REPORT

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Landscape Analysis of Electronic Immunization Registries

Lessons learned from a Landscape Analysis of EIR implementations in Low and Middle Income Countries

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Table of Contents

EIR Landscape Analysis

Acronyms V

Executive Summary 6

Background 8

Methodology of Landscape Analysis 9

- METHODOLOGY 10

Landscape Analysis Findings 10

- SUMMARY OF EARLY EIRs IDENTIFIED: FOCUSED IN PAHO REGION . 10
- Recent EIRs and bid initiative eirs 11

Insights on Sustainability 11

Insights on Functional Requirements 13

- AdDITIONAL REQUIREMENTS to consider 15

  TABLE 2: ADDITIONAL FUNCTIONAL REQUIREMENTS 15

  TABLE 3: FUNCTIONAL REQUIREMENTS BY EIR GOAL 16

- selecting an eir system 18

Promising Practices for Implementation 19

TABLE 4: PROMISING PRACTICES FOR IMPLEMENTATION 20

Equity Considerations 21

- IDENTIFYING AND PREDICTING INDIVIDUALS WHO ARE Un- and UNDER-IMMUNIZED 21

- Ensuring equitable data quality 22
- Preventing misuse of data..... 23

Evidence Gaps And Future Directions 23

Appendix A. Unique Identifiers: Technologies and Practice..24

Appendix B: Considerations in Transitioning from Paper to Electronic Immunization Records 27

Appendix C. References for EIRs in LMICs 29

References.....42

This paper was developed to inform VillageReach's planned Electronic Immunization Registry implementation in Mozambique. These findings are offered in the spirit of sharing with others who may be considering or planning similar projects.

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Acronyms

AEFI	Adverse Event Following Immunization
BMGF	Bill & Melinda Gates Foundation
CRVS	Civil Registration and Vital Statistics
DHIS2	District Health Information Software 2
EIR	Electronic Immunization Registry
GDRP	General Data Protection Regulation
GVIRF	Global vaccine and immunization research forum
HCW	Health Care Worker
IIS	Immunization Information System
LMIC	Low and Middle Income Countries
MOH	Ministry of Health
OpenLMIS	Open Logistics Management Information System
OpenSRP	Open Smart Register Platform
PAHO	Pan American Health Organization
QR	Quick Response
PNV	National Immunization Plan
RNI	Chile's Registerio Nacional de Immunisacion
SMS	Short Message Service
TiMR	Tanzania's Immunization Registry
WHO	World Health Organization

Executive Summary

VillageReach launched a landscape analysis in 2019 to identify EIR implementations in low and middle income countries (LMICs) and identify lessons in sustainability, implementation planning, functional requirements and improving equity. This research, begun in spring 2019, was part of planning for the implementation of an electronic immunization registry (EIR) in Mozambique to increase vaccination coverage and equity, improve data quality and resiliency, and address health care worker data burden. The findings have influenced our approach to this work and are presented here as a means of sharing these insights more broadly.

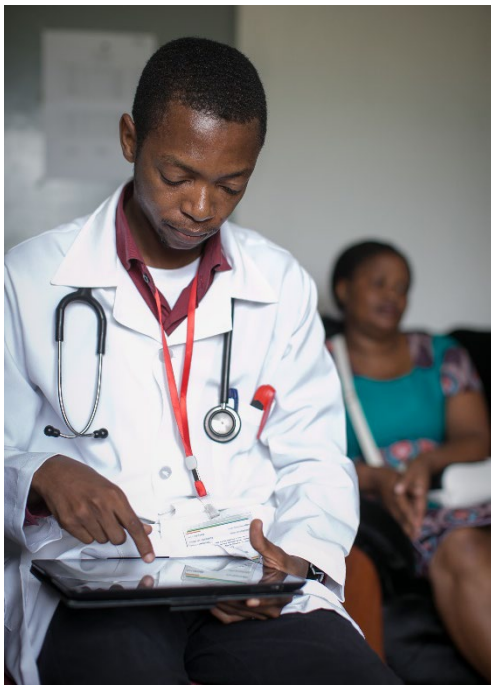
The landscape analysis consisted of a literature review, followed by key informant interviews and a targeted grey literature search for specific implementation questions. The landscape analysis did not include an exhaustive search of all EIRs to date. The literature review focused on EIRs in Africa, Asia or Latin America, EIRs that were scaled beyond an initial pilot and/or included more than 50 sites, and systematic reviews of EIRs or summaries of implementation best practices. The literature review ultimately identified 30 articles. To include more recent thinking on EIRs, interviews were conducted with seven subject matter experts. Grey literature was also included to answer two key questions on transitioning from paper-based to electronic-only systems and developing a unique ID for EIRs.

Several countries in the PAHO region were among the earliest EIR implementors, followed by a wave of EIR implementations in LMICs across the globe starting around 2016. Many of the EIRs implemented in the PAHO region are well documented in the published literature. A significant challenge of several was the inability to interoperate or permit data exchanges with other systems, including within Ministries of Health, as they were developed for exclusive use by the immunization program. They do, however, offer many helpful lessons relevant to designing EIRs for sustainability, and key functional requirements, and equity, which are described below. Published literature on more recent EIRs (ie. post 2016) are scarcer. The Better Immunization Data (BID) Initiative is a notable exception and several of their publications are referenced in the findings below.

In accordance with our research objectives, findings are presented as insights in four areas: 1) sustainability, 2) functional requirements, 3) promising practices for implementation and 4) improving equity. We conclude by identifying existing knowledge gaps and future directions for enhancing the usefulness and value of EIRs. Appendices A and B highlight findings on two unique implementation challenges that were identified during the landscape analysis process: 1) developing a unique ID for EIRs, and 2) transitioning from paper-based to electronic-only systems. Appendix C includes a table of references for publications detailing specific EIR implementations in LMICs.

Sustainability: Given the substantial cost and effort required for launching an EIR, it should first be part of a long-term vision for a country's health system and be designed with sustainability in mind. This means creating a shared plan for the long-term use of an EIR and designing the EIR to meet the needs of its intended users. Lessons for achieving these two goals include:

- Inspire country ownership with early/regular collaboration with government and other stakeholders
- Articulate the value of an EIR to the overall health system – now and in the future
- Create a roadmap for system and data interoperability
- Plan for continuous financial and human resources for the ongoing use of the EIR
- Actively understand vaccinator needs and have this guide solution development
- Approach implementation with flexibility, to ensure system meets user needs
- Incorporate data quality and use components to re-inforce value of the EIR



Functional Requirements: **While neither the WHO nor PAHO has yet published a full list of functional requirements that EIRs must include, we site a list of eleven critical functional capabilities based on the PAHO region implementations and BID Initiative list of minimum viable product requirements as well as a list of six additional optional requirements. We further map requirements to forward-looking project goals, to assist decision-making on the importance of these requirements.** The eleven critical functional capabilities include:

- Enrollment at birth in the EIR
- A unique and unequivocal identifier
- Vaccine event data
- Client managment
- Mechanisms for aggregating data at different geographic levels
- Identification of under-immunized children/missed vaccinations
- Data security and protection and patient confidentiality
- Data entry as close to the time of vaccination as possible
- Offline capability
- Reports
- Stock management.

The six optional requirements we identified for consideration include adverse event reporting, birth and death data, automated individual followup of vaccination schedules, microplanning, data on social determinants of health, and vaccine administration/support for health care workers. We then identify six potential goals of an EIR: 1) improve vaccine coverage and equity, 2) improve dose timeliness, 3) improve vaccine accuracy (ie numerator and denominator accuracy), 4) improve immunization program efficiency, 5) improve data quality and 6) improve primary health care service delivery. We outline how forward-looking functional capabilities can assist in meeting these six goals. Finally, we identify three common open source EIR platforms; OpenSRP, DHIS2 Tracker, and Shifo MyChild. **As a next step, it would be valuable for implementors to understand how each of these systems perform these key functional requirements.**

Promising Practices for Implementation: **Even more critical than the functional requirements necessary for developing an EIR, is the process for integrating it into a health care worker's daily workflow.** We describe considerations and promising practices related to change management, data burden, training, data use and the transition from paper to digital records. All of these pieces should be carefully considered to ensure that EIRs are successfully adopted and become a sustainable part of a health care workers daily activities.

Equity: EIRs can be a valuable tool to improve coverage equity through the identification of under-immunized children (ie. drop-outs) and unimmunized children (ie. zero dose children), assuming data is available that can allow the identification of unimmunized children. More detailed data on these individuals collected in the EIR could also allow better prediction and pre-emptive action to prevent missed immunizations. Program implementers must also ensure the equitable implementation of EIRs by focusing training to those users least prepared to use the technologies so unintended gaps in data quality do not result. Preventing the misuse of data is also important to protecting the health and well-being of all, and especially disadvantaged groups.

This research has revealed valuable insights for planning an EIR implementation in Mozambique. Questions remain, however, for implementors about the ideal use case of an EIR, ways to improve their value to countries that have adopted them, and how to make them sustainable over time. Specifically, to which groups and in which settings are EIRs most beneficial? What is the appropriate scale to get maximum benefit from an EIR (ie. targeted locations vs. nationally scaled)? How can they be used to address the most vulnerable groups (ie. urban poor, migrants, refugees)? How can they advance the delivery of primary care? What is the role of the private sector in creating the best enabling environment? Further research on these questions will be helpful to guide future use.

