks, but not grounded in them.

Study Setting

Our study took place in Siaya County, located in Western Kenya along Lake Victoria with a population of 993,183 people as of 2019, most living in a rural area[36]. According to the most recent Demographic and Health Survey in 2014, 78% of children in Siaya County were fully vaccinated[68]. At the time of this study, multiple DHI projects were being deployed across the county, some HCWs included in our study were involved in other projects.

Electronic Immunization Registry Design and Usage

I-TECH adapted a tablet-based EIR application that was originally designed and developed for Zambia's immunization program, as users and requirements were similar across countries. For development of the Zambia EIR application, stakeholders were brought together to develop functional and system requirements that incorporated business-process workflows, ultimately selecting the open-source OpenSRP/OpenMRS software platform[69]. The platform was updated to reflect Kenya's recommended childhood immunization schedule, closely reflecting the standard paper-based reporting forms used by HCWs during immunization sessions. It was designed as a tablet-based POC system with online/offline functionality connected to a central data repository. Information on a child registered in the EIR could be viewed and edited from any tablet when the system was online. Additional information on EIR design and deployment can be found in our qualitative study[70].

Upon completion of training and receipt of a tablet, HCWs were expected to begin using the EIR immediately, first by retrospectively entering information from the paper-based immunization registry and then for every child seen for immunization services thereafter. Due to the MOH requirement of maintaining paper-based records, HCWs using the EIR completed dual-data entry, inputting patient information into both the paper-based tools and the EIR at the POC or at the end of a clinic session. It should be noted that prior to data collection for this study, the EIR software was upgraded which, anecdotally, solved some of the known software bugs, but slowed the system's performance and caused it to shut down unexpectedly.

Workflow Modification Intervention Description

The baseline workflow generally encompassed a total of seven activities for each child and varied by whether a child was due for vaccinations or needed growth monitoring and the order of activities differed by clinic; both the EIR and paper recording tools were used concurrently at the POC (Figure 3.1). For the modified workflows, HCWs were trained on each data-entry related modification prior to the start of an immunization clinic session and then asked to perform the modification for the length of the daily session. The three modifications introduced were:

1. Preparation: Prior to the start of an immunization clinic session, HCWs prepared a list of children they expected to see coming in for services that day based on their next vaccination due date. Children's names, date of birth, and EIR ID were recorded on one sheet of paper. The HCWs then ensured that complete data on each child on the list was pre-registered in the EIR. In practice, there were two methods for creating the list, either the HCW gathered the home-based records from caregivers in the waiting room and wrote down each child's information or the HCW reviewed the facility's paper-based tools to identify which children were scheduled to come into the facility that day.

   Rationale: In an effort to reduce the time it takes to search for and record information, we believed that by having HCWs gather and update information prior to the start of the session they would reduce the time needed to search for and enter information during the session. We expected to reduce the time needed to identify and register a patient by batching these activities for expected children.

2. Paperless: HCWs were asked to use only the EIR during an immunization session, not paper-based tools, at the POC to record information. To maintain complete records as required by MOH, HCWs entered all information collected in the EIR into the paper-based tools after the clinic was finished.

   Rationale: To simulate an ideal EIR workflow, we wanted to observe time spent by HCWs searching for and recording information when only using the EIR at the POC. The paperless workflow is the basis for how the EIR was designed and is intended to be introduced by the government in the future, when data quality is deemed to be sufficient to remove paper-based tools.

3. Combined: Both of the preparation and paperless modifications described above were implemented simultaneously during a single immunization clinic session.

   Rationale: We wanted to observe whether there was a synergistic effect of implementing both modifications at the same time.

Figure 3.1 Planned data entry touch points during each immunization session activity by workflow type

Workflow Type		Activity	Search	Registration	Growth monitoring	Identify vaccines due	Administer vaccines	Record vaccines	Consult with caregiver
Baseline	**Data Entry Touch Points**	EIR	X	X	X	X		X	
		Paper	X	X	X	X		X	
Preparation*	**Data Entry Touch Points**	EIR			X	X		X	
		Paper			X	X		X	
Paperless	**Data Entry Touch Points**	EIR	X	X	X	X		X	
		Paper							
Combined*	**Data Entry Touch Points**	EIR			X	X		X	
		Paper							

*For both the preparation and combined workflows, HCWs were asked to search for and manage children expected to be seen that day prior to the start of the immunization clinic day, therefore they are not represented in the figure.

Measures

Our outcome of interest was the time taken to complete each task and immunization clinic session, comparing the time between the baseline and modified workflows. Tasks assessed included: searching for a child's record, registering a child in the EIR, identifying vaccines due, administering vaccines, growth monitoring, recording vaccines administered, and providing a consult with the caregiver. We also considered it important to assess session and facility-specific characteristics. Session-specific characteristics included: whether a patient was registered during the session and if it was their first visit, whether the child brought a home-based record (yes/no), whether any vaccines were administered (yes/no), whether 1 or >1 HCW was working at the time of observation, the number of vaccines administered during the session, EIR performance, and the clinic environment. We combined registration and first visit to create one composite categorical variable that captured whether the child was returning to the facility and had previously been registered, if it was either a first visit or new registration, or if it was the child's first visit and they needed to be registered. EIR performance was captured by a composite variable that combined indicators of whether the EIR was working, partially working, or not working, and whether or not it was synching during a session; the three categories created were: EIR working and synching, EIR not synching, EIR partially working but synching, and EIR not working or synching. For clinic environment we created a dichotomous variable that considered a clinic to have a good environment if it was neat, uncrowded, quiet, and well-lit, or to have poor clinic environment if it was messy, crowded, and/or noisy. Facility-specific characteristics included facility type (dispensary, health centre, or referral hospital), facility size (small, medium, or large, described below), if adequate staff were available (yes/no), and whether the facility had <3 or ≥3 months using the EIR.

Sampling

We collected baseline data from 12 purposively selected facilities in three sub-counties based on their length of experience using the EIR (<3 or ≥3 months), facility size based on the 33rd and 66th percentiles of the monthly immunization target population for the county (small ≤10, medium= 11-20, large>20), and logistical ease for data collectors. For the modified workflows, six facilities included in the baseline data collection with ≥3 months using the EIR, with a functional EIR, and located in a single sub-county were selected as these were considered to be the facilities that could most easily accommodate the modifications due to their experience and strong support from the sub-county.

We used an online computation tool for linear models to calculate the estimated sample size needed for testing a difference in time utilization between workflow types; we accounted for clustering by HCW and workflow type[71]. The sample size calculation was performed using a significance level of 0.05 and 80% power. We estimated the mean values for each outcome within each group based on the EIR time-use estimates reported in the literature (see Appendix Table 3.A)[72-74]. Based on our specifications, our sample size was computed to be 9 HCWs, 3 per facility size. We added an additional 3 HCWs in case of attrition, for a total of sample size of 12 HCWs.

At the start of data collection, few children were being seen for vaccinations daily at selected facilities, therefore the number of child-level observations was dropped from 10 to 5 in order to meet the study's timeline and not prolong the need for HCWs to perform modified workflows. This change reduced our study power to 69%.

Data Collection

Quantitative data were collected over the course of two weeks, with the first week devoted to baseline data collection and the second focused on the modified workflows. Data collectors used a standardized tool to observe and document the workflow of HCWs providing services to children seen in the immunization clinic for vaccinations or growth monitoring (data collection tools included in the Supplementary Materials). Data collectors were instructed to stand in the immunization room and observe an entire session, usually conducted in the morning, until at least 5 children had been observed. If less than 5 children were observed during one session, the facility performed the same workflow the following day and the data collectors returned the following day to complete the observations.

Each facility's workflow was documented, including the sequence of activities, characteristics of the child being seen, whether paper tools or the EIR was used, and the number of staff working during the immunization session. Activities were timed and interruptions and/or other clinic observations were noted. Data collectors documented activities completed simultaneously by HCWs. Time utilization was captured from the time a child was called to receive service until they left the clinic. Data were collected on paper forms and later entered into an online GoogleForm.

Four data collectors were trained over two days on immunization program activities, use of the EIR, and how to perform observations and interviews by members of the research team SD and RW, who also served as data collectors. Training included one pilot activity. All data collectors had previous experience collecting data related to health programs. Data collectors were assigned to observe the same facility over the course of the data collection period, as much as was logistically possible, and instructed to visit the facility when it was likely to be providing immunization services.

We used data collected during a readiness assessment completed prior to the deployment of the EIR for I-TECH's project monitoring and evaluation purposes, separate from this study. All facilities were included in the assessment, where one staff from each facility was interviewed about their facility's internet connection, electricity availability, and the facility's vaccination days. These data were collected by trained sub-county health records information officers using GoogleForms or RedCap.

Statistical Analysis

We calculated the frequencies of facility and HCW characteristics. For the workflow observations, we used descriptive statistics to summarize activity times. The mean and standard deviation for the amount of time to perform a given activity were calculated by workflow as well as by length of experience using the EIR (baseline only) and facility size. We also conducted bivariate testing to assess differences between workflow types and session characteristics as well as time utilization for immunization clinic activities and complete workflow time. We used an ANOVA test for unbalanced designs for continuous variables and chi-square test for proportions. For activities that could not be timed as single events, rather multiple activities were timed together either because they occurred too quickly to time separately or occurred concurrently, we took the total time and divided it by the number of activities performed during that time period.

To estimate differences in time utilization between baseline and each workflow modification, we fit multivariate linear mixed-effects models. Nested random effects were included to account for the correlation between observations collected at the same facility. Fixed effects included: workflow type (categorical with the baseline workflow as the reference group), EIR performance (categorical with the EIR not working or synching as the reference group), child having a home-based record (dichotomous, yes vs. no), visit and registration status (categorical with a child having been previously registered and returning to the clinic as the reference group), whether vaccines were administered (dichotomous, yes vs. no), number of vaccines administered (continuous), clinic environment (dichotomous, good vs. poor environment), whether >1 HCW was working at the time of observation (dichotomous, with the reference group being 1 HCW working), facility type (categorical with dispensary as the reference group), facility size (categorical with small as the reference group), if adequate staff were available (dichotomous, yes vs. no), and months using the EIR (dichotomous, <3 months compared to ≥ 3 months). Each task-model included a unique set of fixed effects depending on whether the effect was relevant to the task, i.e., the EIR's performance should have no effect on administering vaccines, therefore EIR performance was not included in that particular model.

The Y_o term represents the minutes taken to complete each given task or workflow for each child observed; B_oX represents the predictors, including the constant term for the mean time to complete the specific task and the workflow type for each observation. A random effect estimated the outcome of interest for each observation nested within each facility and was assumed to be normally distributed.

$$Y_o = B_o X + u_{f|o}$$

$$u_{f|o} \sim N(0, G)$$

$Y - time\ to\ complete\ task\ (minutes)$
$\beta - unknown\ parameters\ for\ fixed\ effect$
X – covariate vector for fixed effects
$u - normal\ (N)\ independent\ and\ identically\ distributed\ random\ effects$
G- variance-covariance matrix for random effects
o –observation of fixed effect during individual child encounter in the immunization clinic
f –facility

All quantitative data were analyzed in R Studio (version 1.1). The lmer function in the R lme4 package was used to model our linear outcomes of interest, the lmerTest package was used to calculate p-values, the lsmeans was used to compute contrasts for fixed effects, and the stargazer package was used to compile model statistics[75]. The Anova function in the R car package was used to analyze variance for unbalanced designs. Significance was determined at a two-sided alpha value of 0.05.

Ethics

This study was determined to be non-human subjects research by the University of Washington Institutional Review Board and received human subjects' ethical approval from Amref Kenya, as routine program evaluation. The research team received written consent from all healthcare workers observed. SD and RW led the design, implementation, and interpretation of findings for this study. SD advised on the design and implementation of the EIR.

RESULTS

Baseline Workflow Characteristics

Among the 12 facilities observed at baseline, 6 (50%) were health centres and 10 (83%) were publicly owned and administered vaccinations daily (Table 3.1). All 12 facilities had electricity, however only two facilities (17%) had a backup power supply. Sessions were observed at 11 facilities, one facility had no children seen for vaccination or growth monitoring services during the study period. Of the 18 HCWs observed at baseline, 14 (78%) had been working at the facility for 1-5 years, 10 (56%) had more than three months of experience using the EIR, and 12 (67%) were nurses (Table 3.2).

Table 3.1 Facility Characteristics

	Baseline, n=12	**Modified workflow, n=6**
Length of time using the EIR		
<3 months	6 (50%)	0 (0%)
≥3 months	6 (50%)	6 (100%)
Facility type		
Dispensary	4 (33%)	2 (33%)
Health centre	6 (50%)	3 (50%)
County referral hospital	2 (17%)	1 (17%)
Facility size		
Small	4 (33%)	2 (33%)
Medium	4 (33%)	2 (33%)
Large	4 (33%)	2 (33%)
Facility ownership		
Faith-based	2 (17%)	0 (0%)
Public	10 (83%)	6 (100%)
Vaccines administered daily		
Yes	10 (83%)	6 (100%)
Facility has electricity		
Yes	12 (100%)	6 (100%)
Facility has backup power		
Yes	2 (17%)	1 (17%)

Table 3.2 Healthcare Worker Characteristics

	Baseline, n=18	Modified workflow, n=6
Years working at facility		
<1 year	1 (6%)	2 (33%)
1-5 years	14 (78%)	3 (50%)
6-10 years	1 (6%)	1 (17%)
>10 years	2 (11%)	0 (0%)
Time spent using EIR		
<1 month	0 (0%)	1 (17%)
1-3 months	8 (44%)	0 (0%)
≥3 months	10 (56%)	5 (83%)
Staff cadre		
Nurse	12 (67%)	5 (83%)
Nurse in-charge	3 (17%)	1 (17%)
Lab technician	1 (6%)	0 (0%)
Missing	2 (11%)	0 (0%)

There were 58 observations of immunization clinic sessions at baseline (Table 3.3). The majority (95%) of children had a home-based record brought by their caregiver and 59% of children were previously registered in the EIR and returning to the facility for services. Only 79% of children observed were administered a vaccination, and among these children the mean number of vaccines administered was two. Generally, the facility environment during the session was good (76%), with 24% of sessions experiencing crowding, noise, and/or were messy, and for 59% of the sessions only one HCW was working in the immunization clinic. The EIR was working and synching during 19% of sessions while it was not synching during 52% of the sessions and not working during 21% of sessions (HCWs only used paper tools).

Modified Workflow Characteristics

The distribution of HCW characteristics during the modified workflows was similar to baseline, with the majority having 1-5 years of experience (50%), ≥3 months experience using the EIR (83%) and were nurses (83%) (Table 3.2). Characteristics of the children seen at a facility during the modified workflows were generally similar across workflow types, except for the number of vaccines administered, the clinic environment, and the EIR performance. Over 89% of children had a home-based record, 57-74% of children were previously registered and returning to the facility (Table 3.3). Compared to baseline, fewer children were seen for vaccination during the modified workflows, ranging from 56-75%, and there was a significant difference in the number of vaccines administered, with those seen during the paperless and combined workflows only receiving one vaccination on average. The facility environment was good across each modified workflow for 70-100% of the sessions, but with significant differences; all sessions observed during the combined workflow had a good clinic environment compared to only 76% of sessions at baseline. The EIR was working and synching for 19-24% of sessions, however it was not synching for 45-82% of sessions, there were significant differences across workflows. There were no significant differences in the number of HCWs working during the session, but there was a wide range with 41% of sessions having >1 HCW at baseline, while 70% of sessions for the preparation workflow had >1 HCW; during the paperless and combined workflows only 43% and 41% were, respectively.

Table 3.3 Session characteristics by workflow type

	Baseline (n=58)	**Preparation** (n=20)	**Paperless** (n=21)	**Combined** (n=27)	**Overall** (n=126)
Child has home-based record					
Yes	55 (95%)	19 (95%)	19 (90%)	24 (89%)	117 (93%)
No	3 (5%)	1 (5%)	2 (10%)	3 (11%)	9 (7%)
Child visit and registration status					
First visit or new registration	11 (19%)	4 (20%)	2 (10%)	2 (7%)	19 (15%)
First visit and new registration	13 (22%)	4 (20%)	7 (33%)	5 (19%)	29 (23%)
Returning and registered	34 (59%)	12 (60%)	12 (57%)	20 (74%)	78 (62%)

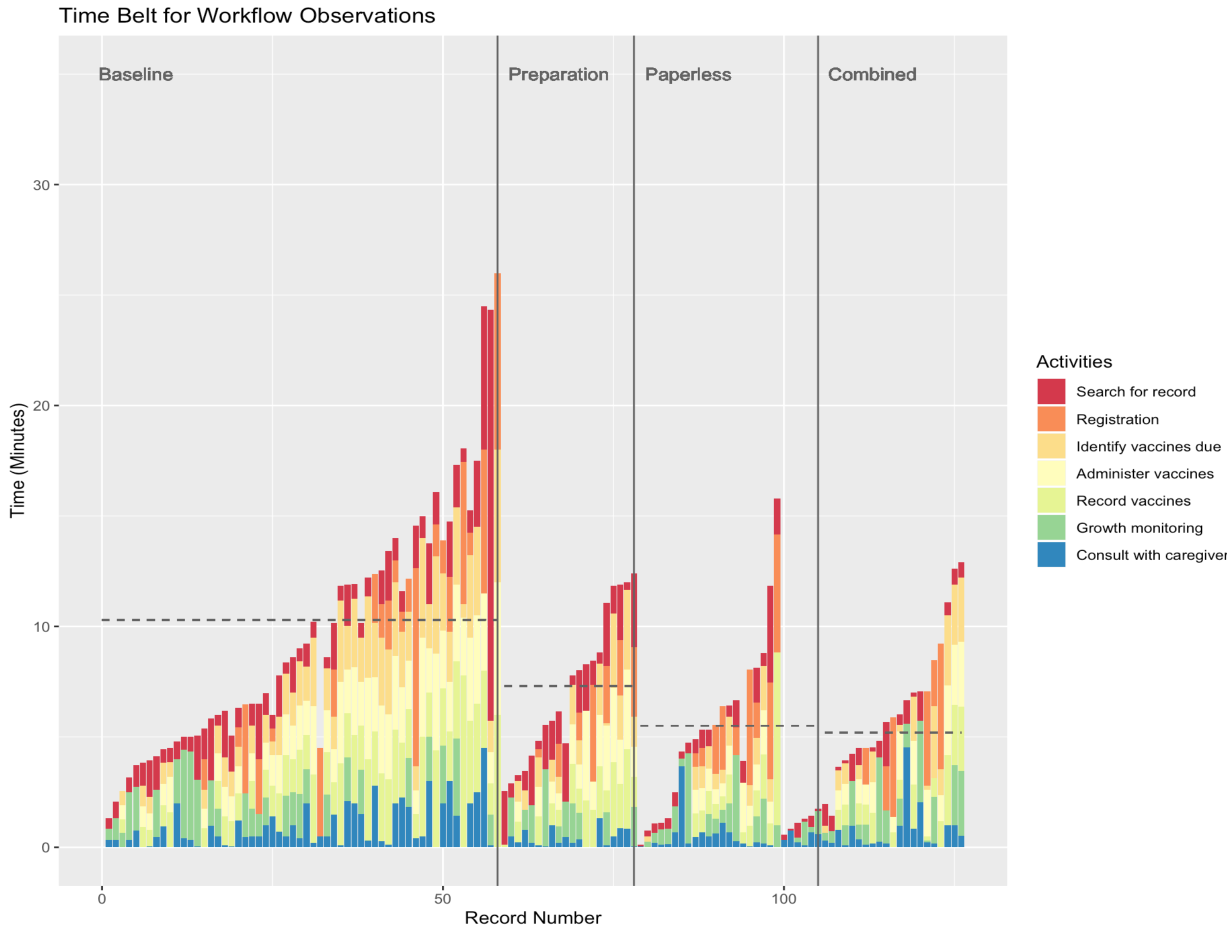
Vaccines administered					
Yes	46 (79%)	15 (75%)	12 (57%)	15 (56%)	88 (70%)
No	12 (21%)	5 (25%)	9 (43%)	12 (44%)	38 (30%)
Number of vaccines administered*					
Mean [Min, Max]	2 [0, 5]	2 [0, 3]	1 [0, 3]	1 [0, 4]	2 [0, 5]
Clinic environment*					
Good	44 (76%)	14 (70%)	15 (71%)	27 (100%)	100 (79%)
Messy, crowded, and/or noisy	14 (24%)	6 (30%)	6 (29%)	0 (0%)	26 (21%)
EIR performance*					
Working, but not synching	30 (52%)	9 (45%)	14 (67%)	22 (82%)	75 (60%)
Not working or synching	12 (21%)	0 (0%)	0 (0%)	0 (0%)	12 (10%)
Partially working and synching	5 (9%)	9 (45%)	2 (10%)	0(0%)	16 (13%)
Working and synching	11 (19%)	2 (10%)	5 (24%)	5 (19%)	23 (18%)
Number of HCWs working in clinic					
1 HCW	34 (59%)	6 (30%)	12 (57%)	16 (59%)	68 (54%)
More than 1 HCW	24 (41%)	14 (70%)	9 (43%)	11 (41%)	58 (46%)

*Statistically significant difference between workflow types; ANOVA for unbalanced designs used for number of vaccines administered and a chi-square test was used for all other variables

Time Utilization for Baseline Workflows

At baseline, the mean time taken to complete a session was 10.29 minutes (Figure 3.2, Table 3.4). Differences were observed by facility size, small facilities took 12.03 minutes per session to serve a patient, medium facilities took 9.69 minutes, and large facilities took 9.68 minutes. Those facilities with ≥3 months of experience served patients over 2 minutes faster than those with <3 months experience, 9.25 versus 11.40 minutes, respectively. Registration took the longest to complete (2.79 minutes), followed by administering vaccinations (2.27 minutes), recording vaccines administered (2.33 minutes), growth monitoring (1.95 minutes), and identifying vaccines due (2.15 minutes). Searching for a record and providing a consult took the least time, 1.68 minute and 1.05 minute, respectively. Based on descriptive comparison of time use, it appeared that facilities with less experience typically took more time to record vaccines and providing a consult, compared to those with more experience using the EIR. On average, HCWs proportionately spent the longest amount of time on registration (22%) and growth monitoring activities (32%) (Appendix Table 3.B).

Figure 3.2 Time Belt for each Session by Workflow Type*



*Dashed lines indicate the mean amount of time for each workflow type.

Table 3.4 Time utilization for immunization clinic activities by workflow type and facility characteristics, minutes, mean (standard deviation)

Workflow Type	Facility Characteristic	Number of Sessions	Search	Registration	Identify vaccines due	Administer vaccines	Record vaccines	Growth monitoring	Consult	Complete workflow
Baseline	**All**	58	1.68 (2.60)	2.79 (2.23)	2.15 (1.26)	2.27 (1.19)	2.33 (1.40)	1.95 (0.87)	1.05 (0.99)	10.29 (1.33)
	Small	15	3.45 (4.81)	3.55 (1.80)	2.52 (0.93)	2.63 (0.93)	2.63 (0.93)	1.91 (0.88)	1.44 (1.29)	12.03 (7.67)
	Medium	21	0.95 (0.57)[c]	1.28 (0.26)	2.36 (1.19)	2.36 (1.19)	2.36 (1.19)	2.12 (0.99)	1.06 (0.93)	9.69 (5.44)
	Large	22	1.22 (0.62)	3.70 (2.80)	1.83 (1.39)	2.04 (1.29)	2.19 (1.72)	1.60 (0.37)[c,d]	0.73 (0.65)[c]	9.68 (5.27)
	< 3 months using EIR	28	1.60 (1.27)	2.47 (2.08)	2.03 (1.26)	2.24 (1.16)	2.35 (1.52)	1.91 (0.92)[b]	1.23 (1.23)	11.40 (5.98)
	≥ 3 months using EIR	30	1.76 (3.49)	3.85 (2.65)	2.31 (1.27)	2.31 (1.27)	2.31 (1.27)	1.97 (0.87)[b]	0.91 (0.73)	9.25 (5.95)
Preparation	**All**	20	1.15 (0.89)	1.75 (1.10)	1.58 (1.02)	1.99 (1.09)	1.53 (0.98)	1.37 (0.91)	0.45 (0.39)	7.27 (2.55)
	Small	8	1.28 (0.85)	NA	2.24 (1.28)	2.57 (1.19)	2.57 (1.19)	1.49 (0.41)	0.70 (0.36)	6.90 (3.61)
	Medium	4	1.06 (0.86)	0.96 (0.90)	1.71 (0.34)	1.71 (0.34)	1.71 (0.34)	2.64 (1.21)	0.30 (0.39)	7.50 (3.18)
	Large	8	1.11 (0.97)	2.15 (1.03)[c]	0.85 (0.47)	1.77 (1.23)	1.01 (0.61)	0.87 (0.67)	0.18 (0.13)[c]	7.53 (3.44)
Paperless	**All**	21	0.90 (0.97)	2.71 (1.86)	1.00 (0.45)[a]	1.18 (0.51)[a]	1.59 (2.00)	1.29 (1.18)	0.53 (0.82)	5.53 (0.12)[a]
	Small	9	0.54 (0.18)	0.72 (0.15)	1.10 (0.14)	1.10 (0.14)	1.10 (0.14)	0.81 (0.37)	0.79 (1.11)	3.60 (2.09)[a]
	Medium	7	1.17 (1.62)	3.63 (2.10)	1.04 (0.73)	1.31 (0.61)	1.31 (0.61)	2.56 (1.80)	0.13 (0.09)	5.85 (4.28)
	Large	5	1.42 (0.36)	3.00 (1.63)	0.82 (0.32)	1.18 (0.76)	2.16 (3.18)	0.86 (0.27)	0.53 (0.43)	8.55 (4.16)
Combined	**All**	27	0.62 (0.49)	3.37 (1.66)	1.33 (1.03)[a]	1.70 (0.86)[a]	1.40 (0.92)[a]	1.35 (1.16)	0.70 (0.92)	5.21 (0.57)[a]
	Small	8	0.65 (0.38)	NA	0.98 (0.90)	1.75 (0.60)	1.28 (0.63)	0.96 (0.63)	1.11 (1.41)	4.05 (2.48)[a]
	Medium	11	0.73 (0.35)	4.01 (1.80)	1.53 (1.23)	2.42 (0.80)	1.84 (1.25)	1.76 (1.61)	0.65 (0.59)	7.02 (4.39)
	Large	8	0.46 (0.76)[e]	2.72 (1.55)	1.07 (0.28)[a]	0.96 (0.26)	0.96 (0.26)	1.09 (0.23)	0.29 (0.29)	3.90 (1.66)[a]
		126	119	46	83	83	88	75	113	

[a] Significant difference observed compared to the baseline workflow using an ANOVA for unbalanced designs
[b] Significant difference observed between lengths of experience using an ANOVA for unbalanced designs
[c] Significant difference observed compared to small facilities using an ANOVA for unbalanced designs
[d] Significant difference observed compared to medium facilities using an ANOVA for unbalanced designs
[e] Significant difference observed compared to preparation workflow using an ANOVA for unbalanced designs

Time Utilization for Modified Workflows

Among the modified workflows, all were typically faster than baseline, and the combined workflow was the fastest, taking 5.21 minutes to complete (Figure 3.2, Table 3.4). The preparation workflow took 7.27 minutes and the paperless workflow took 5.53 minutes, which were significantly different compared to the baseline workflow. For individual activities, the times for all activities except registration were typically faster during the modified workflows compared to the baseline workflow (Table 3.4). There were significant differences for identifying vaccines due, administering vaccines, and recording vaccines for the combined and paperless workflows compared to baseline. There were some significant differences between facility sizes within each workflow, but only for the baseline and preparation workflows.

Similar to the baseline workflows, for each child seen, users proportionately spent the longest amount of time on registration and growth monitoring activities for the paperless and combined workflows, while spending more time searching for records and growth monitoring for the preparation workflow (Appendix Table 3.B). For each modified workflow compared to baseline, improvements in the proportion of time spent on individual activities were observed for registration and growth monitoring (Appendix Table 3.C).

Comparisons between Workflows

The result of the multivariate linear mixed-effects regression analysis confirmed that there were statistically significant differences in session times between the modified workflows compared to baseline, controlling for session- and facility-level characteristics (Table 3.5). A decrease in total session time was observed for all modified workflows, with an estimated reduction of 5.44 minutes for paperless, 4.32 minutes for combined, and 3.39 minutes for preparation. Reductions in time were most frequently observed for individual activities for the paperless and combined workflows for searching for records, identifying vaccines due, recording vaccines, and growth monitoring.

Table 3.5 Multivariate linear mixed-effect model estimates, minutes (95% CI)

		Dependent variable:							
		Amount of Time per Activity							Total Session Time
		Search	Registration	Identify Vaccines due	Administer Vaccines	Record Vaccines	Growth Monitoring	Consult	
		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Constant	1.95 (-1.91, 5.80)	-1.82 (-9.54, 5.89)	3.34* (1.14, 5.55)	2.78* (1.63, 3.93)	2.41* (0.41, 4.41)	-3.10* (-6.03, -0.18)	1.05 (-0.44, 2.53)	6.00* (0.40, 11.61)
Workflow type (compared to baseline)	Modification- Preparation	-1.59 (-3.19, 0.02)	-0.93 (-4.40, 2.54)	-0.81 (-1.68, 0.06)	-0.09 (-0.84, 0.66)	-0.51 (-1.53, 0.51)	-2.01* (-3.03, -1.00)	-0.84* (-1.47, -0.21)	-3.39* (-5.92, -0.86)
	Modification- Paperless	-1.76* (-3.15, -0.37)	-2.49 (-5.49, 0.50)	-2.26* (-3.08, -1.43)	-1.20* (-2.00, -0.39)	-2.09* (-3.09, -1.08)	-1.24* (-1.84, -0.64)	-0.46 (-0.97, 0.04)	-5.44* (-7.62, -3.27)
	Modification- Combined	-1.60* (-2.79, -0.41)	-2.40 (-5.98, 1.18)	-1.30* (-1.95, -0.64)	-0.54 (-1.27, 0.18)	-1.43* (-2.26, -0.60)	-1.10* (-1.61, -0.60)	-0.16 (-0.60, 0.28)	-4.32* (-6.28, -2.36)
Session characteristics	EIR not synching (compared to not working)	0.29 (-1.53, 2.10)	3.86* (1.62, 6.10)	0.29 (-0.65, 1.23)		0.89 (-0.19, 1.98)	1.09 (-0.04, 2.22)	0.30 (-0.45, 1.06)	5.85* (2.93, 8.76)
	EIR partially working (compared to not working)	0.63 (-1.68, 2.93)	1.75 (-2.79, 6.30)	-0.56 (-1.78, 0.66)		-0.12 (-1.30, 1.06)	2.20* (0.47, 3.93)	1.02 (0.10, 1.94)	5.81* (2.62, 8.99)
	EIR working (compared to not working)	-0.44 (-2.97, 2.09)	1.07 (-3.34, 5.48)	-1.20 (-2.56, 0.17)		-0.81 (-2.50, 0.89)	-0.40 (-1.76, 0.95)	0.30 (-0.74, 1.33)	3.55 (-0.45, 7.56)
	Child has home-based record	-0.71 (-3.01, 1.60)	0.28 (-1.88, 2.43)	-0.66 (-1.65, 0.33)		-0.45 (-1.56, 0.66)	0.67 (-0.48, 1.82)	-0.12 (-0.97, 0.72)	-0.91 (-4.21, 2.39)
	First visit, with registration (compared to returning and registered patient)	0.65 (-0.62, 1.93)		0.81* (0.21, 1.41)		0.73 (-0.02, 1.48)	0.59 (-0.18, 1.36)	0.05 (-0.40, 0.49)	3.09* (1.16, 5.03)
	First visit or new registration (compared to returning and registered patient)	0.65 (-0.75, 2.06)		0.46 (-0.24, 1.15)		0.67 (-0.17, 1.51)	-0.42 (-1.31, 0.47)	-0.15 (-0.76, 0.46)	2.05 (-0.27, 4.37)
	Vaccines administered			-0.42 (-1.59, 0.76)					1.62 (-1.07, 4.31)
	Number of vaccines administered			0.33* (0.10, 0.56)	0.25* (0.02, 0.48)	0.39* (0.10, 0.67)			1.40* (0.57, 2.23)
	Good clinic environment (compared to poor)	-0.77 (-2.47, 0.92)	0.06 (-3.76, 3.88)	-1.65* (-2.55, -0.74)	-0.91 (-1.68, -0.14)	-1.52* (-2.48, -0.56)	-0.94 (-2.17, 0.29)	-0.08 (-0.72, 0.55)	-2.99* (-5.42, -0.56)
	More than 1 HCW in workflow (compared to 1 HCW)	-0.50 (-1.68, 0.68)	-0.40 (-2.33, 1.54)	-0.73* (-1.43, -0.02)	-0.57 (-1.23, 0.09)	-0.76 (-1.52, -0.01)	0.29 (-0.38, 0.96)	0.19 (-0.31, 0.69)	-0.40 (-2.31, 1.51)
Facility characteristics	Facility Type- Health centre (compared to dispensary)	-0.16 (-4.09, 3.77)	0.70 (-8.38, 9.78)	2.03 (-0.04, 4.10)	1.32 (-0.24, 2.87)	2.05 (0.03, 4.07)	-0.94 (-3.45, 1.57)	1.00 (-0.60, 2.61)	10.83* (5.62, 16.05)
	Facility Type- County referral hospital (compared to dispensary)	0.19 (-4.02, 4.40)	2.22 (-8.34, 12.77)	1.00 (-1.15, 3.16)	0.52 (-1.12, 2.16)	1.63 (-0.42, 3.68)	0.05 (-2.26, 2.35)	1.80 (0.11, 3.48)	10.21* (4.59, 15.82)
	Facility Size- Large (compared to Small)	-1.24 (-5.75, 3.28)	-0.79 (-12.12, 10.54)	-3.20 (-5.63, -0.77)	-1.66 (-3.43, 0.12)	-3.61* (-5.86, -1.36)	-0.69 (-3.04, 1.65)	-2.00 (-3.78, -0.22)	-15.48* (-21.49, -9.47)
	Facility Size- Medium (compared to Small)	-0.77 (-4.70, 3.17)	-0.19 (-9.02, 8.64)	-1.85 (-3.95, 0.25)	-1.18 (-2.71, 0.34)	-2.27 (-4.23, -0.31)	1.69 (-0.75, 4.14)	-1.36 (-2.96, 0.24)	-11.39* (-16.37, -6.42)
	Adequate staff available	1.12 (-1.01, 3.25)	0.64 (-4.76, 6.03)	0.92 (-0.33, 2.16)	-0.09 (-1.05, 0.88)	1.19 (-0.06, 2.44)	2.31* (1.46, 3.15)	0.38 (-0.41, 1.17)	2.90* (0.56, 5.25)
	More than 3 months using EIR (compared to less than 3)	1.61 (-1.06, 4.28)	2.23 (-2.91, 7.36)	0.91 (-0.51, 2.33)	0.06 (-0.82, 0.94)	0.50 (-0.95, 1.96)	3.46* (1.71, 5.21)	-0.17 (-1.18, 0.83)	-1.80 (-4.73, 1.12)
	Observations	110	42	81	79	83	70	105	124