Background

VillageReach has supported the Mozambique Ministry of Health EPI (MoH-EPI) program to improve immunization coverage and equity since 2002 with a specific focus on strengthening the immunization supply chain. To date, our immunization system enhancements have supported improved vaccine availability, reduced costs, and have increased immunization coverage across the country. In recent years, however, immunization coverage rates have stagnated around 80%. Despite high percentages of children receiving initial vaccinations, the dropout rate is significant at 35%, indicating that barriers beyond infrastructure and supply persist.

The MoH-EPI has been keen to improve immunization data quality, use and resilience. Several studies conducted to assess the quality of data produced by the EPI program, including the EPI review in 2016, DQS assessment in 2018, and onsite supervisions conducted at provincial level between 2015 and 2018, have highlighted the challenges with data quality and limited data use for programmatic decision-making. Health care worker data burden is part of this issue as heavy work loads and inadequate staff support can affect data quality (Ford et al., 2018). Additionally, recent cyclones in several regions of Mozambique exposed the fragility of the country's immunization data through the total loss of the paper immunization records (ie. health cards and associated patient registry books) among many affected families and their local health facilities.

To address these challenges, VillageReach in partnership with the MoH-EPI, initiated the introduction of an electronic immunization registry (EIR). EIRs are computerized, individualized immunization registries that are part of the immunization information system containing both demographic data on individual children and immunization events. EIRs have four main functions, according to PAHO. These are to: 1) facilitate the individualized and timely monitoring of immunization schedules, 2) provide outputs that facilitate monitoring of vaccination coverage, disaggreagated by vaccine, dose, geographical area, age and provider or facility, 3) facilitate the active search of unvaccinated individuals (often called zero dose children) and 4) support and facilitate the identification of immunizations supply requirements at all levels of the health system, especially at the operational level (PAHO, 2018).

An EIR offers the potential to solve these challenges in Mozambique because it can help to improve coverage rates and equity and can provide access to more timely, accurate, complete and resilient immunization data. EIRs can

enhance immunization programs by improving the data collection process, easing immunization programs' ability to track individual children and by supporting more specific monitoring of program inefficiencies and coverage gaps through new measures.

Immunization data in LMICs, as in Mozambique, have traditionally been collected and managed with paper-based tools (ie. registry books, tally sheets, summary reports) at the health facility level, and the data collected has often been of low quality, including high levels of missing data (Ward et al., 2017). This is in part due to data not being recorded in a timely manner (Mckibben et al., 2012) and inadequate training and support of health facility staff (Ford et al., 2018). EIRs can help improve *how* data is collected by lessening the time required to both collect data and create reports, allowing data to be collected only once instead of recording it on multiple forms and by allowing for a more dynamic workflow as the health care worker is able to move with the patient instead of staying seated behind a desk (Werner et al, 2019). It can also help to address accuracy issues related to poor recording practices (Dolan et al, 2019) and detect inaccurate data at the point of data collection (Werner et al, 2019).

Because EIRs collect data at the individual patient level and not at the aggregate level, they allow a better understanding of coverage gaps (Danovaro-Holliday, 2014) and thus can support targeted outreach to different groups or individual children (Dolan et al, 2019) and improve outreach to drop-outs (Werner, 2019). EIRs also have several functions that can contribute to improved coverage including electronic recalls or reminders, the ability to monitor performance by provider, and immunization decision support to assist health care workers ensure that families return at the right time for their next immunization (Groom et al., 2015). The ability to better and more easily track individual children can also assist countries in more effectively and efficiently targeting resources (Namageyo-Funa, 2018; Danovaro-Holliday, 2012).

Further, EIRs can help to improve vaccine coverage by introducing the possibility to track new, more specific measures to improve vaccine program management. These measures can be quickly calculated and allow programs to more easily act on their data at the right time (Dolan et al, 2019). This is because EIRs allow for efficient collection and access to children's vaccination administration dates and date of birth (Dolan et al, 2019). Some of these proposed new measures include dose validity, or the number of doses administered on or after the scheduled date per national schedule, dose timeliness, or the number of doses administered on or after the recommended time interval since the previous dose was administered, and lost to follow-up, or the number of children who never return to a facility for the next scheduled dose after a particular time period (Dolan et al, 2019). This last measure, lost to follow-up, which refers to children who never return to a health facility for a next dose of vaccination, is currently captured in paper format, but is time consuming to compile. EIRs can also introduce the ability to more accurately estimate drop-outs, defined here as vaccine dose-specific and relating to administrative delays in the scheduling of subsequent antigen doses, at the individual level (Dolan et al, 2019). As well, EIRs can improve vaccine coverage estimates reported at the individual, health facility and system level, allowing gaps among particular groups to be quickly identified, as noted above (Dolan et al, 2019).

Methodology of Landscape Analysis

In spring of 2019, VillageReach carried out a landscape analysis of EIR implementataions in LMICs in order to prepare for an EIR in Mozambique. This landscape analysis consisted of a literature review, subject matter expert interviews, and a targeted grey literature search. We conducted the landscape analysis to identify key considerations for ensuring sustainability, key functional requirements, implementation planning and equity. The initial literature review focused on published articles of individual EIR implementations in LMICs that had moved beyond the pilot phase or systematic reviews offering lessons across multiple implementations. After an initial review of 112 articles originally identified in

PubMed, Scopus, Science Direct and the Web of Science databases, a total of 30 articles were finally determined to meet these inclusion criteria. The articles reviewed spanned 10 years, from 2009-2019. The vast majority of these articles focused on individual programs or systematic reviews in LMICs in the PAHO region or documented the Better Immunization Data (BID) Initiative's work in Tanzania and Zambia. To ensure information on the most recent trends and thinking on EIRs, VillageReach conducted subject matter expert interviews with seven individuals. This convenience sample of experts known to our research team included Marcela Contreras and Martha Velandia, both Immunization Advisors and Project Specialists at PAHO, Jan Grevendonk, Immunization, Vaccines and Biologicals Technical Officer at the World Health Organization, Carolyn Gulas, Health Solutions Lead at Ona, Tove Ryman, Program Officer, Vaccine Delivery Team at the Bill & Melinda Gates Foundation, Onei Uetela, Former Immunization Specialist at UNICEF, and Laurie Werner, Global Director of the BID Initiative at PATH.

METHODOLOGY

The landscape analysis included an initial literature review with the following inclusion criteria:

1. EIRs in Africa, Asia or Latin America
2. EIRs that were scaled either beyond an initial pilot, had at least 50 locations, or covered half the state/province/region
3. EIR implementation best practices, or
4. Systematic review of EIRs

Finally, VillageReach included a targeted grey literature search to collect additional, specific information on the BID Initiative EIRs in Tanzania and Zambia, which were identified early on in the published literature review as potential model implementations. Grey literature was also sought to collect additional information on two unique implementation topics 1) developing a unique ID for EIRs and 2) transitioning from paper-based to electronic-only systems. VillageReach acknowledges the existence of additional published literature, grey literature and promotional materials on other EIRs, but an exhaustive literature search on all EIR implementations in LMICs was beyond the scope of this work. See **Appendix C: References for EIRs in LMICs** for more information on the documents included in the Landscape Analysis.

Landscape Analysis Findings

SUMMARY OF EARLY EIRS IDENTIFIED: FOCUSED IN PAHO REGION

Some of the earliest EIRs, as well as the best documented EIR implementations in LMICs, that were revealed through our landscape analysis, were in the PAHO region. The earliest of these implementations were in Mexico (1987) and Uruguay (1991), followed by Panama (2006-2007). There were varying degrees of scale-up and long-term sustainability of these systems. The EIR in Mexico, for example, was discontinued due to poor data registration practices and insufficient funding (Trumbo; 2018). (More recently, however, a new electronic immunization record system, Sistema Integral de Vacunación or SIIVac, was introduced in Mexico.)

EIRs were also implemented or planned in several additional countries within the PAHO region, including Argentina, Belize, Brazil, Chile, Colombia, Costa Rica, the Dominican Republic, Guatemala, Paraguay and Peru. Many of these EIRs were applications developed for exclusive use by the immunization program and could not interoperate or permit data exchanges with other systems, including within Ministries of Health (Danovaro-Holliday, 2014; Contreras/PAHO interview). Additional EIRs that were identified in our landscape analysis as being implemented before 2016, were undertaken in Asia (ie. Vietnam), and Eastern Europe (i.e. Albania).

RECENT EIRS AND BID INITIATIVE EIRS

More recently, EIRs have begun to be implemented in a wide range of LMICs, including in Africa (i.e. Tanzania, Zambia, Kenya, Rwanda) as well as in other countries in Asia (i.e. Pakistan, Bangladesh, India, Afghanistan). Many of these EIRs were launched in 2016 or later (WHO, 2019). While published information on these new pilots are more scarce, most of these EIRs are conceived as modules of a larger health information system, but are often one of the first such modules (Onei/ UNICEF Interview).

The Better Immunization Data (BID) Initiative, funded by the BMGF and implemented by PATH, introduced EIRs in Tanzania and Zambia as part of its efforts to enhance immunization and health service delivery through improved data collection, quality and use. The BID Initiative followed a Collaborative Requirements Development Methodology to pinpoint common EIR requirements across ten African countries with the aim of developing a replicable and holistic package of data quality and use interventions (PHII, 2020). Based on the acceptance and success of the pilot implementations, they have scaled in both Tanzania and Zambia; to over 3,000 facilities in 10 regions in Tanzania and across 320 facilities in two provinces in Zambia. In Vietnam, the EIR implemented by a related scope of work, Project Optimize, also scaled nationwide.

Insights on Sustainability

An important lesson that emerges across the EIR implementations in the PAHO region and through the BID Initiative is that implementing an EIR is a timely process that is best built with sustainability in mind (Danovaro-Holiday; 2014). Ensuring sustainability means creating a shared vision and plan for the long-term use of an EIR and ensuring that the EIR meets the needs of its intended users. Key aspects of this include:

- Ensure country ownership with early/regular collaboration with government, partners and stakeholders
- Articulate the value of an EIR to the overall health system
- Create a roadmap for system and data interoperability
- Plan for continuous financial and human resources for the ongoing use of the EIR
- Actively understand vaccinator needs and have this guide solution development
- Approach implementation with flexibility, to ensure system meets user needs
- Incorporate data quality and use components to reinforce value of EIR

Critical to the adoption of an EIR and its use over the long-term is the ***collaboration of key government, partner and other stakeholders*** from the beginning of the process of developing a solution. These key decision-makers should understand the existing landscape and be engaged in clearly defining the vision and system requirements for an EIR. A county may choose to undergo an EIR readiness assessment, which helps to define key stakeholders and provides a suggested process for helping stakeholders to think through the main aspects of developing a vision and plan for EIR implementation. Additionally, stakeholders need to decide how decisions will be made about the EIR system going forward and by whom. For example, how will decisions be made on when to retire the paper data collection system and when and how to update the system to maximize its value over time.

The cost of EIR systems are not insignificant at the outset, so an important part of ensuring the sustainability of an EIR is laying out its *value to the overall health system* of a country. Information published on the cost of implementing EIRs in the Arusha, Tanga and Kilimanjaro regions of Tanzania and the Southern Province of Zambia, show that the overall initial cost of implementing open source EIRs was $4.2 million (US$709 to US$1,320 per health facility) and $3.6 million (US$2591 per health facility) respectively (Mvundura, 2019). Furthermore, competition with other public health initiatives for human, financial and material resources within the public sector have been shown to be a challenge of implementing EIRs (Grevendonk/WHO interview; Ward et al., 2017). A country must have the opportunity to understand the upfront and long-term costs of investing an an EIR and the potential savings in preventing morbidity and mortality related to vaccine-preventable diseases. This information can help to ensure a long-term commitment to using an EIR to meet health care system needs.

Another key aspect of sustainability is having a *clear roadmap for system and data interoperability*. The value proposition for an EIR grows through increased interoperability. For example, linking utilization data from an EIR and supply data from an eLMIS allows the ability to fine tune vaccination estimates that allow for reduced wastage. Additionally, there is a growing understanding among global stakeholders that piloting health information systems and applications that are not part of a country's long-term vision are unlikely to be sustained over the long-term (Grevendonk/WHO interview). While most EIRs do not initially link across multiple health data systems, and integrations to date have been challenging (Grevendonk/ WHO interview) understanding how the system will link to other systems and data sources is key before a project is implemented. This includes ensuring that clear communication exists between the Expanded Program on Immunization and ICT stakeholders in the government and that project plans link to existing health information strategies, policies and/or policy conversations (Ryman/ BMGF interview). Communities such as OpenHIE (www.ohie.org) are disseminating best practices in health data interoperability at scale. The Principles for Digital Development (https://digitalprinciples.org/principles/) includes a mandate for Open Standards to support interoperability.

Once the vision for an EIR is clear, stakeholders should *plan for the long-term financial and human resources* needs of the EIR. To create stable financial support it is helpful to transparently map out the on-going costs of maintaining an EIR (Ryman, BMGF interview). This includes the maintenance of, and changes to, the system (Grevendonk/ WHO interview). An EIR will also require securing long-term human resources to support EIR usage. This may mean developing a plan for bringing in local technology partners or working towards creating this capacity locally. This roadmap should also clearly define all necessary system requirements with key stakeholders from the beginning.

It is important to the adoption and overall usage of the EIR that it be ***useful to vaccinators***, and not just higher-level decision makers. The BID Initiative recommends using a user-centered design methodology, which involves consulting health care workers at the start of the design phase and then allows for timely testing and input as the system is developed and refined. Human-centered design is a creative approach to ensure the needs of the end user(s) are carefully considered in the design of a health information solution. It is built on three phases; inspiration, ideation and implementation. Human-centered design methods for use in planning an EIR include site assessment, empathy mapping, creating user and stakeholder personas and scenarios, workflow identification and creating a journey map, among other methods. Design With The User is also one of the Principles for Digital Development. In Albania, where the goals of the EIR implementation were successfully communicated to health care workers, consulting nurses in the design and testing phases turned them into project champions and made training easier (Grevendonk/ WHO interview). This means allowing sufficient time for software development and testing to ensure the project scales with a tool that truly meets user needs. Additionally, solution simplicity is an important principle; countries with limited ICT capacity need to support the technology and users need to be able to learn the solution with minimal support and training.

Both PAHO and BID point to the importance of approaching development and implementation of an EIR with ***flexibility***. It is important to design a system that can adapt to new vaccines, new schedules and other unforeseen changes. The BID Initiative demonstrated an ongoing commitment to user needs in its flexible approach; it scrapped early attempts at creating the EIRs in Tanzania and Zambia and adopted another system in both countries because the initial systems were insufficient (Werner et al, 2019).

Further, it is important that implementors ***incorporate data quality and data use components*** as part of their program and include it in their scale-up plans. This will help encourage the best uptake of the EIR and use of the data. In Tanzania, the BID Initiative encouraged data collection and use processes by creating peer networks on WhatsApp, micro-training videos and by developing data-use guides. The data-use guides helped health facility and district staff by outlining easy-to-assess scenarios using their data to determine next steps and follow-up actions (Werner et al., 2019). Supervision coaching tools can also be used in low-performing health facilities to support district staff use data to address existing challenges.

Insights on Functional Requirements

WHO and Gavi continue to examine the evidence and best practices around EIRs, but have not published formal guidance on technical functions and standards. According to a 2014 meta-review of PAHO region EIR

implementations, an ideal EIR should contain seven technical capabilities (Danovaro-Holliday, 2012). Below we expand upon these seven capabilities, identifying a total of eleven critical and six optional functional requirements.

1) Enrollment at birth: EIRs should include information on all the children born in the system's catchment area. For many countries, this has meant that health care workers are required to enter newborn children into the EIR within a set period of time, such as within 48 hours.

2) A unique and unequivocal identifier (ID): Having a unique identification number or system for identifying each child is critical to being able to dependably identify children and track their vaccinations. It also allows the system to easily track populations who are nomadic, seasonal workers, and migrants, as well as individuals who may temporarily access services at a health facility outside their catchment area. ID methodologies are evolving quickly, although some of the most recent biometric technologies have yet to be incorporated for use with EIRs. Please see *Appendix A* for more detailed information on identification methodologies.

3) Vaccine event data: Danovaro-Holliday recommends including data on vaccination provider, vaccine dose and date of immunization in an EIR. In addition, the WHO and PAHO also suggest that an EIR should collect data on patient age, "target group", and geographical area. Contact information, sex and place of residence are also important (Goldstein &Maise, 2012; Onei/UNICEF interview). Related to this, the system should be able to display a list of a child's vaccination schedule.

4) Client management: To avoid duplicate records, EIRs should have the ability to search for, identify and consolidate duplicate records. Duplicate records can accidentally occur when a health care worker tries to create a new record for a child that is already in the system. Ideally a system will warn data collectors if a child being registered may already have an existing record in the system. One point of clarification is whether a system will do this type of identification in real-time. Some systems generate a report of suspected duplications to be reconciled by the health care worker at a later time.

5) Mechanisms for aggregating data at different geographic levels: It is important to allow data users to be able to easily aggregate data at different geographic levels in order to meet reporting requirements.

6) Identification of under-immunized children/missed vaccination.: It is critical that users can easily access information on children who are under-immunized or, when possible, unimmunized. This can be done by highlighting missed vaccinations on a specific child's immunization schedule and also as the ability to generate a list of children who should be prioritized for follow up in order to catch them up on missed vaccinations.

7) Data security and protection, and patient confidentiality: While specific functional requirements were beyond the scope of this landscape analysis, the need to ensure data security and patient protection will continue to grow in importance as some LMICs are working to create a digital civil registry for their citizens. The European Union has enacted the General Data Protection Regulation, or GDRP, which is widely recognized as a leading guideline for the protection of consumer and patient data.