For the other predictors of change in time, when the EIR was not synching or partially working it increased the total workflow time by 5.85 and 5.81 minutes, respectively; there were no additional significant differences when pairwise comparisons were assessed. Additionally, for the total workflow time, registering a patient at their first visit increased the time by 3.09 minutes, each additional vaccine administered increased time by 1.40 minutes, while a good clinic environment decreased the amount of time by 2.99 minutes. Health centres and county referral hospitals had increased workflow times compared to dispensaries, 10.83 and 10.21 minutes, respectively. While we observed decreases in time at large and medium sized facilities of 15.48 and 11.39 minutes, respectively. Having adequate staffing levels increased the total workflow time by 2.90 minutes.

Across the individual activity models, results varied. There were significant reductions for searching for records, identifying vaccines due, recording vaccines, and growth monitoring for the paperless and combined workflows, decreases ranging from 1.10-2.26 minutes. For each additional vaccine administered, the time taken to identify vaccines due, administer the vaccines, and record the vaccines increased activity times by 0.25-0.39 minutes and a good clinic environment reduced the time by 1.65 and 1.52 minutes for identifying and recording vaccines, respectively.

DISCUSSION

Findings

Our study found that for HCWs using an EIR, the introduction of modified workflows decreased the amount of time needed to provide services to children seen in the immunization clinic. The prolonged use of dual data-entry workflow is not ideal from a user or program perspective, but is a mechanism to ensure that immunization records are maintained while the EIR's reliability is tested. This study provides evidence for ensuring the reliability of an EIR as quickly as possible and allow facilities to move to a paperless workflow. With a baseline mean time of 10 minutes spent per child, this decreased by about 3 minutes when the preparation modification was introduced and almost 5 minutes for the paperless and combined modifications. Our initial hypothesis that there would be differences seen at baseline by size of facility and length of experience was confirmed. At baseline larger facilities and those with more experience using the EIR tended to serve patients faster (although not statistically significant), as would be expected if we assumed increased experience, either by patient volume or length of time using the EIR, would lead to more efficient workflows. Differences were also observed during the modified workflows, however the trends were reversed for the preparation and paperless workflows, where larger facilities took more time to complete activities, while medium sized facilities took the longest for the combined workflow. Our model estimates indicated large time utilization differences, in opposite directions, with health centres and referral hospitals having longer times, while large and medium sized facilities had shorter times, despite these characteristics being related. Although this warrants further investigation, we hypothesize that facility size better reflects efficiencies created by high patient volumes and possibly more staff, while facility type is strictly a government designation that could categorize facilities of varying capacity together.

Our expectation that the paperless workflow would decrease the total workflow time was realized, as this was the only workflow where a single data source was used throughout an immunization session. This further emphasized that users should switch to the intended future paperless workflow once managers are satisfied with EIR data quality and performance, and have proper guidance in place. We also observed a small synergistic effect for the combined workflow, leading us to conclude that the optimal workflow is paperless with a child having complete and up-to-date information in the EIR. We also conducted a qualitative study as part of this project to understand the major barriers and facilitators to EIR-use among HCWs; based on our qualitative findings there were no differences observed in users' perceptions of the combined workflow compared to the others[76]. Our finding that larger facilities took more time than small facilities to complete immunization sessions for the modified workflows could possibly be due to the added complexities of introducing workflow changes into already busy and/or crowded settings, where it may take more time to adapt to a change when other environmental factors are at play. Additionally, our finding that sessions with adequate staffing levels increased workflow times was counterintuitive, as we would have expected times to decrease; however, this could potentially be due to facilities having pre-existing limited staffing levels that were anecdotally noted to strain clinic staff.

Results pertaining to the EIR's performance and ability to connect to the internet were particularly insightful about potential causes of delays. Facilities with poor internet access may have experienced delays when the EIR tried to synch records stored in the central server, subsequently causing workflow times to increase and may have led to the large variability we observed in workflow times. When the EIR was fully functional and synching with the server, activities took less time. Our qualitative study found that HCWs felt more time pressure, frustration, and that more effort was required when there were connectivity issues, and that these feelings were exacerbated when there were many patients to be seen or staffing shortages[70].

Our study was guided by multiple DHI-related theories and those data that we could readily collect. These theories provided meaningful structure for designing data collection instruments and our findings reinforced the importance of studying the linkages between individuals, tasks, and technology, as well as taking into consideration the broader environmental and organization context. Our qualitative paper describes the underlying mechanisms linking workflow processes to outcomes in more detail[70].

Time-savings

This study highlights where areas of potential time-savings can be found for immunization clinics using an EIR. In addition to improving EIR performance at the POC to save time, alternative mechanisms for registering children in the EIR should be explored. In terms of session-specific efficiency gains, additional time savings could be observed if facilities were willing to change the order patients were seen for services; for instance, in a clinic with two nurses, if patients needing to be registered were attended to by one HCW, while pre-registered children were seen by another HCW for vaccinations, potentially time could be saved but this would need to be tested. Future studies could consider quantifying EIR/internet performance to determine when to expect time-savings and create a minimum performance standard that could be used to help decision-makers decide when and if this type of technology should be introduced as a paperless alternative to paper-based records. Projecting time-savings and subsequent cost-savings would be important for demonstrating the value of the system.

There are no other published studies that have specifically assessed time-utilization between a dual-data entry workflow and a paperless workflow, however there are evaluation reports in the grey literature of time-utilization following the introduction of an EIR implemented in Afghanistan, the Gambia, and Uganda[72-74] comparing paper-based to paperless data management activities. In each country reductions in time utilization for a child's first immunization visit were observed, ranging from 1:45 to 6:21 minutes. The authors estimated that in Afghanistan the EIR would save 2.9 million USD over five years, which would be 0.40 USD per child, based on the value of the time saved from completing data administration tasks, and 2.1 million USD, 0.28 USD per child, in Uganda.

Numerous studies have estimated the time-savings of implementing electronic health record systems (EHR), with varied results. A systematic review of the impact of EHRs on documentation time found that when physicians and nurses used bedside terminals and central station desktops, they saved around 24% of their overall time spent documenting during their shift, but when they used POC systems, their documentation time increased by 18%[65]. While a study of an electronic medication management system found no significant change in the proportion of time clinicians spent on direct care or medication-related tasks[77]. Furthermore, evaluations conducted soon after introduction of a technology initially observed reductions in documentation time, however increases were observed among those evaluations taking place after a longer period of time had passed between introduction and evaluation[77].

Future Research

In light of our study's findings and the discrepancies in time-savings found in the literature, there is further need for DHI researchers to use methodology that assists with understanding the relationship between intervention innovation and service innovation[28]. Both HCD and implementation science methods need to be used together to better understand this relationship, where HCD methods are used to study an intervention's acceptability in a lab-based setting while implementation science methods aim to understand if an intervention is effective in a healthcare delivery setting. Other DHI researchers have pointed out that taking a service design approach that explicitly acknowledges how new interventions need to be adapted to fit their setting can bridge the gap between methodologies and researchers should in fact be evaluating the interaction between a DHI and established healthcare service delivery routines[28]. Conducting clinical simulations, similar to our study, can provide researchers a low-cost approach to evaluating DHI in complex healthcare systems and generate evidence needed between formative and large-scale implementation stages[78].

Although time-use was our study's outcome of interest, quantifying time-savings may not always be the best metric for assessing the impact of a DHI. Time-savings may be realized within a well-functioning healthcare system with adequate resources, however for systems lacking these assets, DHI may increase the amount of time needed to perform routine tasks because they add complexity to HCW duties. Time is a finite resource that has implications for budgeting and reaching every child in need of health services but measuring time may not be the ideal metric when attempting to improve the quality of healthcare services. Monitoring changes in data quality to understand the accuracy and completeness of records, or how time is used to improve service quality, such as measuring whether caregiver consultations cover all recommended topics, could be alternative metrics. Researchers studying DHI should be encouraged to measure intermediate metrics over the course of an intervention's introduction and scale-up to understand if the DHI is achieving high fidelity before assessing efficiencies and impact.

We sought to examine the use of time for patient-facing activities during an immunization session, this was used as a proxy for overall client time in the facility, since we did not measure patient waiting time. Typically, DHIs seek to maximize patient-time with a provider, while minimizing total time to seek services. Our study of patient-time was focused on whether the workflow modifications could reduce the total session time and whether time to complete data-management activities could be reduced. Since we did not design this study to maximize patient-time with a provider, future interventions should consider how workflows can be modified to repurpose time used for data management activities into time used for patient-facing consultation.

Study Strengths

We were able to conduct a fairly quick clinical simulation exercise of introducing modified workflows and estimating their impact on time utilization in immunization clinics using an EIR. This study demonstrated the necessity of assessing and incorporating contextual factors in order to adequately understand the impact of a new technology on a healthcare setting in a LMIC. Additionally, the study provided pragmatic, policy-relevant evidence in support of the paperless data-entry workflow as quickly as possible once the EIR performance and internet connectivity issues have been solved.

Limitations

This study faced several limitations. Our sample size was halved due to the unexpectedly few children that visited immunization clinics daily, far below what routine health information system data estimated. Because of the nature of performing time-and-motion observations, this study potentially could have suffered from the Hawthorne effect because data collectors were required to stand in the immunization room and their presence could have influenced how the HCWs performed their tasks. Our study suffered from low fidelity of the EIR due to unexpected issues with the platform's performance and intermittent internet connectivity. Also, as this was a cross-sectional assessment, we are not able to assess how as HCWs become more familiar with the workflow modifications. Activity times had lower than ideal precision due to difficulty with capturing activities that occurred quickly in sequence or were simultaneous. The use of purposive sampling could have potentially introduced bias because it was non-randomized and facilities selected may not provide representative results.

CONCLUSION

Using a time-and-motion study we were able to demonstrate the necessity of modifying immunization clinic workflows to actualize value when introducing an electronic system. We found that the paperless workflow provided the largest time savings when delivering services, although this was threatened by poor EIR performance and internet connectivity. This study demonstrated the benefit of evaluating a DHI in different settings in order to better understand and find the best fit between user tasks and the technology, ultimately demonstrating that not only should DHI be built and adapted for particular use-cases, but that existing user workflows also need to adapt to new technology.

APPENDIX

Table 3.A Workflow Time Estimates for Sample Size Calculations

Workflow	**1 (Baseline)**	**2 (Workflow Redesign 1)**	**3 (Workflow Redesign 2)**
Facility Size			
Small	8 min	7 min	7 min
Medium	6 min	5 min	4 min
Large	5 min	4 min	4 min

We used an online computation tool for linear models to calculate the estimated sample size needed for testing a difference in time utilization between workflow types; we accounted for clustering by HCW and workflow type [71]. The sample size calculation was performed using a significance level of 0.05 and 80% power. To account for clustering at the HCW level, we estimated an intracluster correlation of 0.8 for all observations from each HCW and assumed that we would observe each HCW vaccinate 10 children. The size of a facility (categorical) was entered as a between-participant factor (fixed predictor) as we wanted to assess changes in time by facility size, we assumed that there would be an equal number of HCWs observed in each category. We estimated the mean values for each outcome within each group based on the EIR time-use estimates reported in the literature (see Appendix Table 1)[72-74]. We expected a correlation of 0.5 between workflow types for each HCW, and a constant standard deviation across observations of 1 minute. Based on our specifications, our sample size was computed to be 9 HCWs, 3 per facility size. We added an additional 3 HCWs in case of attrition, for a total of sample size of 12 HCWs.

Table 3.B Mean proportion of time spent on each activity for an individual workflow

Workflow Type	Facility Characteristic	Number of Workflows	Search	Registration	Identify vaccines due	Administer vaccines	Record vaccines	Growth monitoring	Consult
Baseline	All	58	18%	22%	19%	20%	21%	32%	11%
	Small	15	28%	32%	17%	17%	17%	29%	13%
	Medium	21	14%	11%	21%	21%	21%	36%	12%
	Large	22	16%	28%	19%	21%	22%	25%	10%
	< 3 months using EIR	28	17%	20%	19%	20%	21%	24%	10%
	>= 3 months using EIR	30	20%	31%	20%	20%	20%	34%	12%
Preparation	All	20	25%	24%	20%	23%	20%	29%	7%
	Small	8	24%		26%	26%	26%	38%	12%
	Medium	4	18%	14%	22%	22%	22%	43%	3%
	Large	8	30%	28%	13%	22%	16%	14%	3%
Combined	All	27	19%	49%	19%	24%	19%	30%	20%
	Small	8	23%		16%	30%	22%	24%	30%
	Medium	11	21%	49%	18%	23%	16%	26%	19%
	Large	8	11%	50%	26%	22%	22%	42%	11%
Paperless	All	21	23%	32%	17%	17%	18%	33%	14%
	Small	9	21%	14%	20%	20%	20%	36%	22%
	Medium	7	30%	40%	19%	14%	14%	50%	7%
	Large	5	15%	35%	12%	17%	19%	11%	8%
		126	119	46	83	83	88	75	113

Table 3.C Difference in Mean Proportion Time Used between Baseline and Each Modified Workflow

Workflow Type	Facility Characteristic	Search	Registration	Identify vaccines due	Administer vaccines	Record vaccines	Growth monitoring	Consult
Preparation	All	7%	2%	1%	3%	-1%	-2%	-4%
	Small	-4%	-32%	8%	9%	9%	9%	-1%
	Medium	4%	4%	2%	2%	2%	7%	-8%
	Large	14%	0%	-5%	1%	-7%	-11%	-6%
Combined	All	1%	27%	0%	4%	-1%	-2%	9%
	Small	-5%	-32%	-1%	13%	5%	-5%	17%
	Medium	8%	38%	-3%	2%	-4%	-10%	7%
	Large	-5%	22%	8%	1%	0%	17%	1%
Paperless	All	4%	10%	-2%	-3%	-3%	1%	3%
	Small	-8%	-18%	3%	3%	3%	7%	9%
	Medium	16%	30%	-2%	-7%	-7%	14%	-5%
	Large	-1%	7%	-7%	-4%	-4%	-14%	-1%

Chapter 4: Changes in on-time vaccination following the introduction of an electronic immunization registry, Tanzania 2016-2018: Interrupted time-series analysis

ABSTRACT

Digital health interventions (DHI) have the potential to improve the management and utilization of health information to optimize health care worker performance and provision of care. Despite the proliferation of DHI projects in low-and middle-income countries, few have been evaluated in an effort to understand their impact on health systems and health-related outcomes. Although more evidence is needed on their impact and effectiveness, the use of DHIs among immunization programs has become more widespread and shows promise for improving vaccination uptake and adherence to immunization schedules. Our aim was to assess the impact of an electronic immunization registry (EIR) using an interrupted time-series analysis to analyze the effect on proportion of on-time vaccinations following introduction of an EIR in Tanzania. We hypothesized that the introduction of the EIR would lead to statistically significant changes in vaccination timeliness at 3, 6, and >6 months post-introduction. For our primary analysis, we observed a decrease in the proportion of on-time vaccinations following EIR introduction. In contrast, our sensitivity analysis estimated improvements in timeliness among those children with complete vaccination records. However, we must emphasize caution interpreting these findings as they are likely affected by implementation challenges. This study highlights the complexities of using digitized individual-level routine health information system data for evaluation and research purposes. EIRs have the potential to improve vaccination timeliness, but analyses using EIR data can be complicated by data quality issues and inconsistent data entry leading to difficulties interpreting findings.