8) Data entry as close to vaccination as possible: PAHO considers data entry at vaccine administration a best practice. This means that, if possible, data on vaccine administration should be entered into the EIR at the time the vaccination is given. This can be particularly challenging when doing outreach campaigns and when vaccination is being done simultaneously in outreach and health facility-based sessions. It is important, though, both for minimizing worker data burden and improving the timeliness and quality of vaccine data. Doing so may require re-examining the workflow for health care workers.

9) Offline capability: Due to infrastructure limitations in some areas of LMICs, it is very important to consider an EIR's capability to work in offline mode. Many existing EIR systems have been designed to operate offline until the system can be synced online. This means that the EIR has the capability to access and manipulate patient data on the most

recent download and then upload the data changes at next syncing. In areas where internet connectivity is not available, it may be useful to consider how alternate technologies, such as smart paper technology, can be used to digitalize the analysis, reporting and use of immunization data by health care workers. Advancements in smart paper technology have occurred in the last few years, but no publications were found of recent applications of this approach.

10) Reports: The ability to automatically create simplified reports on vaccine administration greatly increases its usefulness. Two useful reports identified by the BID project include 1) vaccine coverage as a percentage of children living in a certain area who are born in a certain timeframe and were vaccinated with a certain dose, and 2) categorize defaulters by location and community health worker as well as report adverse events (Werner, 2019).

11) Stock management: Stock management refers to managing inventories of commodities, such as vaccines, used in public health programs. It includes ordering, storing, tracking and controlling inventory. Ideally, this function includes interoperability with an existing eLMIS system. Both the Tanzania and Zambia implementations found supply stock management to be a key component for making an EIR useful to health care workers and the BID Initiative included it on their list of requirements for a minimum viable product (Seymour, 2019). These systems included the ability to receive notifications when vaccination stocks were low and the ability to reorder vaccinations within the EIR system (Werner/ PATH interview). It is also potentially useful to better understanding consumption needs (Ryman/BMGF interview, 2019).

ADDITIONAL REQUIREMENTS TO CONSIDER

This analysis has identified additional functional requirements for considerations that are important in the EIR planning and development stage, which are identified in Table 2. Further, Table 3 identifies functional requirements as they relate to key overarching goals of an EIR, as a means of helping implementors to prioritize functionality by goal. Some of these functional requirements are forward-looking and will require refining to work well on the ground.

TABLE 2: ADDITIONAL FUNCTIONAL REQUIREMENTS

Additional Functional Requirements	Lesson Learned
Adverse event reporting	It is a best practice, according to the WHO, for an EIR to collect information on adverse event reporting. This is a good way to collect information on unexpected negative reactions to a vaccination administered as well as documenting the death of a child, who will no longer be followed in the system.
Automated individual follow up of vaccination schedules	SMS messages or voice messages can be valuable to remind caregivers that it is time to return for their child's next vaccination dose where caregivers use mobile phones. The BID initiative recommends using SMS messages in areas where there is literacy, high use of mobile devices for communication and high numbers of home births to remind individuals to bring their children in for vaccination in order to maximize value/reduce unnecessary costs (Werner, 2019). In addition, other types of outreach such as two-way communication via text, or email or voice has been used to ensure a more personalized touch where access to mobile phones, internet, and literacy is not a concern (Grevendonk/WHO interview).
Birth and death data	Having access to information on births and deaths of children in the geographic area is necessary to identify children who are unimmunized, often called zero-dose populations and defined as lacking a DTP-1 vaccination, as well as target children who are behind on their immunizations. To address this need, some systems have required

Additional Functional Requirements	Lesson Learned
	that all children be registered at birth within the EIR; ideally within 48 hours. Alternately, an EIR can be made interoperable with a country's Civil Registration and Vital Statistics (CRVS) system, if it is electronic, so that the data can be cross-referenced.
Microplanning	A potential future use of decision support in an EIR is micro-planning. Data from an EIR on the timing and locations of immunization sessions might allow vaccinators to better time clinic hours, and mobile and outreach strategies (Ryman/BMGF interview, 2019).
Social determinants of health	Social determinants of health include information on a family's socio-economic situation such as caregiver education level, heating source and indicators of overcrowded living. Collecting this data can be off-putting to families, so the value of the data should be carefully considered and the number of questions should be minimized. Research is underway to examine the utility of including additional population health demographic characteristics that might provide insights on social determinants of health and trends in populations subgroups around accessing immunization services (Namageyo-Funa et al., 2018). The BID Initiative collected a wide range of data, including demographic data, adverse events, and information on other health services provided at the same time (Werner/ PATH interview).
Vaccine administration/ decision support for health care workers	EIRs can provide important support to health care workers by helping to calculate an individual's follow-up vaccination schedule, particularly when vaccinations are outside of the normal vaccination timeline. This information can ideally be paired with visit reminders to ensure a patient remembers to return at the correct time. It is also helpful to allow an authorized individual at the national level to set/change the vaccination schedule.

As a country considers the possible functional requirements to include in its EIR, their implementation goals can help to guide these decisions. This chart aligns functional requirements with goals that countries may wish to pursue in adopting an EIR. It is intended to be forward-thinking and includes functional requirements that many systems may not have included in their EIRs to date.

TABLE 3: FUNCTIONAL REQUIREMENTS BY EIR GOAL

EIR Implementation Goals	Key EIR Functional Requirements	Considerations
IMPROVE VACCINE COVERAGE/EQUITY	• Inclusion of data on births and/or deaths, to identify and target zero-dose kids. • Report of under-vaccinated and zero dose children, ideally by geographic location. • Ability to work in offline environment. • Ability to uniquely identify children.	• Birth and death data from a civil registry is often not available in an electronic format. Short-term solutions may include information collected by community health worker applications in select geographies. • The ability for a system to work offline is critical in areas where

EIR Implementation Goals	Key EIR Functional Requirements	Considerations
		there is no regular internet connectivity.
IMPROVE DOSE TIMELINESS (ie. dose is administered on or after the recommended time relative to previous dose) 	• Decision support for health care workers around scheduling next immunization visit • Micro-planning to ensure optimal timing of clinic operating hours. • Reminders to parents to bring their child in for an immunization.	• Decision support to assist in scheduling next visit, especially when vaccines are given off their schedule
IMPROVE VACCINE ACCURACY (ie. correctness of numerator and denominator data) 	• Incorporation of data from additional sources (such as CHWs) on children in the target age group in target geographic areas. • Incorporation of data on births from vital records, if available electronically. • Reduction of data entry error through on the spot data verification (ie. can not enter a future date, etc).	• Requires triangulation of data to determine actual number of children in the target geographic area.
IMPROVE IMMUNIZATION PROGRAM EFFICIENCY 	• Incorporation of data from an electronic logistics management information system (eLMIS) • Ability to record and track consumption data on vaccine doses • Ability to re-order vaccines and/or related supplies • Ability to reduce wastage • Planning for vaccination sessions, and for outreach sessions	• Incorporating barcodes with a VVM (ie. a portion of the barcode changes color when a vial has been exposed to extreme temperatures) onto vaccination vials can allow insight into cold chain management and vaccine wastage. Incorporating supply and demand data allows for knowledge (and potentially prediction) of consumption. • A simplified, quicker workflow for health care workers can result if the paper system is retired.

EIR Implementation Goals	Key EIR Functional Requirements	Considerations
IMPROVE DATA QUALITY	• Entering data into the EIR as close to the collection of data (in terms of time-frame) as possible to ensure accurate, timely data. • Including data verification and completeness checks • Including client management features to identify duplicate child registration at the time a record is created (as opposed to a later time).	• Emphasize consistent use of the EIR in initial and follow-up trainings. • Avoiding any unnecessary delays in phasing out the paper system and sharing plans for this process may help to ensure regular EIR use. • Invest in strategies to improve data use such as on-going peer learning and support (ie What App groups, data competitions, etc) to ensure health care workers are invested in data quality outcomes.
IMPROVE PRIMARY HEALTH CARE SERVICE DELIVERY	• Incorporation of antenatal, prenatal and child health modules. • Consideration of "whole child" health needs in development of the system.	• Some software systems have modules for tracking these outcomes that can be incorporated at the start or over time. • Additionally, planning for interoperability with other electronic data sources (ie. electronic medical records) could help to create a wholistic approach to primary health outcomes.

The BID Initiative has published a more extensive list of 81 requirements for a minimum viable product for a electronic immunization record (Seymour, 2019) based on the inputs generated during requirements-gathering with leaders from 10 African governments, which we refer to in Appendix C. Additionally, the WHO is in the process of creating technical standards for the key functionalities of an EIR to ensure that core functionalities of an EIR can be met by any system (Grevendonk/ WHO interview).

SELECTING AN EIR SYSTEM

Once the required functionality of an EIR is well understood, an implementer should consider these along with the financial resources available to select from various EIR system options. For example, it is possible to purchase a commercial system or use a commercial software as a service, implement a freely available system provided by a donor or partner, create a custom system, or use an open-source EIR system (PAHO, 2018). PAHO has already created a detailed list of the advantages, disadvantages and needs of each of these options (PAHO, 2018). There are a few major variables to consider between these options when selecting a system in a specific context.

The variables include:

- Degree of control or customization required over the end product,
- Dependence on a single vendor or flexibility to export data and switch platforms,
- Time available for creating or customizing a system,
- Country-level capacity and/or knowledge available to support the system over time,
- Cost; including the balance between up-front and long-term costs, and

- Compatibility with existing health information technology.

Many of the earlier EIR systems were created by a country for their specific needs, but commercial software systems and services were also used. Recently, open source systems has gained popularity as a means of encouraging sustainable health information technology solutions. Open Source is one of the Principles for Digital Development. These systems are usually designed to be compatible with a wide range of health information technologies, are intended to be freely available to all implementors and are often surrounded by a large community of users, meaning that human capacity to work in the systems are high.

The following is a list of software systems with EIR modules that are either open source or were built by a non-profit foundation and have been included because they have been used in multiple contexts in the last few years. Two of the solutions are also identified by Digital Square as global goods, meaning that they are scalable, sustainable, accessible, interoperable and evidence-based (PATH, 2019). This is an important designation for countries to consider as adopting global goods can help to prevent "re-inventing the wheel" and the inefficient use of resources often seen in the creation of a single application solution. Adopting global goods can help to ensure a country is pursuing a strategic approach to developing its health information technology infrastructure because these solutions have been vetted in a wide range of settings and have been shown to work well with other health information technologies. We do not include a list of all proprietary software available.

- OpenSRP: Like other open source systems, OpenSRP has been designed to be compatible with a wide range of existing health information technologies (ie. DHIS2 and OpenLMIS), is freely available, and is supported by a large community of users. OpenSRP has been shown to be successfully used as an EIR in Zambia, as part of the BID Initiative, and was more recently used in Kenya. OpenSRP has also been identified as a global good by Digital Square (PATH, 2019).
- DHIS2 Tracker: DHIS2 Tracker has also been used as an open source platform for an EIR. A benefit of this system in Africa is that the majority of countries are already using this open source software system to report, disseminate and analyze aggregate (not patient-level) health data. It was recently deployed in Rwanda as an EIR. DHIS2 has been identified as a global good by Digital Square (PATH, 2019).
- Shifo MyChild: This product has some of the functions of an EIR and combines smart paper functionality and the digitization of data with a card to support paper-based data collection. It is designed to support child registration, individual follow-up on a child's vaccine schedule and other preventative health services.

While it is beyond the scope of this analysis to evaluate the ability of these systems to deliver on key functional requirements, it is important for countries to evaluate the ability of individual systems to help them meet their program goals according to their ability to perform many of the functional requirements identified here.

Promising Practices for Implementation

While it is critical to plan for all of the functional requirements necessary for implementing an EIR, it is perhaps even more critical to consider the process for developing and introducing an EIR and ultimately integrating it into a health care worker's daily workflow. Table 4 describes considerations for successfully planning the implementation of an EIR to ensure its adoption at the point of service.

TABLE 4: PROMISING PRACTICES FOR IMPLEMENTATION

Implemenation Area	Considerations
Change management	If health workers do not get adequate support to adopt the EIR, this can undermine the EIR's data quality, use and success. To this end, a clear change management plan is important. A human centered design process can help to engage health care workers at the start of the planning process and ensure the change management plan addresses user concerns. Understanding how health workers created or embraced change previously in their work can also help in adopting another new process and EIR tool. The BID initiative recommends asking health care workers open ended questions about their impressions of the EIR and its use to develop a communications strategy that addresses any concerns among staff (Werner/PATH interview).
Data use components	The BID initiative's work in Tanzania and Zambia shows the importance of including data use components as part of the overall EIR implementation to both improve data quality and decision-making based on the data. Components may include building user networks, creating micro-training videos and/or creating data use guides (Werner, 2019).
Peer learning and support	In addition to using peer mentoring as a traning method, on-going peer learning and support is important to ensuring the sustained use of an EIR. The BID Initiative used WhatsApp to allow health workers to share experiences and support each other with the EIR and data collection and use generally.
Plan to target follow-up to low-performing areas	In Tanzania and Zambia, implementors worked with the district to identify low-performing health facilities and determined questions to ask about health facility data to address performance gaps, encourage feedback loops and build a stronger data use culture. Supportive supervision, from implementors and supervisors, is also needed to follow-up on areas of poor-quality data and discrepancies in the data.
Training	Training is a key component of successfully implementing an EIR. Ideally all health workers from the health facility and select staff from the district, or sub-district where that administrative unit exists, should be trained in the EIR to allow multiple staff to support any new staff in its consistent use. This also helps to guard against knowledge loss if health workers leave. The BID initiative followed an "on-the-job" methodology, bringing training to each health facility and incorporating a train-the-trainer approach as well as a series of 3-5 follow up "touches" or facility visits. The project also advises that trainings should be tailored to the health worker's level of proficiency of using digital tools. A particular focus in implementing an app-based EIR system, for example, should be training individuals who have never used a smartphone. Data quality and careful use must be emphasized throughout the EIR implementation process and monitored through supportive supervision. Consistent use of the tools should also be reinforced to have high-quality data accessible for action.

Implemenation Area	Considerations
	The BID initiative also used a phased approach to its training. The first 2-3 weeks were focused on emphasizing data collection, the second 2-3 weeks were focused on improving data quality and a third phase was then introduced to continually emphasize data use. Using a peer mentoring model, in which trained 'data mentors' trained staff in new health facilities, can also help to reduce costs. Having government staff play these key roles also increased government ownership of the EIRs as the EIR scaled beyond the initial test sites (Werner, 2019).
Transition from paper to digital records	How the transition from paper to digital records is handled may have a substantial impact on how receptive health care workers are to using and sustaining a new system. In the few countries that have successfully transitioned to an electronic-only immunization registry system in some portion of their geography, this goal was achieved only after a period of successful dual paper and electronic immunization registry implementation. Governments need to thoughtfully define what measures and process they will use to determine when it is time to phase out paper registries *in advance* of implementing the EIR. This can help to prevent an unnecessary delay in the transition. Important aspects of this transition include carefully considering whether or not to transfer initial data from paper records to the digital system in advance of its launch, aiming to minimize the length of time a parallel reporting system is in place, adopting a phased approach to transitioning provinces or districts to an electronic-only system and developing context-appropriate targets for readiness for the transition. Please see *Appendix B* for additional information.

Equity Considerations

Understanding how EIRs can contribute to more equitable vaccine coverage was an important goal of undertaking this landscape analysis. Below, we highlight three considerations for how EIRs can help improve the equity of immunization programs. Implementors need to consider how to:

- Identify and predict individuals who are un- and under-immunized,
- Ensure "equitable" data quality through targeting trainings to those without the requisite technology experience, capturing vaccination data from mobile and outreach sessions, and supplementary campaigns, and ensuring access to as many health facilities as possible, and
- Guarantee there are safeguards against data being misused.

IDENTIFYING AND PREDICTING INDIVIDUALS WHO ARE UN- AND UNDER-IMMUNIZED

Collecting both demographic data and data on social determinants of health, can provide health care workers with a more comprehensive picture of the communities that they serve (Bosch-Capblanch et al, 2009) including identifying

or confirming inequities among specific groups (Dolan et al. 2019). Over time, more detailed data on drop-outs (eg. home address, barriers to accessing healthcare, social determinants of health) may be useful to better predict individuals that are likely to miss subsequent vaccinations so that steps can be taken to pre-emptively target services to them.

Social determinants of health that have been suggested as being helpful to understand and target individuals include data on nutrition, parents' employment status, family income, accessibility of health services, and parents' education level, among others. The EIRs implemented in Tanzania and Zambia both included some demographic questions as well as some questions on social determinants of health (PATH Vietnam Brief, 2018), although the exact questions were not specified.

The time and energy necessary to collect additional data must be balanced, however, with the potential benefits it can add. As well, program implementors should carefully consider whether asking for data on any specific social determinant of health (ie. income, legal status, educational level, etc.) might make families uncomfortable, and steer away from doing so.

In the face of stagnating immunization rates, moving the needle on reaching zero-dose children (ie. children who never receive the DTP-1 dose) remains an important step for improving overall vaccine coverage rates and their equity. When combined with vaccination-event data and birthdates for individual children contained with an EIR, the introduction of birth and death data from a civil registry or from community health workers can identify zero-dose children who have not been registered in an EIR. Identifying zero-dose children has been challenging for EIRs to date (Tove/BMGF Interview; 2019), however, given the lack of data sources that could help to identify them (ie. an electronic birth and death data registry) in many LMICs. Reaching these populations will also require a better understanding of the reasons why some families may choose not to vaccinate their children. Some of this information may be recorded in the adverse events fields in an EIR when a family refuses to vaccinate a child, making it a good starting point for outreach efforts.

Migrants are another population that may be helped by EIRs. Individuals that move from place to place can be difficult to track using a paper registry system should the family lose the child's health card or other documentation of when the child received her vaccinations. As EIR records are regularly synced to a central database, migrant families can recover their records at any connected health facility where they seek service once the child's record is identified in the system.