INTRODUCTION

As information technology becomes more accessible, health programs are adopting digital health interventions (DHIs) to improve the provision and demand for health services[16]. DHI have the potential to improve the management and utilization of health information to optimize health care worker (HCW) performance and provision of care, and ultimately improve health outcomes. The importance of digital technologies was highlighted in 2018 by the World Health Assembly, noting that these tools could be integrated into existing health systems and scaled-up to help achieve the Sustainable Development Goals[7]. Despite the proliferation of DHI projects in low-and middle-income countries (LMICs), few have been evaluated in an effort to understand their impact on health systems and health-related outcomes[8, 11, 16]. Although more evidence is needed on the impact and effectiveness of DHIs within existing healthcare settings, the use of DHIs among immunization programs has become more widespread and shown promise for improving vaccination uptake and adherence to immunization schedules[14, 15, 79].

Globally 86% of children in 2018 received recommended childhood vaccinations, falling below the Global Vaccines Action Plan national goal of 90%[80, 81]. In Africa, 84% of children received their first dose of pentavalent vaccine, while only 76% received the third dose in the recommended series[82]. Receiving a vaccination on-time ensures a child has an optimal immune response and that they can be protected from vaccine-preventable diseases as quickly as possible[83]. To better track children's vaccination histories and identify those children behind on their schedules, electronic immunization registries (EIRs) have been introduced among some immunization programs in LMICs to replace health facilities' paper-based tools. EIRs are "confidential, population-based and computerised systems that collect vaccination data about residents within a geographic area or with a healthcare provider" and allow for the monitoring of vaccination coverage by provider, vaccine, dose, age, target group, and geographical area, and facilitate the monitoring of individuals receiving immunizations[25, 63, 64].

DHIs have ushered in a data "revolution" that introduces new possibilities, and potential hurdles, for public health research[10]. They have the potential to improve data quality and provide greater insight into program performance as they aim to efficiently capture and report standardized, individual-level health data[15, 25, 84-87]. The global community has recommended that the effectiveness of EIRs for monitoring immunization programs be demonstrated in comparison to existing methods[88]. However, despite the potential of EIRs, the best approach to using data from these tools for analytics has yet to be determined. They offer a promising change from the typical use of routine surveys and/or ad-hoc efforts to collect information in these settings and instead allow health programs with few resources to leverage existing, routinely collected data[10].

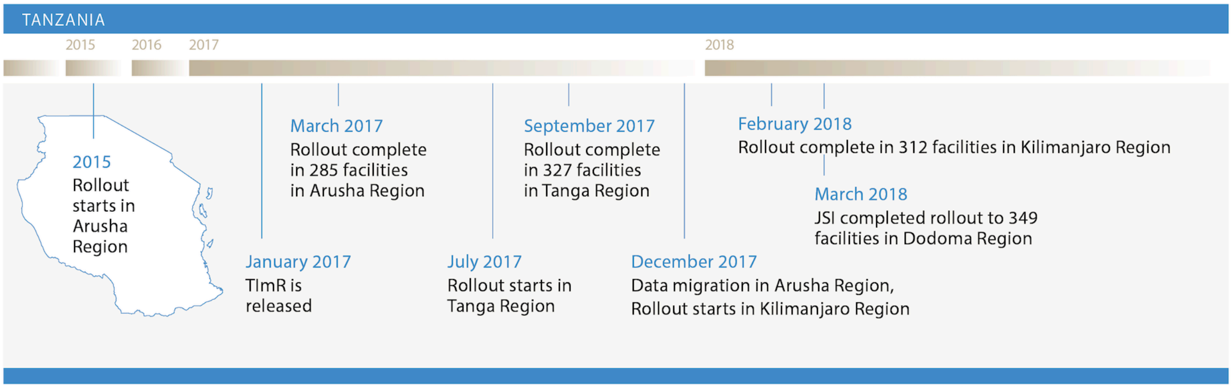
EIRs can hypothetically improve accessibility of vaccination data by HCWs, therefore these systems should allow HCWs to more easily identify vaccines due and follow-up with defaulters, thereby improving both immunization timeliness and coverage[13, 89]. One study based in Vietnam found that an EIR and a short-message service (SMS) reminder system improved coverage, however there are few studies that have assessed the effectiveness of EIRs on immunization timeliness[15]. For this study, we assessed the impact of a DHI on immunization timeliness by using an interrupted time-series analysis to investigate the proportion of on-time vaccinations following introduction of an EIR in Tanzania. We were also interested in showcasing how individual-level routine health information system (RHIS) data from EIRs could be analyzed and used for future research purposes.

Study Context and Intervention Description

The Better Immunization Data (BID) Initiative partnered with the Ministry of Health (MOH) in Tanzania to address key challenges in immunization data collection, quality, and use beginning in 2013[90]. The government identified areas of concern at the outset of the project were poor data quality, inaccurate denominator data, defaulter tracing, poor data visibility, complex data systems, and inadequate data management and use[69]. Digital technologies can help overcome these types of health system challenges, particular through interventions built for clients and health care providers[16].

The BID Initiative implemented an intervention package to address the challenges identified, including: establishment of user-advisory groups (UAGs); development of tablet-based EIR software, the establishment of the Tanzania Immunization Registry (TImR), with online and offline functionality that enabled automated, simplified reports; development of logistics management information systems; provision of targeted supportive supervision for HCWs; establishment of peer support networks (via WhatsApp groups); and support for a data-use culture[69]. By 2018, the package was deployed in the regions of Arusha, Dodoma, Kilimanjaro, and Tanga of Tanzania (Figure 4.1). Project staff used a phased roll-out approach to introduce the intervention package to each district within these regions. Completing paper-based forms and reports remained a requirement by the MOH throughout the project; therefore, all facilities completed dual data entry from the time of EIR introduction and onwards. The EIR allowed HCWs to register children, record vaccinations administered, quickly identify vaccinations due, and generate aggregate facility-level reports that fed into the health management information system. The intention of the EIR was to replicate and eventually replace the use of paper-based data collection tools used in immunization clinics, and in March 2018 facilities in the Tanga region of Tanzania started transitioning to entirely digital reporting. Additionally, beginning in April 2018 SMS vaccination reminders were sent automatically through the EIR's server to the caregivers of children with delayed vaccination visits.

Figure 4.1 Timeline of EIR Introduction



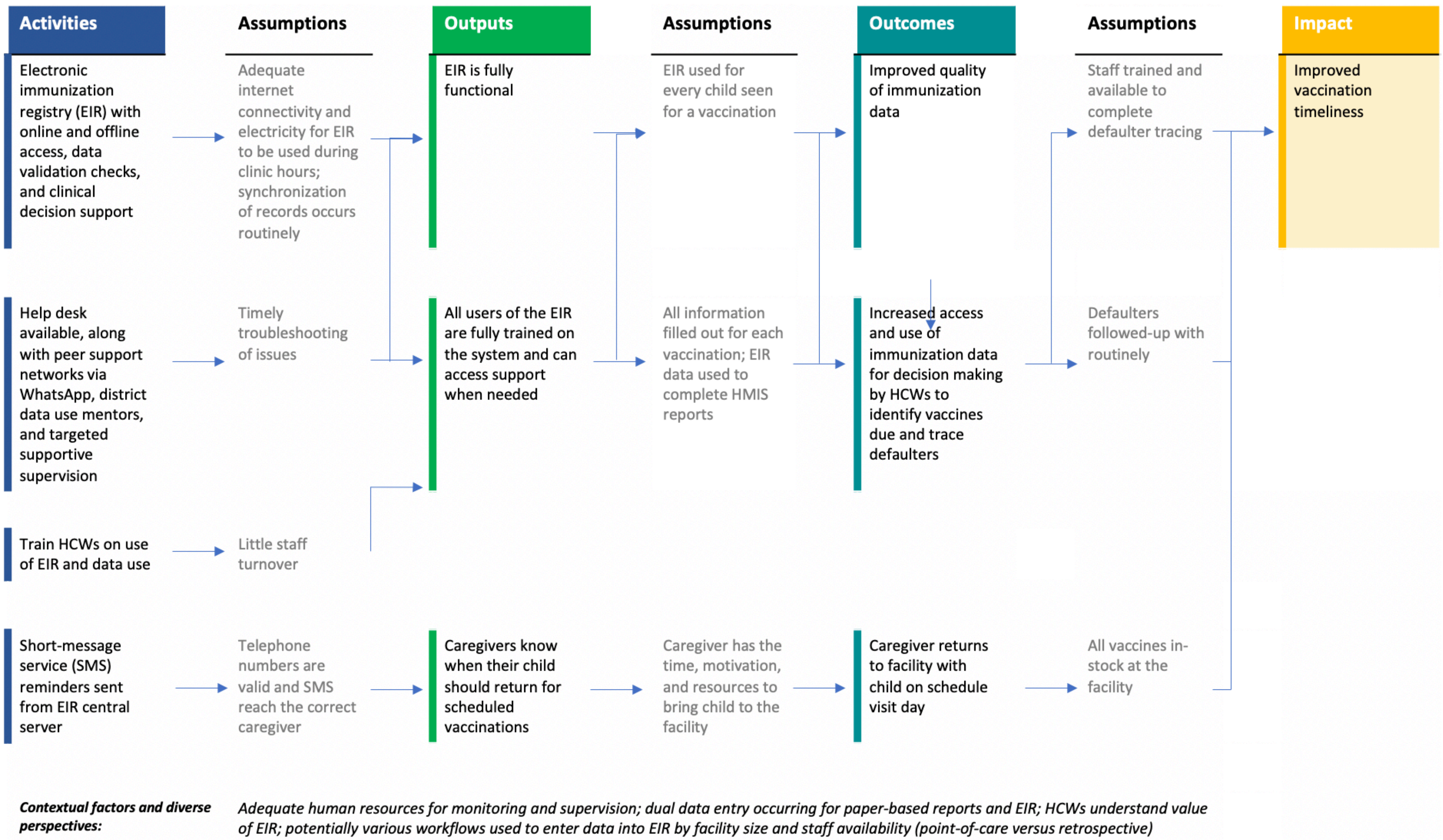
Note: JSI: John Snow, Inc.; TImR: Tanzania Immunization Registry;

Upon introduction of the EIRs, HCWs were instructed to register each child seen for immunization services and to retrospectively enter all vaccines the child had previously received in order to maintain a complete vaccination record for every child in the EIR. Facilities underwent a data back-entry process when the EIR was introduced, where all records included in the facility's paper-based vaccination register were input into the EIR in batches. When children were seen for services at the facility, they were assigned unique patient identifiers which were printed on barcode labels and provided to caregivers, so records could be quickly retrieved upon a child's subsequent visit at any facility using the EIR. Vaccination information was entered into the EIR for registered children returning to the facility either at the point-of-care (POC) or retrospectively on the same day after the immunization clinic ended. Within the EIR records there is no indication of whether a record was back-entered.

Theoretical Background

Our causal linkage diagram is specific to our study, including key assumptions, and describes our theory of change for the EIR (Figure 4.2), however a separate theory was developed for the BID intervention package[91]. Briefly, we believed that by introducing the BID intervention package, HCWs should have improved access to and use of data to identify vaccines due and follow-up with defaulters, therefore vaccination timeliness should improve. This theory makes the following assumptions: a) every child seen at a facility is entered into the EIR; b) all required information is entered into the system; and c) HCWs actively complete follow-up with defaulters, including the use of automated SMS-reminders.

Figure 4.2 Casual linkage diagram of the relationships and assumptions between implementation of an electronic immunization registry and improved vaccination timeliness



METHODS

Study Design

We used secondary data from the EIR as implemented in over 1000 health facilities to test the following hypothesis: the introduction of the EIR in Tanzania lead to improvement in vaccination timeliness after 3,6, and >6 months post-introduction. We used an interrupted time-series (ITS) analysis study design to measure changes over time. We chose this design for several reasons. First, we could not use any experimental designs that randomized intervention sites on practical grounds, as the MOH and BID Initiative dictated where and when the intervention would be introduced and our analysis began after implementation. Second, we had limited resources to collect new data, so we had to leverage existing routine health information system data and the EIR data. These constraints made a quasi-experimental study design like ITS a good choice as it is logistically easier to conduct than a randomized trial and minimizes threats to ecological validity [92].

Primary Analysis

We set up our primary analysis based on our hypothesized theory of change, but quickly found substantial levels of missingness in the data. Missingness could be either due to a child not receiving a vaccination or lack of recording. As such, we conducted a sensitivity analysis to attempt to address this limitation using only registered children with a subsequent vaccination dose recorded in the EIR as this likely meant their record had less missing information.

Data Acquisition and Population of Interest

All data available from the time the EIR was first used at each facility were acquired from the central EIR repository. Duplicate records, records with erroneous dates for vaccination or date of birth such as those with implausible or invalid dates, and records of children born before 2010 were all excluded. Only data from the regions of Arusha, Kilimanjaro, and Tanga were included, since these regions had more than 6 months of experience with the EIR at the time of analysis; these data included EIR records from January 2015-September 2018. Facilities with fewer than 6 months of data were excluded because they did not have enough data to be assessed at our 6-month endpoint, also we assumed that these facilities were still adjusting to the EIR and not consistently using the system to capture vaccinations. Observations were excluded if the date of vaccination (real or planned) occurred after the dataset was created. Children >2 years were excluded based on the assumption that their records may have been incomplete, since they were unlikely to visit a facility to receive vaccinations following introduction of the EIR. To assess time trends relative to EIR introduction across all implementation waves, time was centered relative to the date of EIR introduction for each health facility despite receiving the EIR at different times. Vaccinations administered before EIR introduction were captured from the retrospectively entered data; the original data were recorded in vaccination registers held at the facilities. Because we could not disentangle back-entered data from records entered in real-time, we relied on EIR-introduction date as a proxy.

Outcome Measure

We measured proportion of on-time vaccinations per facility per month for the 1st, 2nd, and 3rd doses of pentavalent vaccine, which covers diphtheria, tetanus, and whole-cell pertussis, hepatitis B, and *Haemophilus influenzae* type b (DTP); and 1st dose of measles-containing vaccine (MCV1). Timeliness of vaccination was based on each child's date of birth for the first dose in a series or the date of the previous dose administered in a vaccination series, e.g., time between DTP2 and DTP3 vaccination was calculated to determine timeliness, while time since birth was used to determine timeliness of DTP1 and MCV1. We used the MOH's definition of timeliness, vaccinations were considered on-time if they were administered within 7 days on the due date; doses administered early were included in our analysis, but not considered on-time.

Statistical Analysis

We summarized health facility characteristics by the number of children registered in the EIR, time since EIR introduction, primary power source, facility ownership (private or public), and facility type using data from RHIS, including the EIR. Counts and proportions were used to summarize facility characteristics within each region. Facility types were categorized based on government definitions; dispensaries were the lowest level of health service provision, health centers provide a wider range of services, and district or regional hospitals offer inpatient, outpatient, and specialized services[93]. Vaccination characteristics were summarized by vaccine type, region, and pre- or post-EIR time period.

We calculated the number of eligible children per vaccine type based on a child's age at the time EIR data were acquired of the EIR in September 2018 and recommended vaccination schedule for Tanzania[94]. On-time vaccinations were summarized by individual-level data transformed into counts and proportions with the denominator as all eligible children. The number of days after the scheduled date among eligible children and number of vaccinations administered per facility per month were summarized using means and standard deviations. Vaccination history missingness was summarized by the number of children with no vaccinations recorded, no vaccinations beyond birth doses, those with a second or third dose recorded, but missing an earlier dose in a vaccine series, and those receiving one, but not all vaccines due at a single visit.