ENSURING EQUITABLE DATA QUALITY

As mentioned above, the careful development of training and change management plans are key tools for ensuring the uptake of an EIR. This has an important equity aspect; it is critical to ensure and re-ensure that all staff are properly trained in using the EIR and collecting high quality data. Inequities in vaccine coverage and vaccine service delivery can be unintentionally continued or amplified where inequities are overlooked due to lack of good information for decision-makers. While not a magic bullet, it is particularly important to target training to staff who lack experience using the requisite EIR technology (i.e. tablet or smartphone) (Ward et al, 2017; Trumbo et al., 2018) and in areas where there are existing data quality challenges (Werner, 2019).

Another aspect of ensuring equitable access to quality data, is ensuring that an EIR can work in offline mode, in clinics that have intermittent internet connectivity, to ensure the widest number of health clinics can use the EIR. In areas where there is no connectivity, health facilities may also benefit from using smart paper technology to support digitalizing data initially collected on paper forms. This can allow for easy data analysis, including the quick identification of drop-outs and thus provide some of the benefits of an EIR system. Additionally, community health workers, as potential drivers of outreach to under-reached groups, can also be equipped with EIR-enabled

smartphones to ensure the collection of quality data on under- or unimmunized individuals identified in mobile and outreach sessions, campaigns and in other contexts.

PREVENTING MISUSE OF DATA

As several LMIC governments are considering or actively creating digital civil registries of their citizens, the demographic indicators that are collected need to be carefully considered. The ability to target vaccination campaigns and alternate outreach methods to under-reached groups must be balanced with privacy concerns. It has been suggested that religion and ethnicity are two data points that should not be collected, given their use at different times in history to discriminate and incite violence against minority populations (The Economist, 2019). Legal status is another data point that program implementors may want to avoid asking about as collecting this data may make individuals who are not legal residents fear that they will be persecuted.

Evidence Gaps And Future Directions

As noted above, this landscape analysis identified findings from a subset of EIRs that have been published (ie. most from EIRs implemented pre-2016), as well as targeted grey literature and interviews with subject matter experts. These documents have revealed valuable insights for planning an EIR implementation in Mozambique. Questions remain, however, for implementors about the ideal use case of an EIR, ways to improve their value to countries that have adopted them, and how to make them sustainable over time.

Better understanding the value of an EIR: Among which groups and in which situations are EIRs most useful? How can EIRs best help those groups that are most vulnerable, such as the urban poor, migrants and refugees? What is the business case for the value of investing in an EIR? Given the substantial cost and effort of implementing an EIR, it is important to be able to articulate the value of an EIR to improve health outcomes or program management; for example, in terms of increased vaccine coverage, timeliness or efficiencies gained (Tove/BMGF interview). Beyond the basic functions of tracking immunizations, there is some evidence to suggest that they have value in improving the quality of data reporting, targeting defaulters, automating processes for health care workers, and improving understanding of stock consumption needs (Tove/BMGF interview). The better we can quantify the value of an EIR's benefits to address specific problems in immunization delivery, and among specific populations, the better we can determine whether an EIR is a good fit for a specific government or context.

Using EIRs in combination with other tools to improve primary health care: One important question is how broadly should we think about the use of an EIR? Might data on the under-immunized or unimmunized be useful to helping target children in need of other primary health care services? What is the potential to expand data collection beyond immunizations to include other primary health care services and indicators over time? What other data platforms should EIRs interoperate with to provide high quality primary care for the whole child? The experience of high-income countries suggests that EIRs can serve as a building block of a primary health care patient data registry system, which can provide important insights into access, quality and a variety of health outcomes (Hinman and Ross, 2010). Nutrition and growth indicators have been collected in Vietnam and Rwanda, and the capacity exists in some EIR software packages to incorporate prenatal, antenatal and other primary health service data. If implemented in the context of a strong enabling environment and a clear health information technology vision, these additions may strengthen both the value of the investment in EIRs and improve their long-term value to health care workers as well.

Engaging the private sector: What is the long-term financial viability of open source systems like EIRs? How can EIR systems help to bridge the gap between private sector and public health care systems in LMICs? Regarding the involvement of private enterprises in immunization delivery, Gavi and the Global Fund have recently entered into

strategic partnership agreements with several private companies including Mastercard, the financial services company, and Orange, a leading telecommunications operator. These partnerships encourage private corporations' involvement in supporting Gavi's goals to increase vaccine coverage, reduce vaccine wastage, increase efficiency and ensure better vaccine potency. Given multilateral funders push for health information solutions to become sustainable and questions about the long-term financial viability of open source software platforms, the role of private companies in creating a supportive enabling environment for EIRs is an area for further exploration and deeper understanding.

Appendix A. Unique Identifiers: Technologies and Practice

The interest in uniquely identifying individuals has been growing in importance across many LMICs, both in the health sector and beyond.

- Civil Registries: In LMICs, many births go unregistered, which results in the lack of official documentation for those individuals. This has increasingly become known as the identification gap and is thought to waste resources (e.g. redundant vaccinations), limit information, and impede access to health services. To this end, many African countries are currently exploring or have begun to improve their civil registries, including incorporating the use of biometrics to identify citizens.
- Patient Health Data Registries: With the growing interest in ensuring that health information solutions are connected in an overall health information strategy and infrastructure, unique identifiers offer a key to sharing health data across multiple programs and health sectors.
    - *Electronic Immunization Registries*: In the context of an EIR, being able to uniquely identify children is crucial to ensure the right child receives the correct dose of a vaccine at the proper time and to enable countries to calculate accurate denominators of target populations. They allow health workers to search for and manage a child's records.

With this growing interest and a proliferation of new technologies for performing unique identification, what technologies and practices exist? What are the best ways to incorporate unique identification into an EIR?

What Has Been Done

Unique IDs used in EIRs have included both human-generated and machine-generated identifiers. In addition, several private companies have developed biometric systems that can be deployed for use as the basis of a civil registry, as noted above, or for tracking patients in public health programs. If a country has laid out an approach to a unique identification system in their national digital strategy, it is ideal to align with this approach. However, in the absence of this, there are a variety of strategies to consider when adopting a unique ID system as part of an EIR.

Table 5: Unique Identification Generatation Method and Associated Technology

Type of Identification	Technology	Description	Notes
Human - generated	**Unique Combination of Variables**	Some EIRs have created a unique ID by combining a variety of variables such as names, parental names, date of birth, place of birth, etc.	
	National Identification Number or **Birth Registration Number**	Several EIRs in Latin America used a child's national identification number provided by the civil registry office or birth registration number as a unique ID.	This method requires countries to have a high level of timely birth registration. In these cases, it may be advantageous for countries to consider linking to this in their EIR.
Machine-generated	**Barcodes/QR Codes**	Health workers register a child at the facility or immunization session using a tablet, which automatically generates a barcode/QR code that has a unique ID number on it and assigns it to that child. Then the same barcode/QR code gets printed and adhered to the child's health card. The unique ID is generated by the underlying EIR software system (ie. OpenSRP).	Tanzania's registry uses barcodes and Zambia's registry uses QR codes as children's unique IDs. Children can be added and tracked in the EIR by either scanning the barcode/QR code itself or by a health worker manually typing in their ID number.
	Simcards	In instances where an EIR is cell-phone based, some projects are using simcard information as the basis for identifiying care givers.	
	Near-Field Communication Chip cards	Machine-generated unique IDs can also be linked to a near-field communication chip-enabled card, which would allow a health care worker to access information on the child's immunizations on a tablet capable of reading it.	
Biometrics	**SimPrints**	Gavi and SimPrints (a UK-based non-profit social enterprise) have collaborated to develop a biometric innovation that links children to health records through their fingerprints. Health workers use a pocket-sized fingerprint scanner to scan a child's fingerprint. The scanner wirelessly syncs with a health worker's tablet that houses the EIR.	The hardware created is robust, portable, low-cost, and wireless.

		This enables the linkage of children's fingerprints to their immunization records.	
	Element, Inc.	Element is an artificial intelligence powered, software-only biometric recognition solution. The software uses a tablet or phone's camera to create a unique biometric identity based on multiple body part. This solution was developed to identify children and can run offline and on any mobile device with a camera.	

Things to Think About

Interoperability

A sustainable EIR system will ideally be linked to additional personal health data, for example in a electronic health record, and health system data, for example in a vaccine logistics management system. In instances where a unique identification system (such as an OpenHIE Client Registry) has not been identified by a country, it is very important that projects consider the systems the EIR will need to connect with in the long run and select both an EIR system and a unique identification approach that is compatible.

Privacy & Security

As EIRs store individualized, identifiable information about sensitive topics such as one's health and demographics, it is important to put safeguards in place to ensure personal data are not used improperly. An EIR should fulfill any guidelines the country has laid out in their digital health policy or other policies they may have regarding keeping individual health information confidential. If policies do not exist, it is important to formulate, implement, and enforce data security and professional ethics policies.

Measures to address privacy and security concerns identified include:

- Requiring passwords on tablets that health workers use to collect EIR information (PAHO, WHO; 2017)
- Where national standards do not exist, reference international standards on security and privacy. For example, when PATH partnered with countries to determine the critical requirements for an EIR, they agreed that an EIR should include international standards around security (e.g., authentication, encryption, and secure communication), as well as around privacy (e.g., handling personal health information) (Seymour; 2019)
- Ensure extra precautions for storing biometric data. For example, SimPrints does not store fingerprint data as images, but instead stores them as encrypted templates through database anonymization. (Storisteanu; 2015)

Equipment Procurement & Cost

There are upfront costs and logistics associated with purchasing and procuring the hardware needed to use different unique identification technologies. The cost of this hardware can vary dramatically. For example, a tablet used to scan barcodes/QR codes should be equipped with a five-megapixel camera or greater (BID; 2018). Understanding the upfront and on-going costs associated with a unique identification system are key to its sustainability. Additionally,

identifying a local vendor that is capable of supporting the technology (ie. the ability to print barcodes/QR codes) is key to sustainability of that method over the long term.

Change Management

As new tools and technologies get introduced into facilities, it is important to keep in mind how it will be perceived by community members such as mothers and caretakers. Messaging around how the tools are used, what they are being used for, and how they impact the services community members receive should be developed and disseminated

When Tanzania's Immunization Registry and barcodes were rolled out, some communities thought that the barcodes were a way for their children to be marked and then later kidnapped. This led to fear around bringing children to immunization services. The BID Initiative worked with health workers to create messaging around the barcodes and had the health workers, a trusted source in communities, communicate the information to caregivers and mothers. This small change improved perceptions of the barcodes and eased fears regarding their use (BID; 2018).

Appendix B: Considerations in Transitioning from Paper to Electronic Immunization Records

Transitioning from paper tools to an electronic immunization registry is a big decision. If fully integrated into health care worker practices and a MoH's long-term strategic vision, it has the potential to allow countries to reap the full benefits of an EIR implementation, including optimizing workflow, reducing burden and improving data quality and analysis capabilities. But it is a major undertaking that requires a long-term commitment and buy-in. To date, these decisions have taken a long time, in part because decision-makers want to know that they are making the right decision. How can program implementors ensure readiness to transition? What mechanisms can make the transition smooth?

What Has Been Done

While many EIR pilots in specific regions of LMICs have been implemented, only a few have scaled-up nationally. In addition, few EIR implementors have attempted to transition their data collection system to an electronic-only immunization registry system. The EIRs that have made this transition in some health facilities and have published information about it include Tanzania's Immunization Registry (TiMR) (BID; 2019), Vietnam's ImmReg (now National Immunization Information System) (PATH; 2017), and Chile's Registerio Nacional de Immunisacion (RNI) (BID; 2017).

Things to Think About

From the limited literature that is available on these countries' experiences, the following considerations can be helpful to ensuring a transition is made successfully:

- Planning for the initial transfer of data: The Kenya EIR implementation indicates the importance of planning to invest time in initial transfer of data from paper records to the electronic system in advance of official deployment of an EIR. This can help to ensure a smooth initial launch and can be accomplished by hiring data technicians (not normal health facility staff) to ease this burden on health care workers. In some countries, by contrast, the data quality of paper records may be so poor that it is not advisable to attempt to transfer data from the paper to electronic system. The BID Initiative found that in facilities serving a large population, it worked best to hire data technicians to register each child in the EIR as they came in for immunizations over a

short initial period (ie. four to six weeks). This prevented health care workers from having to go through the time instensive process of simultaneously registering families and administering immunizations and allowed for verification of the data in the paper registries.

- Minimize length of parallel reporting systems: When EIRs are introduced, countries have usually had health workers maintain the legacy paper tools while also using the EIR. This allows the program to work through any bugs and update the EIR based on user feedback, while utilizing the paper tools as a data quality check against data entered in the EIR. While having a parallel reporting system allows for a smoother transition, they can also inhibit adoption of the new tools by greatly increasing health worker burden (Ryman/BMGF Interview). Thus countries should develop an assessment framework from the beginning to plan which indicators and process will be used to determine when the legacy system can be phased out. This approach can minimize the time needed to maintain parallel reporting systems.

- Determine targets: Countries will need to set evidence-based targets for when EIR data is considered accurate enough to replace paper-based immunization registries, as well as what is considered sufficient EIR use. These targets will help countries determine when they are ready to transition from a paper to electronic immunization registry. In Chile, sufficient EIR usage for transition was determined on a facility by facility basis. The target usage rates was for the EIR to be used consistently 90% of the time (BID; 2018). In both Tanzania and Vietnam, the government has been working to develop a set of key indicators to measure progress in EIR use and what targets facilities have to meet for each indicator. Potental indicators may include HCWs degree of comfort using the system, the existence of a back up system, and the ability to transfer data among systems (Ryman/ BGMF interview).

- Phased approach to transition: To reduce the amount of time health workers have to use parallel reporting systems, take a phased approach to transition. Once facilities/districts/regions/etc. have reached the targets that have been set for data accuracy and sufficient EIR use, allow them to retire the legacy system. In this way, facilities that were the first to start using the EIR are not stuck using both systems until all of the country is ready to transition. Stakeholders in Chile recommended against waiting for the entire country to reach their 90% target for consistent EIR use and instead, transitioned regions as soon as the target was met. Similarly, in Tanzania, health facilities are transitioned once set performance targets are met.

Appendix C. References for EIRs in LMICs

General							
Title and Link	**Author/ Organization**	**Publication Year**	**Brief Description**	EIR Type	Reference Type	Year EIR implemented	Scaled Nationally?
Redefining vaccination coverage and timeliness measures using electronic immunization registry data in low- and middle-income countries (Link)	Dolan	2019	This article discusses how measures for assessing vaccination status and program performance can be redefined and recalculated using EIR data when generated at the health facility level and the implications of the use and availability of electronic individual-level data.	N/A	Peer Review Article (Vaccine)	N/A	N/A
The use of eHealth with immunizations: An overview of systematic reviews (Link)	Dumit	2018	A literature review that encourages using eHealth to increase vaccination adherence and uptake	N/A	Peer Review Article (Vaccine)	N/A	N/A
Handbook on designing and implementing an immunization information system (Link)	ECDC	2018	The handbook gives strategies that build on the experiences of IIS experts; provides case studies from programs, including functionalities, benefits, challenges, and implementation. It shares experiences and explores ideas that are valuable for developing a new IIS or upgrading an existing system.	N/A	Handbook	N/A	N/A
Meeting report: Global vaccine and immunization research forum (Link)	Ford	2018	A report from the GVIRF meeting on the scientific advances and innovative technologies to design and deliver vaccines as well as novel tools and approaches to increase the uptake of vaccines throughout the world.	N/A	Meeting Summary	N/A	N/A

Fingerprint records and digital health cards to help solve global identity crisis (Link)	GAVI	2018	Gives high level details on unique ID technologies that can be used to identify children and track immunizations.	Element, Inc, Ona (OpenSRP), iCivil Africa, Simprints	Press Release	N/A	N/A
Immunization registries can be building blocks for national health information systems (Link)	Hinman	2010	The article is a high-level description how IIS systems are an essential component and allow Public Health workers to asses changes and impacts of immunizations.	N/A	Peer Review Article (Health Affairs)	N/A	N/A
GAVI, NEC, and Simprints to deploy world's first scalable child fingerprint identification solution to boost immunization in developing countries (Link)	GAVI, NEC, Simprints	2019	Gives high level details on unique ID technologies that can be used to track children's immunizations, specifically Simprints' work.	Non-EIR technology Simprint	Press Release	Planning proof of concept validation in Bangladesh and Tanzania in 2020	No
Immunization information systems to increase vaccination rates (Link)	Groom	2015	A review of available literature on how EIRs can be used to increase vaccination rates. They looked at studies where 5 capabilities of IIS were used which included: client reminder and recall, health care workers used the system to determine a client's vaccination status, guide public health responses during a vaccine preventable outbreak, inform assessments of vaccination coverage, and facilitate vaccine management.	N/A	Peer Review Article (Journal of Public Health Management and Practice)	N/A	N/A
A realist review of what works to improve data use for immunization (Link)	IDEA (PAHO, WHO, PATH)	2019	This report tried to answer the two following questions about EIRS: 1) what are the most effective interventions to improve the use of data for immunization programs and policy decision-making and 2) why and how do these interventions produce the outcomes that they do?	N/A	Report	N/A	N/A

Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation, and Evaluation (Link)	PAHO; WHO	2017	This guide provides a comprehensive guide and recommendations for EIR work across the entire process from planning through implementation.	N/A	Report	N/A	N/A
The purpose and functions of immunization information systems within health care organization (Link)	Sinn	1997	A broad overview of issues and capacity that public and private health care organizations need to consider when starting to build and implement an EIR in a place practicing patient care.	N/A	Peer Reviewed Article (Arch Pediatr Adolesc Med)	N/A	N/A
Can digital tools be used for improving immunization programs? (Link)	Tozzi	2016	The article discusses the importance of immunization programs but points out that there are only a few examples of implementation. They identify different dimensions of these types of programs: immunization registry, surveillance of vaccine-preventable diseases, surveillance of AEFI, and monitoring confidence in immunization systems.	N/A	Peer Review Article (Frontiers in Public Health)	N/A	N/A
Biometric Fingerprint System to Enable Rapid and Accurate Identification of Beneficiaries (Link)	Storisteanu	2015	This article discusses how SimPrints can address the challenges mHealth programs face with patient identification due to lack of identity documents.	N/A	Peer Reviewed Article (Global Health: Science and Practice)	N/A	N/A