To estimate the changes in vaccination timeliness, we fit a hierarchical binomial model with a logit link at the level of the health facility, where the outcome was proportion of on-time visits per facility per month. Recall that we hypothesized that the introduction of the EIR would lead to changes in vaccination timeliness over time. We chose to assess the time periods of 0-3, 4-6, and >6 months post EIR-introduction based on programmatic expectations for when EIR-users would become comfortable using a new technology at the POC and when we expected to see routine use of the system. To test this hypothesis we structured our model to estimate the immediate impact on the level of vaccination timeliness at each time period post EIR-introduction compared to pre EIR (level change) coded as a categorical variable, the slope of the change in successive months for each time period (slope change) was coded as sequentially numbered months during the time period and 0 before or after, and the secular trend in timeliness (time) was centered on the date of EIR-introduction as time 0 and coded sequentially throughout the entire study period. Random intercepts were included at the district and regional levels to account for clustering of observations.

The p_{ft} term represents our outcome of interest denoting the proportion of on-time vaccinations for each facility *f* (running from 1 to 937 facilities) at month *t* (running from -16 to 27, with month centered on the date of EIR introduction); β_0 estimates the mean level of the outcome; β_{1-4} are variables measuring slope changes for each time period *t* and facility *f*, $\beta_1(Time)$ estimates the baseline monthly secular trend in on-time vaccinations before EIR-introduction, β_2 (*TimeAfterIntro3mos*) estimates the slope change during months 0-3 post EIR-introduction, β_3(*TimeAfterIntro6mos*) estimates the slope change for months 4-6 following EIR-introduction, and β_4 (*TimeAfterIntrogt6mos*) estimates the slope change for >6 months post-introduction; β_{5-7} are intercept variables measuring immediate level changes in the proportion of on-time vaccinations post EIR-introduction for each time period *t* and each facility *f* compared to time pre EIR, segmenting time for 0-3 months (*3mosAfterIntro*), 4-6 months (*6mosAfterIntro*), and >6 months (*gt6mosAfterIntro*) following EIR-introduction. Random effects separately estimated the outcome for each district and region and were assumed to be normally distributed on the log-odds scale. No other covariates were included in the model for simplicity of interpretation.

$$Y_{ft} \sim Binomial(p_{ft}, N_{ft})$$

$$\begin{aligned} logit(p_{ft}) = \; & \beta_0 + \beta_1 Time_{ft} + \beta_2 TimeAfterIntro3mos_{ft} + \beta_3 TimeAfterIntro6mos_{ft} \\ & + \beta_4 TimeAfterIntrogt6mos_{ft} + \beta_5 3mosAfterIntro_{ft} + \beta_6 6mosAfterIntro_{ft} \\ & + \beta_7 gt6mosAfterIntro_{ft} + u_{fR} + u_{fD} \end{aligned}$$

$$u_{fR} \sim N(0, \sigma_R^2)$$

$$u_{fD} \sim N(0, \sigma_D^2)$$

$Y - number\ of\ on - time\ vaccinations$
$N - elgible\ children$
$p - proportion\ on\ time$
$\beta - parameters\ for\ fixed\ effects$
$u - normal\ independent\ and\ identically\ distributed\ random\ effects$
t – time (month for β_{1-4} *and time period for* β_{5-7}*)*
f – facility
R- region
D- district

Due to the amount of missing data found during our primary analysis, we conducted a sensitivity analysis to understand if timeliness differed among children with multiple vaccinations recorded. To conduct this analysis, we estimated timeliness of DTP1 among children with a documented dose of DTP2 in the EIR, which could have been retrospectively or prospectively entered. For the sensitivity analysis, we used the same model, but estimated the proportion of on-time visits only for DTP1 per facility among only children that had received DTP2.

All analyses were conducted in RStudio (version 1.1). The glmer function in the R lme4 package was used to model our binomial outcome for the four vaccines of interest, weighted by the number of eligible children. Significance was determined at a two-sided alpha value of 0.05.

Ethics

This study was determined to be non-human subjects research by PATH, as it is part of routine program evaluation. SD, RB, HL, and JS led the design, implementation, and interpretation of findings for this study and were not involved in the BID Initiative design or implementation.

RESULTS

Facility Characteristics

In Tanzania, 1,006 facilities within 20 districts and 3 regions had initiated using the EIR and were included in this study, totaling 251,815 children with vaccinations recorded in the EIR (Table 4.1). At the time of data extraction from the EIR database, facilities had used the EIR from 9 to 27 months. The most commonly used power source amongst facilities was grid power (33%). The majority of facilities were public, government-owned (66%) and were dispensaries (72%).

Table 4.1 Characteristics of health facilities using the electronic immunization registry (EIR) in Tanzania, by region*

Characteristics	Arusha	Kilimanjaro	Tanga	All Regions
Number of districts	6	6	8	20
Number of facilities	306	357	355	1,006
Number of children[1]	88,492	53,068	110,255	251,815
Date range of EIR records (including retrospectively entered data)	January 2015-September 2018	January 2015-September 2018	January 2015-September 2018	NA
Date range of EIR introduction	June 2016-March 2017	December 2017-February 2018	July 2017-August 2017	NA
Primary power source, n(col%)[2]				
Grid	102 (33%)	226 (63%)	-	328 (33%)
Solar	87 (28%)	22 (6%)	-	109 (11%)
None	11 (4%)	-	-	11 (1%)
Ownership type, n (col %)[3]				
Private - FBO	90 (29%)	70 (20%)	37 (10%)	197 (20%)
Public - Government	181 (59%)	201 (56%)	279 (79%)	661 (66%)
Facility type, n (col %)[4]				
Dispensary	218 (71%)	226 (63%)	280 (79%)	724 (72%)
Health center	47 (15%)	45 (13%)	36 (10%)	128 (13%)
Hospital	13 (4%)	14 (4%)	8 (2%)	34 (3%)

*Amongst those facilities that input at least one record into the EIR
[1]Children under 2 years as of the time the data were acquired (September 2018)

[2] Facilities missing data on primary power source: in Arusha (n=106), Kilimanjaro (n=109), and Tanga (n=355); All regions (n=558)
[3] Facilities missing data on ownership type: in Arusha (n=35), Kilimanjaro (n=86), and Tanga (n=39); All regions (n=148)
[4]Facilities missing data on facility type: in Arusha (n=28), Kilimanjaro (n=72), and Tanga (n=31); All regions (n=120)

Individual-Level Vaccination Summaries

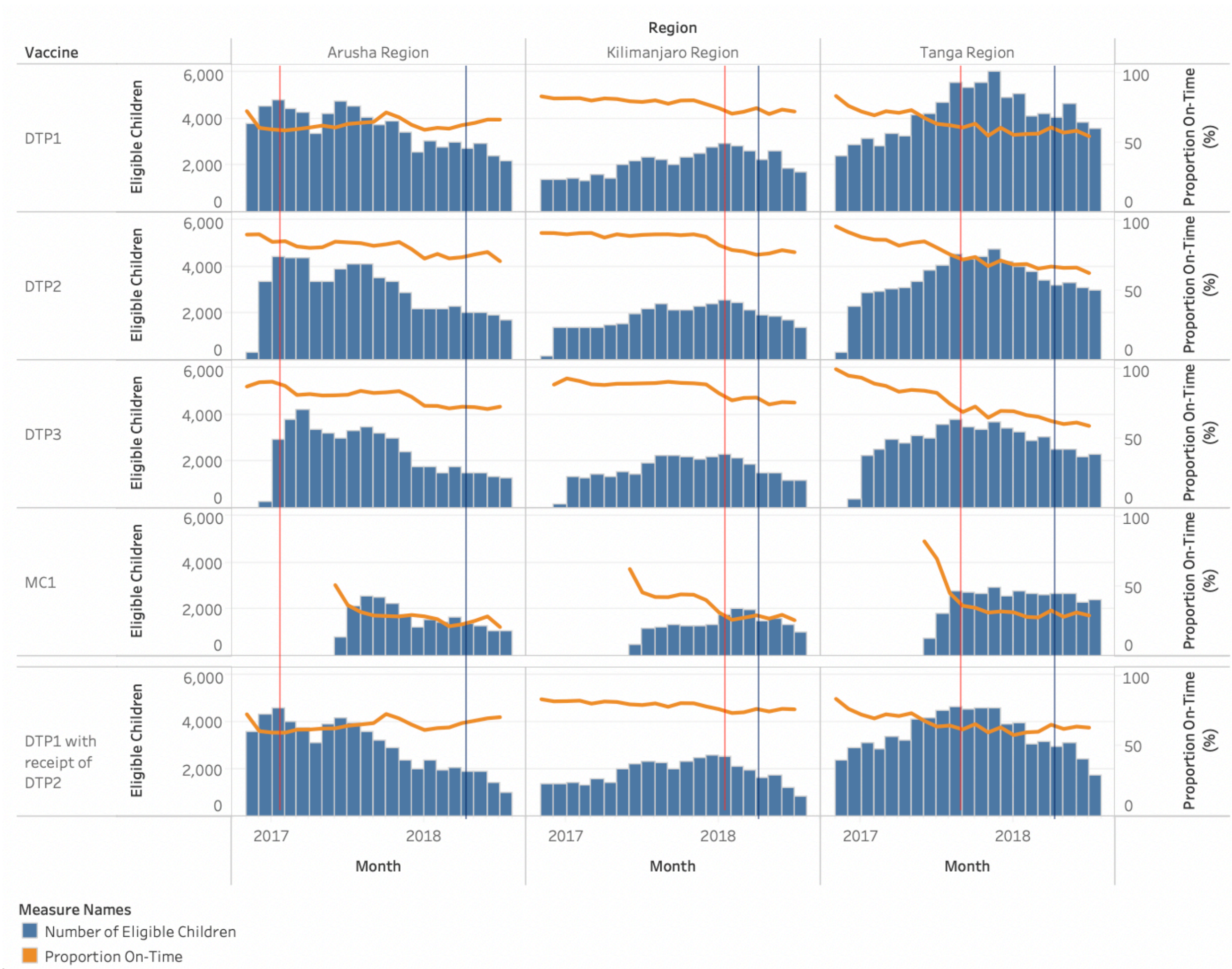
There were 246,940 children eligible for DPT1, 243,871 for DTP2, 236,691 for DTP3, and 170,279 for MCV1 vaccines (Table 4.2). The DTP1 vaccine was most frequently on-time (57.9%) with a mean of 13 days after the scheduled date, while MCV1 vaccine was least likely to be on-time (15.8%), with a mean of 25 days off-schedule. For all vaccine types, vaccinations were more frequently on-time or early before introduction of the EIR. Differences between pre- and post-EIR time periods were observed for all vaccines, with DTP3 and MCV1 vaccines having the largest differences. For all vaccine types, on average more vaccinations were recorded post-EIR introduction per month, with an average of 11 doses administered per month per facility pre-EIR compared to 16 doses post-EIR for DTP1. Fewer doses of MCV1 were administered pre-EIR, 6 versus 15 post-EIR. There were no differences in the direction of the trends observed across regions. Variations by vaccine were observed, with the proportion of vaccinations on-time generally decreasing over time, but a slightly positive trend was observed in Arusha for DTP1 (Figure 4.3). Amongst all children under 2 years at the time the data were acquired, 479 (0.2%) had no recorded vaccinations, 22,321 (8.9%) received no doses after their birth doses, 8,778 (3.5%) had DTP2 or DTP3 recorded, but not the previous dose (these were dropped from the analysis), and 5,734 (2.3%) had a recorded MCV1 vaccine, but no DTP3 recorded. There were 10,797 (4.3%) children receiving at least one, but not all of the vaccines recommended at their 6-week visit, 23,757 (9.4%) at the 10-week visit, and 7,648 (3.0%) at the 14-week visit. (Figure 4.4)

Table 4.2 On-Time Vaccinations, Days Off-Schedule, and Weekly Vaccinations per Facility, by Vaccine Type and Region

Vaccine	Characteristics	Arusha	Kilimanjaro	Tanga	All Regions
DTP1	Number of eligible children[1]	87,084	51,729	108,127	246,940
	On-time vaccination (%)	49,349 (56.7)	35,384 (68.4)	58,210 (53.8)	142,943 (57.9)
	Mean number of days off-schedule, (SD)	13 (34)	9 (32)	16 (47)	13 (40)
	Early vaccination, pre-EIR (%)	719 (5.5)	1149 (4.1)	1756 (4.4)	3624 (4.4)
	Early vaccination, post-EIR (%)	2200 (3.0)	686 (2.9)	2900 (4.3)	5786 (3.5)
	On-time vaccination, pre-EIR (%)	7,881 (60.5)	22,439 (79.1)	25,643 (63.9)	55,963 (68.7)
	On-time vaccination, post-EIR (%)	41,468 (56.0)	12,945 (55.4)	32,567(47.9)	86,980 (52.6)
	Mean vaccinations administered per facility per month- pre-EIR (SD)	17 (29)	7 (8)	12 (15)	11 (15)
	Mean vaccinations administered per facility per month- post-EIR (SD)	16 (26)	11 (18)	18 (22)	16 (24)
DTP2	Number of eligible children[1]	83,836	50,687	106,348	243,871
	On-time vaccination (%)	51,565 (59.4)	33,764 (66.6)	55,549 (52.2)	140,878 (57.8)
	Mean number of days off-schedule, (SD)	7 (25)	5 (19)	9 (29)	8 (25)
	Early vaccination, pre-EIR (%)	445 (4.4)	801 (3.1)	1241 (3.6)	2487 (3.5)
	Early vaccination, post-EIR (%)	2101 (2.7)	655 (2.6)	2496 (3.5)	5253 (3.0)
	On-time vaccination, pre-EIR (%)	7,834 (77.5)	22,423 (87.1)	25,236 (72.7)	55,493 (78.6)
	On-time vaccination, post-EIR (%)	43,731 (57.0)	11,341 (45.5)	30,313 (42.3)	85,385 (51.4)
	Mean vaccinations administered per facility per month- pre-EIR (SD)	17 (30)	7 (8)	12 (15)	10 (15)
	Mean vaccinations administered per facility per month- post-EIR (SD)	17 (27)	11 (18)	19 (23)	16 (24)
DTP3	Number of eligible children[1]	82,079	47,841	98,106	236,691
	On-time vaccination (%)	40,713 (47.9)	29,200 (59.8)	44,185 (2.9)	114,098 (48.2)
	Mean number of days off-schedule, (SD)	9 (32)	6 (25)	13 (38)	10 (33)
	Early vaccination, pre-EIR (%)	288 (4.0)	775 (3.4)	966 (3.4)	2029 (3.4)
	Early vaccination, post-EIR (%)	1742 (2.2)	566 (2.2)	2071 (2.8)	4379 (2.5)
	On-time vaccination, pre-EIR (%)	5,148 (71.0)	19,758 (86.0)	20,375 (71.0)	45,281 (76.8)
	On-time vaccination, post-EIR (%)	35,565 (45.8)	9,442 (36.5)	23,810 (32.1)	68,817 (38.7)
	Mean vaccinations administered per facility per month- pre-EIR (SD)	16 (29)	7 (8)	11 (14)	9 (13)
	Mean vaccinations administered per facility per month- post-EIR (SD)	17 (27)	11 (18)	19 (23)	17 (24)
MCV1	Number of eligible children[1]	65,848	30,978	73,453	170,279
	On-time vaccination (%)	6,832 (10.4)	6,953 (22.4)	13,194 (18.0)	26,979 (15.8)
	Mean number of days off-schedule, (SD)	27 (49)	21 (41)	26 (47)	25 (47)
	Early vaccination, pre-EIR (%)	1 (100)	1191 (12.8)	507 (8.5)	1699 (11.1)
	Early vaccination, post-EIR (%)	2721 (4.1)	1166 (5.4)	2810 (4.2)	6697 (4.3)
	On-time vaccination, pre- EIR (%)	0 (0)	3,746 (40.2)	3,084 (51.8)	6,833 (44.7)
	On-time vaccination, post- EIR (%)	6,832 (10.4)	3,206 (14.8)	10,108 (15.0)	20,146 (13.0)
	Mean vaccinations administered per facility per month- pre-EIR (SD)	1 (NA)	5 (6)	7 (10)	6 (7)
	Mean vaccinations administered per facility per month- post-EIR (SD)	17 (28)	9 (12)	17 (21)	15 (23)

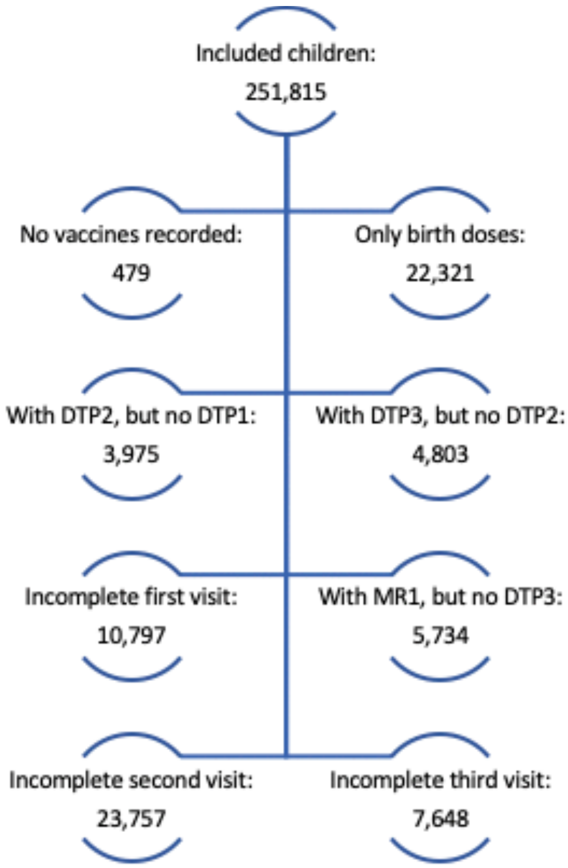
[1]Children over the recommended age of vaccination (6 weeks for DTP1, 10 weeks for DTP2, 14 weeks for DTP3, and 9 months for measles-containing vaccine) and under 2 years as of the time the data were acquired(September 2018)

Figure 4.3 Number of children with a documented vaccination and proportion vaccinated on-time by vaccine type and region, Tanzania, November 2016-July 2018*



*Red line indicates when the EIR was introduced (approximately); blue line indicates when the SMS reminders were introduced

Figure 4.4 Incomplete or missing vaccination records among all children registered in the EIR*

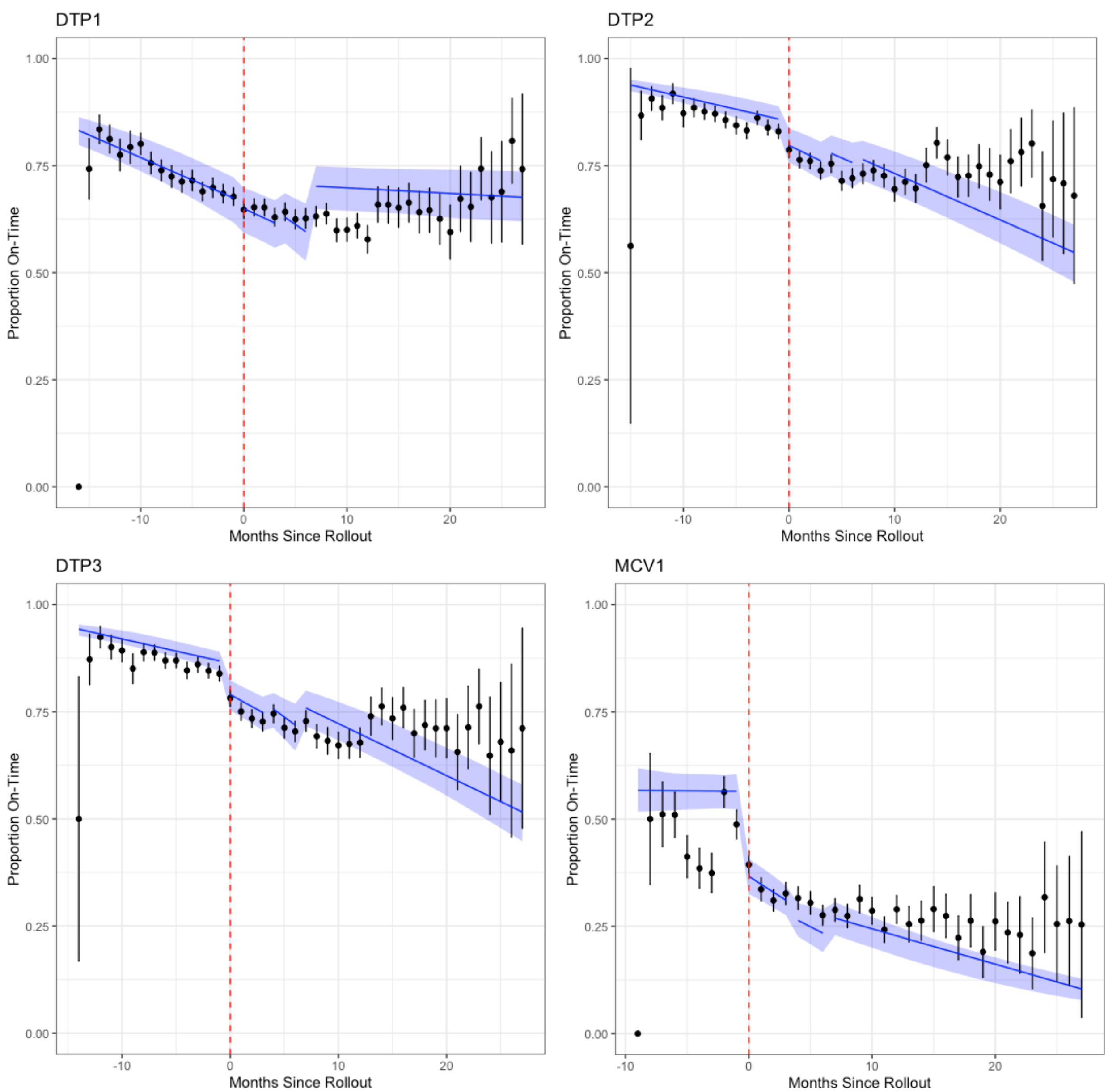


*For the selected vaccines of interest and includes doses administered after data were acquired and doses administered before a date-of-birth, which were removed for the analysis

Model Findings

The binomial regression models estimated significant differences in proportion of on-time vaccinations before and after rollout of the EIR, based on level changes (Table 4.3 and Figure 4.5). Compared to the pre-EIR time period, the likelihood of an on-time DTP1 vaccination decreased by 5% (OR:0.95, 95% CI: 0.90-0.99) in the first three months following EIR-introduction, but increased 14% (OR:1.15 95% CI: 1.07-1.22) and 25% (OR:1.26, 95% CI: 1.15-1.35) 4-6 months and >6 months post-EIR, respectively. For DTP2, the likelihood of on-time vaccinations was lower post-EIR, compared to pre-EIR, although the reduction decreased over time with 32% (OR:0.68, 95% CI: 0.62-0.75) reduced likelihood 0-3 months post-EIR, 22% (OR:0.78, 95% CI: 0.68-0.88) 4-6 months post-EIR, and 20% (OR:0.80, 95% CI: 0.68-0.93) post-EIR >6 months after. A similar trend in level changes was observed for DTP3, with a consistent lower likelihood of on-time vaccination post-EIR introduction, but with improvements seen over time. For MR1 vaccinations, compared to the pre-EIR time period, the likelihood of on-time vaccination was 55% lower (OR:0.45, 95% CI: 0.36-0.53) 0-3 months post-introduction, 62% lower (OR:0.38, 95% CI: 0.23-0.54) 4-6 months, and 57% lower (OR:0.43, 95% CI: 0.25-0.61) >6 months post-introduction.

Figure 4.5 Regression results for primary model*



*Red dotted line indicates EIR-introduction date; black dots indicate the average proportion of vaccinations per facility per month with the black lines indicating their associated 95% confidence intervals; blue lines indicate the change in slope for the proportion of children vaccinated on-time per month per facility

Statistically significant changes in the slope of the trend were estimated for >6 months post-EIR introduction, compared to pre-EIR, for all vaccine types. For DTP1 vaccinations, the likelihood of on-time vaccinations increased by 5% per month (OR:1.05, 95% CI: 1.05-1.06), for DTP2 the likelihood increased by 2% (OR:1.02, 95% CI: 1.01-1.03), for DTP3 the likelihood increased by 2% (OR:1.01, 95% CI: 1.00-1.03), and for MCV1 the likelihood decreased by 6% per month (OR:0.94, 95% CI: 0.92-0.97).

Table 4.3 Parameters estimates for likelihood of change in the proportion of on-time vaccinations pre- and post-introduction of an EIR, Tanzania*

	Dependent variable:			
	On-Time Vaccination			
	DTP1	DTP2	DTP3	MCV1
	(1)	(2)	(3)	(4)
Baseline monthly change in slope	0.94* (0.94, 0.95)	0.94* (0.93, 0.94)	0.93* (0.92, 0.94)	1.00 (0.98, 1.02)
Level change 0-3 Months after EIR	0.95* (0.90, 0.99)	0.68* (0.62, 0.75)	0.61* (0.54, 0.67)	0.45* (0.36, 0.53)
Level change 4-6 Months after EIR	1.14* (1.07, 1.22)	0.78* (0.68, 0.88)	0.74* (0.62, 0.85)	0.38* (0.23, 0.54)
Level change >6 Months after EIR	1.25* (1.15, 1.35)	0.80* (0.68, 0.93)	0.75* (0.61, 0.89)	0.43* (0.25, 0.61)
Change in slope 0-3 Months after EIR	1.01 (0.99, 1.03)	1.00 (0.98, 1.02)	0.99 (0.96, 1.02)	0.92* (0.89, 0.96)
Change in slope 4-6 Months after EIR	0.99 (0.96, 1.02)	1.01 (0.97, 1.04)	0.97 (0.93, 1.01)	0.92* (0.88, 0.97)
Change in slope >6 Months after EIR	1.05* (1.05, 1.06)	1.02* (1.01, 1.03)	1.02* (1.00, 1.03)	0.94* (0.92, 0.97)
Observations	17,092	15,854	14,546	9,562

*p<0.05; Intercept estimates are not presented

Findings of Sensitivity Analysis

Changes over time were observed showing a decrease and then roughly a plateau in timeliness following the introduction of the EIR (Figure 4.3). We estimated significant differences in the likelihood of on-time DTP1 vaccination post-EIR introduction compared to pre-EIR, with a 19% increased likelihood of being on-time 4-6 months post-EIR (OR: 1.19, 95% CI: 1.11-1.27) and 34% increase >6 months post-EIR (OR:

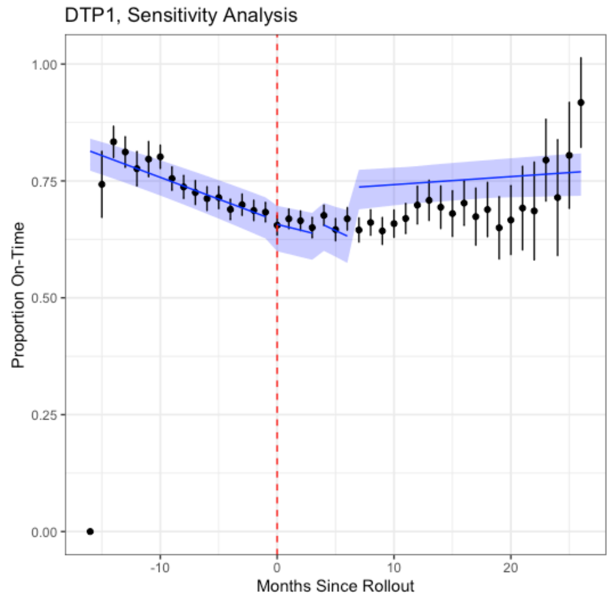
1.34, 95% CI: 1.23-1.45) (Table 4.4 and Figure 4.6). Significant increases in the likelihood of on-time vaccinations were estimated for 0-3 months and >6 months following EIR-introduction, with 2% increase per month (OR: 1.02, 95% CI: 1.00-1.04) and 6% increase per month (OR: 1.06, 95% CI: 1.05-1.07), respectively.

Table 4.4 Parameter estimates for likelihood of change in proportion of on-time DTP1 vaccination pre- and post-introduction of an EIR among children with a documented dose of DTP2 (sensitivity analysis)*

	Dependent variable:
	On-Time Vaccination DTP1
Baseline monthly change in slope	0.95* (0.95, 0.96)
Level change 0-3 Months after EIR	0.98 (0.93, 1.03)
Level change 4-6 Months after EIR	1.19* (1.11, 1.27)
Level change >6 Months after EIR	1.34* (1.23, 1.45)
Change in slope 0-3 Months EIR	1.02* (1.00, 1.04)
Change in slope 4-6 Months after EIR	1.00 (0.97, 1.03)
Change in slope >6 Months after EIR	1.06* (1.05, 1.07)
Observations	15,743

*p<0.05; Intercept estimates are not presented

Figure 4.6 Regression results for sensitivity analysis*



*Red dotted line indicates EIR-introduction date; black dots indicate the average proportion of vaccinations per facility per month with the black lines indicating their associated 95% confidence intervals; blue lines indicate the change in slope for the proportion of children vaccinated on-time per month per facility

DISCUSSION

Findings

We observed decreases in the proportion of on-time vaccinations following EIR-introduction. However, we must emphasize caution interpreting these findings as additional information is needed to understand if the changes observed reflect true estimates of timeliness or if they reflect “noise” due to incompleteness of EIR vaccination records and biases from the data capture process. From our sensitivity analysis, we observed that among those children receiving DTP2, there were improvements in DTP1 timeliness following EIR-introduction, indicating that our belief about incomplete EIR records may very well be valid and the decreases in timeliness observed from the primary analysis are not accurate.

Upon a crude comparison of our estimates to the most recent Demographic and Health Survey (DHS) conducted in Tanzania for 2015-2016, we found further evidence for inconsistent EIR data entry if we assume true immunization coverage did not vary much between 2015 and 2018. The DHS defines timeliness as children receiving recommended vaccinations before age 12 months[95]. Comparing the survey estimates to EIR estimates using the same timeliness definition, we observed that prior to EIR-introduction national timeliness estimates were comparable across data sources, for instance DTP1 timeliness was 96.5% in the EIR and estimated to be 96.6% nationally from DHS (See Appendix Table 4.A). However, we found that estimates for DTP2, DTP3, and MR1 decreased following EIR-introduction, suggesting inconsistent data entry post-EIR. We should note that DHSs use information recorded from vaccination cards and parental recall, these data have been found to be unreliable when compared to medical records, and therefore the DHS should not be considered the gold standard for our comparison[96].

Our research group previously noted, "completeness and quality of data input into a system dictates the accuracy of the estimates generated by the system, contingent on the system's design, user compliance, and system maintenance", and that "calculating accurate estimates of performance measures using EIR data will likely remain elusive until the challenges" have been addressed[97]. Implementation challenges that may have affected the completeness and/or accuracy of the data in our study included: inconsistent use of the EIR over time, the official requirement of completing dual data entry with the paper record remaining the official record potentially causing HCWs to ensure paper records were more complete than EIR records, inconsistent use of unique patient identifiers causing individuals to have multiple IDs, or poor data entry practices leading to inaccuracies due to workflow or training issues[98, 99]. Inconsistent use of the system is further complicated by facilities using different methods for entering data retrospectively and documenting outreach sessions, as well as staffing changes. During early to mid-2017, the Tanzanian government began restricting public employees who could not prove they had completed their secondary education via a paper certificate. This resulted in the loss of approximately 10,000 employees, including HCWs, who were fired from their positions if they could not present the certificate[100]. The drop in the workforce likely affected the capacity for HCWs to consistently use the EIR during our study period. Additionally, there were potentially server-side issues that could have prevented all data from being made available due to the server timing out or being overloaded. Also, the EIR's validation rules may not have been functioning correctly, since we found a large number of records with implausible vaccination dates based on the date of birth. Studies based in other countries have found similar challenges, particularly a high rate of under-reporting which causes underestimation of vaccination coverage, low IT literacy needed for adoption of DHI, and poor integration of the DHI within the existing health system[79, 101-103].

Considering our study team found no alternative reason for true vaccination timeliness to decrease following EIR-introduction after consulting with implementers and MOH staff, and that our results did not align with survey data, the most likely explanation is that our primary analysis results suffer from presumed threats to validity. Rather than timeliness decreasing at a population-level, it seems more likely that the results reflect the EIR implementation challenges described above. However, some facilities may have captured more accurate information in the EIR than previously captured by paper-based tools, and post-EIR, we may have observed true vaccination timeliness previously uncaptured in surveys and other assessment methods, which is useful when reviewing the descriptive results, but is less useful for our time-series analysis. It will be important to reanalyze the data again in a couple of years to understand if the trends have changed due to improvements in EIR-use. Additionally, these threats to validity also further violate the exchangeability assumption needed to assess impact using an interrupted time-series analysis, where we cannot assume that children's records entered retrospectively versus prospectively are comparable. There may be multiple potential explanations for the trends seen in our data that would require primary data collection to confirm.

Can digital health interventions improve health outcomes?

We have outlined the potential implementation challenges that may have impacted our analysis; however, it is worth revisiting our theoretical framework to understand where gaps in adoption and use of the EIR may have occurred and subsequently affected vaccination timeliness. EIRs are implemented within complex health systems and require HCW activities to accommodate new workflows that incorporate the tool so their effectiveness relies on how well they are designed, developed, implemented, and used[13]. Consistent entry of data into an EIR may be dependent on HCW competency in using DHI tools, a facility's internet and electricity connectivity, dual data entry, and HCW motivation, all of which could impact the completeness of EIR records.

Simply having HCWs utilize an electronic tool will not on its own increase timeliness of vaccinations; our causal linkage diagram shows that HCWs would have to use the information in the EIR to encourage caregivers to bring children on-time for their next scheduled immunization appointment and follow-up with defaulters. A realist review found similar findings, with only moderate to low-certainty evidence of EIRs improving data use amongst district- and facility-level staff[13, 104]. Although in Tanzania HCWs were trained to follow-up using EIR information, it is unclear how consistent this was performed. We did not estimate the effect of the SMS-reminders component of the intervention due to the limited follow-up time, but this is a future area of research as it could have affected timeliness. Finally, the length of time to observe behavior change is unknown as it likely varies by caregiver, HCW, and facility. Our assumptions may have underestimated the amount of time needed for HCWs' behaviors to change.

Furthermore, these challenges beg the question: if these systems make no impact on timeliness, should we invest in them? Improvements have been seen in other settings, an EIR and SMS-reminder system was successfully deployed in Vietnam, where improvement in vaccination timeliness was observed two years following system introduction[15]. Additionally, in high-income settings, improvements in coverage and timeliness have been observed due to electronic systems [14]. However, it is worth first asking whether health-related outcomes are the best measures to quantify the impact of these digital systems. Considering the large footprint required for deployment, that often involves cross-team collaborations and implicates staff at each health system level, these systems have additional effects and impacts that are not captured by patient health outcome metrics but may still improve healthcare provision. Digital systems can provide a secure location for record storage, increase patient trust in the healthcare system, improve data quality and accessibility, and can reduce the burden of data management activities, freeing up time for staff to focus on patient care[105]. As the health benefits of DHI may take 3-13 years to be observed, the importance of these more proximal process outcomes should be acknowledged and these metrics used in DHI evaluations[106].

Study Strengths

Our study took advantage of the opportunity to use individual-level RHIS data to conduct a quasi-experimental analysis. We were able to showcase the utility and power of these data for answering an implementation science research question by developing appropriate performance metrics within the Tanzanian context that considered changes over time, clinician practices at the facility and district levels, and the cohort of children we expected to see most affected by the EIR's introduction. The study design process required that the research and implementation teams worked closely together to create a model that would accurately capture EIR introduction and use among facilities and provide interpretable findings.

Limitations

We encountered numerous challenges using these data to answer our research question, mostly due to EIR-implementation complexities. Upon review of the challenges, we considered some of them to be natural to the process of implementing a new DHI. However, using these data "as-is" for our analysis was difficult due to poor data quality, necessitating a need for a clear understanding of the implementation setting and challenges to continuous data entry and use. There are several important contextual factors which were not accounted for in our models. Because time was centered on EIR introduction date, we were unable to account for the timing of other events or secular trends, such as the public employee dismissal, that could have potentially impacted vaccination timeliness, including changes made to the intervention package. Additionally, without further verification through other data sources and observations, it is difficult to know the level of completeness of the EIR data or when to consider the data to have “normalized”. We also recognized that our study could be affected by system impacts not accounted for in the analysis and other unmeasured confounders. A key limitation of this study is that we were unable to assess immunization coverage as an outcome since we lacked data on the full denominator population of children eligible for vaccination in the community. Future analyses should assess vaccination drop-out, comparing the number of children receiving the first to the third dose, as this is a better measure of timeliness because it accounts for the entire vaccine series and allows changes in timeliness to be measured at the individual-level, rather than facility-level.

CONCLUSION

We assessed changes in vaccination timeliness following EIR-introduction and found that timeliness decreased over time, likely due to inconsistent data entry and use of the EIR, rather than a true decrease in timeliness in the population. To more accurately interpret our findings, contextual information about EIR implementation would have helped to provide a comprehensive understanding of the validity of this finding. EIRs have the potential to improve vaccination timeliness but need to be used consistently in order to provide accurate metrics on target populations. Use of individual-level RHIS data generated from these systems can provide greater insight into immunization program performance and ultimately help reduce gaps in vaccination coverage once implementation challenges are overcome.

APPENDIX

Table 4.A. Immunization coverage from most recent demographic and health survey

Metric, region, and vaccine		**Pre-EIR**	**Post-EIR**	**Overall**		**DHS Survey**
Amongst children receiving vax before age 12 mos (DHS appropriate age def)						
All Regions	**DTP1**	96.5	93.0	95.0		96.6
	DTP2	92.6	81.5	87.1		93.4
	DTP3	89.1	68.4	77.5		87.7
	MR1	90.1	47.1	52.2		78.0

Chapter 5: Conclusions

SUMMARY OF FINDINGS

In this dissertation we provided insights as to why many DHI may fail to reach scale and fulfill their potential to improve provision of healthcare services in LMICs. We used mixed-methods and quasi-experimental study designs to produce evidence on the use and effectiveness of EIRs after initial introduction and scale-up of the tools. Our research considered the use of the EIRs after introduction into existing healthcare settings and their impact on users and health-related outcomes, ultimately finding that misalignment between the system and reality, as well as inconsistent use of the system (potentially due to misalignment), prevents DHI from being widely accepted and used with high fidelity to produce intended improvements in health systems and outcomes.

This research described the underlying mechanisms needed to encourage high fidelity of system-use and improve user acceptance, and how these mechanisms were influenced by the enabling environment of a particular setting. We found that in order to ensure alignment between the EIR and reality, system implementers should: ensure users complete training to build familiarity with the system, understand the value of the system and data, and know where to find support; confirm the system captures all data needed for users to provide routine healthcare services and is easy to navigate; identify workarounds for poor network, system performance, and too few staff or resources; and, make users aware of expected changes to their workflow, and how these changes might differ over time and by facility size/number of patients. This research also demonstrated the necessity for immunization clinics to move from a dual-data entry to paperless workflow as quickly as is feasible to improve workflow efficiencies. However, this ideal workflow may cause additional challenges to users if EIR performance is poor or if EIR-workflows cannot accommodate limited staffing and facility resources. To improve workflow efficiency, both the DHI and existing-user workflows, need to be adapted to fit within a given setting in order to encourage close alignment between the system and users' tasks. This research was particularly helpful in illustrating the, ideally, iterative nature of DHI design and evaluation throughout the lifespan of a system, in an effort to build DHI that can adapt to changes to ensure systems are acceptable in all user settings.

For understanding the impact of an EIR on health-related outcomes, this research assessed changes in vaccination timeliness following EIR-introduction in Tanzania, only to find that challenges with implementation hindered the analysis. Due to concerns of inconsistent use of the EIR, we attempted to overcome these challenges by conducting a sensitivity analysis using only complete EIR records and found vaccination timeliness did improve after EIR-introduction. The findings of this research suggest that EIRs can improve health-related outcomes, but using these types of real-world, individual-level data can be complicated by data quality concerns stemming from implementation challenges, and therefore lead to difficulties with interpretation of results.

IMPLICATIONS FOR RESEARCH

The field of digital health has put a large focus on building appropriate technologies that follow the Principles of Digital Development [107]. However, there has been little focus on strategies to implement these technologies using values aligned with the Principles. Often one-size fits all implementation strategies are used, when mixed models of implementation that acknowledge changing practice settings and environmental factors may be more appropriate. More consideration is needed on how to introduce technology while accommodating parallel reporting systems, the transition from paper to digital forms, the mixed use of technologies, and different sizes and types of facilities. Strategies will likely change over time as infrastructures, health systems, and technologies improve. Using HCD and implementation science research to understand the most appropriate strategy will allow for us to better understand which implementation strategies work in particular contexts and avoid unintended consequences. Building solutions that can adapt to the existing environment, rather than trying to impose solutions, will be important for long-term DHI sustainability. Qualitative and mixed-methods studies that summarize how and why one strategy is more beneficial than another will be particularly important to address these issues, along with quantitative and costing studies that look at effectiveness of particular strategies.

Acronyms

BID- Better Immunization Data

DHI- Digital health intervention

DHS- Demographic and Health Survey

DTP- diphtheria, tetanus, and whole-cell pertussis, hepatitis B, and *Haemophilus influenzae* type b vaccine

EHR- Electronic health record

EIR- Electronic immunization record

EMR- Electronic medical record

HCD- Human-centered design

HCW- Health care worker

I-TECH- International Training and Education Center for Health

ITN- Insecticide treated net

KEPI- Kenya expanded programme for immunizations

LMICs- Low- and middle-income countries

MC- measles containing vaccine

MOH- ministry of health

POC- Point-of-care

RHIS- routine health information system

SCHRIO- Sub-county health records information officer

SMS- short-message service

TImR- Tanzania Immunization Registry

UAG- User-Advisory Group

References

1. Brown DW, Burton A, Gacic-Dobo M, Karimov R. A Comparison of National Immunization Programme Target Population Estimates with Data from an Independent Source and Differences in Computed Coverage Levels for the Third Dose of DTP Containing Vaccine. World J Vaccines 2014, 4:18-23.
2. Lim SS, Stein DB, Charrow A, Murray CJ. Tracking progress towards universal childhood immunisation and the impact of global initiatives: a systematic analysis of three-dose diphtheria, tetanus, and pertussis immunisation coverage. Lancet 2008, 372(9655):2031-2046. 10.1016/S0140-6736(08)61869-3.
3. Murray CJ, Shengelia B, Gupta N, Moussavi S, Tandon A, Thieren M. Validity of reported vaccination coverage in 45 countries. Lancet 2003, 362(9389):1022-1027. 10.1016/S0140-6736(03)14411-X.
4. World Health Organization. *Limitations related to globally reported immunization subnational data*. www.who.int/immunizatio/monitoring_surveillance/data/limitations.pdf; 2018.
5. Dehnavieh R, Haghdoost A, Khosravi A, Hoseinabadi F, Rahimi H, Poursheikhali A, Khajehpour N, Khajeh Z, Mirshekari N, Hasani M *et al*. The District Health Information System (DHIS2): A literature review and meta-synthesis of its strengths and operational challenges based on the experiences of 11 countries. Health Inf Manag 2019, 48(2):62-75. 10.1177/1833358318777713.
6. World Health Organization. Digital Health Atlas, https://www.digitalhealthatlas.org; 2018 [Accessed: October 17 2018].
7. World Health Assembly. Seventy-First World Health Assembly- Digital Health, Agenda item 12.4, http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R7-en.pdf; 2018 [Accessed: September 2018].
8. Labrique A, Vasudevan L, Weiss W, Wilson K. Establishing Standards to Evaluate the Impact of Integrating Digital Health into Health Systems. Glob Health Sci Pract 2018, 6(Suppl 1):S5-S17. 10.9745/GHSP-D-18-00230.
9. Wilson K, Gertz B, Arenth B, Salisbury N. *The journey to scale: Moving together past digital health pilots*. Seattle; https://www.path.org/resources/the-journey-to-scale-moving-together-past-digital-health-pilots/; 2014.
10. Kumar S, Nilsen WJ, Abernethy A, Atienza A, Patrick K, Pavel M, Riley WT, Shar A, Spring B, Spruijt-Metz D *et al*. Mobile health technology evaluation: the mHealth evidence workshop. American journal of preventive medicine 2013, 45(2):228-236. 10.1016/j.amepre.2013.03.017.
11. The Bellagio eHealth Evaluation Group. *Call to Action on Global eHealth Evaluation: Consensus Statement of the WHO Global eHealth Evaluation Meeting*. Bellagio, IT; 2011.

12. World Health Organization. Classification of Digital Health Interventions v1.0, http://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf?sequence=1; 2018 [Accessed: September 2018

13. *Immunization Data: Evidence for Action. A Realist Review of What Works to Improve Data Use for Immunization, Evidence from Low- and Middle- Income Countries*. Seattle: PATH: Washington DC: PAHO; 2019.

14. Dumit EM, Novillo-Ortiz D, Contreras M, Velandia M, Danovaro-Holliday MC. The use of eHealth with immunizations: An overview of systematic reviews. Vaccine 2018, 36(52):7923-7928. 10.1016/j.vaccine.2018.06.076.

15. Nguyen NT, Vu HM, Dao SD, Tran HT, Nguyen TXC. Digital immunization registry: evidence for the impact of mHealth on enhancing the immunization system and improving immunization coverage for children under one year old in Vietnam. Mhealth 2017, 3:26. 10.21037/mhealth.2017.06.03.

16. World Health Organization. *WHO guideline: recommendations on digital interventions for health system strengthening*. Geneva; 2019.

17. Carayon P, Wood KE. Patient safety - the role of human factors and systems engineering. Studies in health technology and informatics 2010, 153:23-46.

18. Carayon P. Human factors of complex sociotechnical systems. Appl Ergon 2006, 37(4):525-535. 10.1016/j.apergo.2006.04.011.

19. Carayon P, Wetterneck TB, Hundt AS, Ozkaynak M, DeSilvey J, Ludwig B, Ram P, Rough S. Evaluation of Nurse Interaction With Bar Code Medication Administration Technology in the Work Environment. Jouranl of Patient Safety 2007, 3(1):34-42.

20. Organization WH. Global and immunization profile: African region, https://www.who.int/news-room/fact-sheets/detail/immunization-coverage; 2019 [Accessed: June 8 2020].

21. Andre FE, Booy R, Bock HL, Clemens J, Datta SK, John TJ, Lee BW, Lolekha S, Peltola H, Ruff TA *et al*. Vaccination greatly reduces disease, disability, death and inequity worldwide. Bull World Health Organ 2008, 86(2):140-146. 10.2471/blt.07.040089.

22. Remy V, Zollner Y, Heckmann U. Vaccination: the cornerstone of an efficient healthcare system. J Mark Access Health Policy 2015, 3. 10.3402/jmahp.v3.27041.

23. Scobie HM, Edelstein M, Nicol E, Morice A, Rahimi N, MacDonald NE, Carolina Danovaro-Holliday M, Jawad J, Immunization SWGo, Surveillance Data Q *et al*. Improving the quality and use of immunization and surveillance data: Summary report of the Working Group of the Strategic Advisory Group of Experts on Immunization. Vaccine 2020, 38(46):7183-7197. 10.1016/j.vaccine.2020.09.017.

24. eHealth WGOf. mHealth: new horizons for health through mobile technologies: second global survey on eHealth, https://apps.who.int/iris/handle/10665/44607; 2011 [Accessed:

25. Pan American Health Organization. *Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation*. http://iris.paho.org/xmlui/handle/123456789/34865; 2018.

26. Organization WH, PATH. *Planning an Information Systems Project: A Toolkit for Public Health Managers*. Seattle: PATH; 2013.

27. Holeman I, Kane D. Human-centered design for global health equity. Inf Technol Dev 2019, 26(3):477-505. 10.1080/02681102.2019.1667289.

28. Shaw J, Agarwal P, Desveaux L, Palma DC, Stamenova V, Jamieson T, Yang R, Bhatia RS, Bhattacharyya O. Beyond "implementation": digital health innovation and service design. NPJ Digit Med 2018, 1:48. 10.1038/s41746-018-0059-8.

29. Fabricant R. When will design get serious about impact? , https://ssir.org/articles/entry/when_will_design_get_serious_about_impact; 2014 [Accessed: May 5 2020].

30. Lyon AR, Munson SA, Renn BN, Atkins DC, Pullmann MD, Friedman E, Arean PA. Use of Human-Centered Design to Improve Implementation of Evidence-Based Psychotherapies in Low-Resource Communities: Protocol for Studies Applying a Framework to Assess Usability. JMIR research protocols 2019, 8(10):e14990. 10.2196/14990.

31. Bazzano AN, Martin J, Hicks E, Faughnan M, Murphy L. Human-centred design in global health: A scoping review of applications and contexts. PLoS One 2017, 12(11):e0186744. 10.1371/journal.pone.0186744.

32. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review--a new method of systematic review designed for complex policy interventions. J Health Serv Res Policy 2005, 10 Suppl 1:21-34. 10.1258/1355819054308530.

33. Robert E, Samb OM, Marchal B, Ridde V. Building a middle-range theory of free public healthcare seeking in sub-Saharan Africa: a realist review. Health Policy Plan 2017, 32(7):1002-1014. 10.1093/heapol/czx035.

34. Pawson R. Middle-range realism. Europeaan Journal of Sociology 2000, 41(2):283-325.

35. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International journal for quality in health care : journal of the International Society for Quality in Health Care 2007, 19(6):349-357. 10.1093/intqhc/mzm042.

36. Statistics KNBo. *2019 Kenya Population and Housing Census: Volume I Population by County and Sub-County*. https://www.knbs.or.ke/?wpdmpro=2019-kenya-population-and-housing-census-volume-i-population-by-county-and-sub-county; 2019.

37. Statistics KNBo, Kenya MoH, Kenya NACC, Institute KMR, Kenya NCfPaD, International I. *Kenya Demographic and Health Survey 2014*. Rockville, MD, USA; 2015.

38. ISO/IEC. *Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — System and software quality models*. Geneva: Standardisation IOf; https://www.iso.org/obp/ui/#iso:std:iso-iec:25010:ed-1:v1:en; 2011.

39. Ammenwerth E, Iller C, Mahler C. IT-adoption and the interaction of task, technology and individuals: a fit framework and a case study. BMC medical informatics and decision making 2006, 6:3. 10.1186/1472-6947-6-3.

40. Smith MJ, Sainfort PC. A balance theory of job design for stress reduction. International Journal of Industrial Ergonomics 1989, 4:67-79.

41. Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, Grimshaw JM. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. Psychol Health 2010, 25(10):1229-1245. 10.1080/08870440903194015.

42. Carayon P, Wetterneck TB, Hundt AS, Ozkaynak M, Ram P, DeSilvey J, Hicks B, Robert TL, Enloe M, Sheth R *et al*: **Observing Nurse Interaction with Infusion Pump Technologies**. In: *Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology).* edn. Edited by Henriksen K, Battles JB, Marks ES, Lewin DI. Rockville (MD); 2005.

43. Carayon P, Wetterneck TB, Hundt AS, Ozkaynak M, Ram P, DeSilvey J, Hicks B, Roberts TL, Enloe M, Sheth R *et al*: **Assessing Nurse Interaction with Medication Administration Technologies: The Development of Observation Methodologies**. Kuala Lumpur, Malaysia: Damai Sciences; 2004.

44. Miller K, Capan M, Weldon D, Noaiseh Y, Kowalski R, Kraft R, Schwartz S, Weintraub WS, Arnold R. The design of decisions: Matching clinical decision support recommendations to Nielsen's design heuristics. International journal of medical informatics 2018, 117:19-25. 10.1016/j.ijmedinf.2018.05.008.

45. Ryan RM, Deci EL. Intrinsic and Extrinsic Motivations: Classic Definitions and New Directions. Contemp Educ Psychol 2000, 25(1):54-67. 10.1006/ceps.1999.1020.

46. Van Wingerden J, Van der Stoep J. The motivational potential of meaningful work: Relationships with strengths use, work engagement, and performance. PLoS One 2018, 13(6):e0197599. 10.1371/journal.pone.0197599.

47. Flott K, Callahan R, Darzi A, Mayer E. A Patient-Centered Framework for Evaluating Digital Maturity of Health Services: A Systematic Review. Journal of medical Internet research 2016, 18(4):e75. 10.2196/jmir.5047.

48. Bloland P, MacNeil A. Defining & assessing the quality, usability, and utilization of immunization data. BMC Public Health 2019, 19(1):380. 10.1186/s12889-019-6709-1.

49. Mennito SH, Darden PM. Impact of practice policies on pediatric immunization rates. J Pediatr 2010, 156(4):618-622. 10.1016/j.jpeds.2009.10.046.

50. Heeks R. Health information systems: failure, success and improvisation. International journal of medical informatics 2006, 75(2):125-137. 10.1016/j.ijmedinf.2005.07.024.

51. What are Global Goods, https://wiki.digitalsquare.io/index.php/What_are_Global_Goods; 2020 [Accessed: October 11 2020].

52. Ahlbrandt J, Henrich M, Hartmann BA, Bundschuh BB, Schwarz J, Klasen J, Rohrig R. Small cause - big effect: improvement in interface design results in improved data quality - a multicenter crossover study. Studies in health technology and informatics 2012, 180:393-397.

53. Steen M. Tensions in human-centered design. CoDesign 2011, 7(1):45-60.

54. Black AD, Car J, Pagliari C, Anandan C, Cresswell K, Bokun T, McKinstry B, Procter R, Majeed A, Sheikh A. The impact of eHealth on the quality and safety of health care: a systematic overview. PLoS Med 2011, 8(1):e1000387. 10.1371/journal.pmed.1000387.

55. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information technology: a review of the recent literature shows predominantly positive results. Health affairs (Project Hope) 2011, 30(3):464-471. 10.1377/hlthaff.2011.0178.

56. Sandhu JS, Hosang RN, Madsen KA. Solutions that stick: activating cross-disciplinary collaboration in a graduate-level public health innovations course at the University of California, Berkeley. American journal of public health 2015, 105 Suppl 1:S73-77. 10.2105/AJPH.2014.302395.

57. Beres LK, Simbeza S, Holmes CB, Mwamba C, Mukamba N, Sharma A, Munamunungu V, Mwachande M, Sikombe K, Bolton Moore C *et al*. Human-Centered Design Lessons for Implementation Science: Improving the Implementation of a Patient-Centered Care Intervention. J Acquir Immune Defic Syndr 2019, 82 Suppl 3:S230-S243. 10.1097/QAI.0000000000002216.

58. Vechakul J, Shrimali BP, Sandhu JS. Human-Centered Design as an Approach for Place-Based Innovation in Public Health: A Case Study from Oakland, California. Matern Child Health J 2015, 19(12):2552-2559. 10.1007/s10995-015-1787-x.

59. Battles JB, Keyes MA. Technology and patient safety: a two-edged sword. Biomed Instrum Technol 2002, 36(2):84-88.

60. World Health Organization. *WHO guideline: recommendations on digital interventions for health system strengthening. Web Supplement 1: Evidence-to-Decision Frameworks.* Geneva; 2019.

61. Kellermann AL, Jones SS. What it will take to achieve the as-yet-unfulfilled promises of health information technology. Health affairs (Project Hope) 2013, 32(1):63-68. 10.1377/hlthaff.2012.0693.

62. Shuchman M. The promise and pitfalls of global mHealth. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne 2014, 186(15):1134-1135. 10.1503/cmaj.109-4861.

63. Freeman VA, DeFriese GH. The challenge and potential of childhood immunization registries. Annu Rev Public Health 2003, 24:227-246. 10.1146/annurev.publhealth.24.100901.140831.

64. Johansen K, Lopalco PL, Giesecke J. Immunisation registers--important for vaccinated individuals, vaccinators and public health. Euro Surveill 2012, 17(16).

65. Poissant L, Pereira J, Tamblyn R, Kawasumi Y. The impact of electronic health records on time efficiency of physicians and nurses: a systematic review. J Am Med Inform Assoc 2005, 12(5):505-516. 10.1197/jamia.M1700.

66. Carayon P, Alvarado CJ, Hundt AS. *Reducing workload and increasing patient safety through work and workspace design*. http://www.engr.wisc.edu/centers/cqpi/reports/pdfs/r185.pdf; 2003.

67. Zheng K, Guo MH, Hanauer DA. Using the time and motion method to study clinical work processes and workflow: methodological inconsistencies and a call for standardized research. J Am Med Inform Assoc 2011, 18(5):704-710. 10.1136/amiajnl-2011-000083.

68. Statistics KNBo. *2014 Kenya Demographic and Health Survey*. Program DHS, International ICF; 2015.

69. Seymour D, Werner L, Mwansa FD, Bulula N, Mwanyika H, Dube M, Taliesin B, Settle D. Electronic Immunization Registries in Tanzania and Zambia: Shaping a Minimum Viable Product for Scaled Solutions. Front Public Health 2019, 7:218. 10.3389/fpubh.2019.00218.

70. Dolan SB, Wittenauer R, Shearer JC, Njoroge A, Tabu C, Kamau O, Onyango P, Owiso G, Lober B, Liu S *et al*. Integration of a digital health intervention into immunization clinic workflows in Kenya: A qualitative realist evaluation of technology-usability. In preparation.

71. Kreidler S, Muller K, Grunwald G. GLIMMPSE: Online Power Computation for Linear Models with and without a Baseline Covariate. Journal of statistical software 2013, 54(10):i10.

72. Chowdhury M, Sarker A, Sahlen K-G. *Questing the MyChild Solution in Afghanistan: An external evaluation of data quality, operational cost and efficiency*. 2018.

73. Chowdhury M, Sarker A, Sahlen K-G. *Evaluating the data quality, efficienyc and operational cost of MyChild Solution in Uganda: The assessment report*. 2018.

74. Sowe A, Putilala O, Sahlen K-G. *Assessment of MyChild Solution in The Gambia: Data quality, administrative time efficiency, operation costs, and users' experiences and perceptions*. 2018.

75. Hlavac M. stargazer: Well-Formatted Regression and Summary Statistics Tables. R package version 5.2.2., https://CRAN.R-project.org/package=stargazer; 2018 [Accessed: November 15 2020].

76. Wittenauer R, Dolan SB, Njoroge A, Tabu C, Onyango P, Owiso G, Rabinowitz P, Puttkammer N. Usability and acceptability of electronic immunization registry (EIR) data-entry workflows from the healthcare worker perspective in Siaya, Kenya. In preparation.

77. Westbrook JI, Li L, Georgiou A, Paoloni R, Cullen J. Impact of an electronic medication management system on hospital doctors' and nurses' work: a controlled pre-post, time and motion study. J Am Med Inform Assoc 2013, 20(6):1150-1158. 10.1136/amiajnl-2012-001414.

78. Guo C, Ashrafian H, Ghafur S, Fontana G, Gardner C, Prime M. Challenges for the evaluation of digital health solutions-A call for innovative evidence generation approaches. NPJ Digit Med 2020, 3:110. 10.1038/s41746-020-00314-2.

79. World Health Organization. *Report of the Strategic Advisory Group of Experts on Immunization Working Group on Quality and Use of Immunization Surveillance Data: Novel approaches to data collection, management and analysis to improve immunization coverage and use*. Geneva; 2019.

80. World Health Organization. Immunization Coverage, https://www.who.int/news-room/fact-sheets/detail/immunization-coverage; 2019 [Accessed: Jun 8 2020].

81. World Health Organization. *Global Vaccine Action Plan 2011-2020*. www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/; 2013.

82. World Health Organization. Global and regional immunization profile: Africa region, https://www.who.int/news-room/fact-sheets/detail/immunization-coverage; 2019 [Accessed: Jun 8 2020].

83. National Center for I, Respiratory D. General recommendations on immunization --- recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2011, 60(2):1-64.

84. Froen JF, Myhre SL, Frost MJ, Chou D, Mehl G, Say L, Cheng S, Fjeldheim I, Friberg IK, French S *et al*. eRegistries: Electronic registries for maternal and child health. BMC Pregnancy Childbirth 2016, 16:11. 10.1186/s12884-016-0801-7.

85. Groom H, Hopkins DP, Pabst LJ, Murphy Morgan J, Patel M, Calonge N, Coyle R, Dombkowski K, Groom AV, Kurilo MB *et al*. Immunization information systems to increase vaccination rates: a community guide systematic review. J Public Health Manag Pract 2015, 21(3):227-248. 10.1097/PHH.0000000000000069.

86. Merrill J, Phillips A, Keeling J, Kaushal R, Senathirajah Y. Effects of automated immunization registry reporting via an electronic health record deployed in community practice settings. Appl Clin Inform 2013, 4(2):267-275. 10.4338/ACI-2013-02-CR-0009.

87. Project Optimize- PATH and the World Health Organization. Immunization Systems and Technologies for Tomorrow, https://www.who.int/immunization/programmes_systems/supply_chain/optimize/mobile_phones_immunization_registries.pdf?ua=1; 2012 [Accessed: April 15 2020].

88. World Health Organization. *Report on the Immunization and Vaccine related Implementation Research Advisory Commitee (IVIR-AC) Meeting*. http://www.who.int/immunization/research/committees/IVIRAC_Report_2016.pdf?ua=1; 2016.

89. Danovaro-Holliday MC, Ortiz C, Cochi S, Ruiz-Matus C. Electronic immunization registries in Latin America: progress and lessons learned. Rev Panam Salud Publica 2014, 35(5-6):453-457.

90. PATH. BID Initiative, https://bidinitiative.org; [Accessed: September 2020].

91. BID Initiative Theory of Change Interventions: Primary Outcomes 1 & 2, https://www.path.org/resources/bid-initiative-theory-of-change/; 2015 [Accessed: September 2020].

92. World Health Organization. *Monitoring and Evaluating Digital Health Interventions: a practical guide to conducting research and assessment*. Geneva; 2016.

93. National Bureau of Statistics Tanzania, Macro International Inc. *Tanzania Service Provision Assessment Survey 2006*. Dar es Salaam, Tanzania; https://dhsprogram.com/pubs/pdf/SPA12/SPA12.pdf; 2007.

94. World Health Organization. WHO vaccine-preventable diseases: monitoring systems. 2020 global summary, https://apps.who.int/immunization_monitoring/globalsummary/schedules; 2020 [Accessed: Jan 2020].

95. Ministry of Health Community Development Gender Elderly and Children- Tanzania Mainland, Ministry of Health- Zanzibar, National Bureau of Statistics- Tanzania, Office of the Chief Government Statistician- Zanzibar, ICF. *Tanzania Demographic and Health Survey and Malaria Indicator Survey 2015-16*. Dar es Salaam, Tanzania; 2016.

96. Miles M, Ryman TK, Dietz V, Zell E, Luman ET. Validity of vaccination cards and parental recall to estimate vaccination coverage: a systematic review of the literature. Vaccine 2013, 31(12):1560-1568. 10.1016/j.vaccine.2012.10.089.

97. Dolan SB, Carnahan E, Shearer JC, Beylerian EN, Thompson J, Gilbert SS, Werner L, Ryman TK. Redefining vaccination coverage and timeliness measures using electronic immunization registry data in low- and middle-income countries. Vaccine 2019, 37(13):1859-1867. 10.1016/j.vaccine.2019.02.017.

98. Carnahan E, Ferriss E, Beylerian E, Mwansa FD, Bulula N, Lyimo D, Kalbarczyk A, Labrique AB, Werner L, Shearer JC. Determinants of Facility-Level Use of Electronic Immunization Registries in Tanzania and Zambia: An Observational Analysis. Global Health: Science and Practice 2020. 10.9745/ghsp-d-20-00134.

99. Dolan SB, Alao ME, Mwansa FD, Lymo DC, Bulula N, Carnahan E, Beylerian E, Werner L, Shearer JC. Perceptions of factors influencing the introduction and adoption of electronic immunization registries in Tanzania and Zambia: a mixed methods study. Implement Sci Commun 2020, 1:38. 10.1186/s43058-020-00022-8.

100. Tanzania's President Magufuli sacks 10,000 over fake certificates, https://www.bbc.com/news/world-africa-39745362; 2017 [Accessed: November 23 2020].

101. Adetifa IMO, Karia B, Mutuku A, Bwanaali T, Makumi A, Wafula J, Chome M, Mwatsuma P, Bauni E, Hammitt LL *et al*. Coverage and timeliness of vaccination and the validity of routine estimates: Insights from a vaccine registry in Kenya. Vaccine 2018, 36(52):7965-7974. 10.1016/j.vaccine.2018.11.005.

102. Clarke KEN, Phiri Chibawe C, Essiet-Gibson I, Dien Mwansa F, Jacenko S, Rhee C, Kwendakwape M, Kashoka A, MacNeil A. Strengths, pitfalls, and lessons learned in implementing electronic collection of childhood vaccination data in Zambia: The SmartCare experience. International journal of medical informatics 2019, 129:146-153. 10.1016/j.ijmedinf.2019.06.006.

103. Luhm KR, Cardoso MR, Waldman EA. Vaccination coverage among children under two years of age based on electronic immunization registry in Southern Brazil. Rev Saude Publica 2011, 45(1):90-98.

104. Kindoli R. *BID Initiative Final Evaluation Report: Immunization Data Quality and Use in Tanzania*. Dar es Salaam, Tanzania; http://bidinitiative.org/wp-content/uploads/BID-Initiative_ME-Endline-Report_Tanzania_FINAL_20August2018.pdf; 2018.

105. Mvundura M, Di Giorgio L, Vodicka E, Kindoli R, Zulu C. Assessing the incremental costs and savings of introducing electronic immunization registries and stock management systems: evidence from the better immunization data initiative in Tanzania and Zambia. Pan Afr Med J 2020, 35(Suppl 1):11. 10.11604/pamj.supp.2020.35.1.17804.

106. D'Agostino M, Novillo-Ortiz D: **PAHO/WHO: eHealth conceptual model and work programme for Latin America and the Caribbean**. In: *The Global People-centered eHealth Innovation Forum: 2011*: Satellites; 2011: 10-12.

107. Principles of Digital Development, https://digitalprinciples.org/principles/; [Accessed: Apr 18 2019].