Africa								
Countries	**Title and Link**	**Author/ Organization**	**Publication Year**	**Brief Description**	**EIR Type**	**Reference Type**	**Year EIR implemented**	**Scaled Nationally?**
General	Considerations for the development and implementation of electronic immunization registries in Africa (Link)	Namageyo-Funa	2018	A commentary piece that discusses opportunities and challenges in the adoption of EIRs in the African context.	N/A	Peer Review Article (PanAfrican Medical Journal)	N/A	N/A
Tanzania	Intervention spotlight: Electronic immunization registry (Link)	BID	2015	High level overview of EIRs and what challenges they can help address in immunization services including: defaulter tracing, planning immunization services, estimating target populations, and streamlining monthly reporting.	N/A	Press Release	N/A	N/A
Tanzania	Tanzania makes history as first facilities retire paper immunization registries (Link)	BID	2019	A brief blog about Tanzania's transition process from paper to digital immunization records	TimR - DHIS2	Press Release	2017	Yes

Tanzania & Zambia	BID Initiative lessons learned encyclopedia (Link)	BID	2018	This document captures the various lessons learned throughout the BID Initiative, from the design and testing phase through implementation from both Tanzania and Zambia.	Tanzania - TimR developer Mohawk Zambia - ZEIR developer Ona - Opensource (OpenSRP), Commerical, etc.	White paper, grey literature, EIR User Guide	Does not state	Yes
Tanzania & Zambia	BID Initiative shares lessons and recommendations in new series of briefs (Link)	BID	2017	A blog post that covers 8 briefs including: overview, data use, EIRs, software development cycle, rollout strategy, Change management, peer learning, and sustainability.	Does not give specifics	Press Release	Does not state	Does not state
Tanzania & Zambia	Three Waves of Data Use Among Health Workers: The Experience of the BID Initiative in Tanzania & Zambia (Link)	Werner	2019	This paper discusses how data quality and rollout in Tanzania's and Zambia's immunization programs progressed along 3 phases—from strengthening data collection, to improving data quality, to increasing data use for programmatic decision making.	Both countries use open source software platforms. Tanzania (OpenSRP) & Zambia (Open Smart Register Platform)	Peer Reviewed Article (Global Health: Science and Practice)	Tanzania - 2015 Zambia - 2017	Not when article was written but yes today

Tanzania & Zambia	Electronic Immunization Registries in Tanzania and Zambia: Shaping a Minimum Viable Product for Scaled Solutions (Link)	Seymour	2019	This paper describes collecting common system requirements from 10 sub-Saharan African countries; these requirements represented the countries' vision of an ideal system to track individual child vaccination schedules and elements of supply chain. It outlines the process undertaken and analyzes similarities and differences across the iterations of the EIR in Tanzania and Zambia, culminating in the development of a registry in Zambia that includes the most critical aspects required for initially deploying the registry and embodies what could be considered the minimum viable product for an EIR.	Tanzania - Started with Generic Information System (GIIS) then switched in 2015-2016 to Open Immunize (OpenIZ) now called Tanzania Immunization Registry (TImR) - Zambia started out with DHIS 2 but change to Open Smart Registry Platform (OpenSRP) now called Zambia Electronic Immunization Registry (ZEIR)	Peer Reviewed Article (Frontiers in Public Health)	Tanzania - 2015 switched in 2016 & Zambia 2016, switched 2017	Yes

Tanzania and Zambia	Perceptions of factors influencing the introduction and adoption of electronic immunization registries in Tanzania and Zambia: a mixed methods study (Link)	Dolan	2020	This peer reviewed article did not find a one single factor that influenced the introduction or sustained adoption of the EIRs since many of the factors were interrelated. They found that when an EIR is introduced that strong strategic engagement among partners was important. When the EIR was being adopted they found that adequate staffing at facilities, training, use of data for supervision, internet and electricity connectivity, and community sensitization were important.	OpenSRP	Journal from BMC	Tanzania & Zambia - 2018	No
Uganda	Enhancing workforce capacity to improve vaccination data quality, Uganda (Link)	Ward	2017	Data improvement teams (DITs) visited health facilities in Uganda and identified gaps in awareness and processes, assessed accuracy of data, and provided on-the-job training.	HMIS (but other non electronic methods as well)	Journal from CDC	Does not state	Not at the time the article was written
Zambia	Lessons learned in electronic immunization registry development (Link)	BID	2016	A brief blog providing 7 overall lessons learned from EIR development in Zambia	DHIS2	Press Release	N/A	N/A
Asia								
Countries	Title and Link	Author/ Organization	Publication Year	Brief Description	EIR Type	**Reference Type**	**Year EIR implemented**	**Scaled Nationally?**

China	Human vaccines and immunotherapeutic ten years of experience and progress of electronic immunization registry system in Jiangsu Province, China (Link)	Kang	2017	This paper summarized the mechanism and structure of the EIR implemented in Jiangsu Province in 2006.	Does not give specifics about the EIR used	Peer Review Article (Human Vaccines & Immunotherapeutic)	2006	No, not nationally but yes to Jiangsu Province
Vietnam	Vietnam's digital immunization registry: Important lessons and parallels to BID Initiative (Link)	BID	2017	A brief blog highlighting lessons from Vietnam's EIR that can be applied to BID's work including: 1) country-led, country-owned; 2) ensuring health leader buy-in; 3) building a foundation for sustainability; and 4) vaccines and beyond	Vaxtrak and ImmReg	Press Release	2012	Yes
Vietnam	From paper to e-records: Vietnam's electronic immunization registry (Link)	PATH	2017	A brief document that describes how Vietnam's EIR (ImmReg) went from a pilot to a national program and some of the specific features that have been built in to make the system easier for health workers and families.	ImmReg (Vietnam)	Press Release from organization	2012	Nearly as of 2017, scaled up to 90% of Commune Health Center (CHC) across the country
Vietnam	Vietnam's immunization registries go online meeting the challenge: Creating a new system (Link)	National Institute of Hygiene and Epidemiology, PATH, WHO	2014	The press release discusses the investments and improvements seen in the Ben Tre Province of Vietnam during the pilot phase of implementing an EIR.	ImmReg	Factsheet/Press Release	2012	No, not when article was written but yes today

Vietnam	Improving immunization registration, coverage and monitoring in Viet Nam--Path's Digital Immunization Registry (IR) System (Link)	WHO; UN	2014	Provides some details about PATH's work in Vietnam and how the test EIR works and plans for future growth.	Digital IR	Press Release	Does not state	No, not when article was written but yes today

Latin America								
Countries	Title and Link	Author/ Organization	Publication Year	Brief Description	EIR Type	Reference Type	Year EIR implemented	Scaled Nationally?
Brazil	Monitoring vaccination coverage by electronic immunization registry in medium-sized city, Brazil (Link)	Sayuri	2018	Araraquara, Brazil uses the Juarez System, an EIR that integrates data from disease notification, healthcare, laboratory, and pharmaceutical assistance, to analyze vaccination rates from 51,241 individuals under 18 years of age. They found that vaccination rates were above 95% for almost all cohorts, even though vaccination schedules changed over the 17 years.	Does not state	Peer Reviewed Article (ScienceDirect)	Brazil since 2014 however Araraquara had one of the oldest EIRs in Brazil, 1986.	Yes
Chile	BID Learning Network participants trade experiences and share learnings in Santiago, Chile	BID	2017	This brief blog gives insight into Chile's experience with an implementing and scaling an EIR nationwide and now Chile is looking to expand the capacity of the EIR to incorporate information about stock levels and alerts for health care	Registro National de immunizaciones (RNI)	Press Release	2010	Yes, at more than 1,100 private and public health facilities

	(Link)			workers about patients who are missing a vaccine or are overdue.				
General	Recommendations from the technical advisory group on vaccine-preventable diseases (Link)	TAG	2014	The report focuses on vaccines and gives a very high-level overview of EIRs in Latin America. They brief details on data quality and use and finally follow up with recommendations moving forward.	N/A	Meeting Report	N/A	N/A
General	Electronic immunization registries in Latin America: progress and lessons learned (Link)	Danovaro-Holliday	2014	This article provides lessons learned for EIRs implemented or in the process of being implemented in Latin America. They lay out modalities used for EIR development, which provides a breakdown of different ways to construct/design/implement an EIR.	Nicaragua - (mVac) open source mobile application	Peer Reviewed Article (Pan America Journal of Public Health)	Does not state for each country	Does not state for each country
General	Immunization registries in Latin America and the Caribbean (Link)	Danovaro	2014	A presentation that highlights the benefits of EIRs and gives brief overview of Latin American countries progress on implementing EIRs.	EPI (Bolivia) & SIPNI (Brazil)	Presentation	N/A	N/A
Honduras & Panama	Assesing electronic immunization registries: the PAHO experience (Link)	Danovaro-Holliday	2019	This article focused on developing a methodology to assess EIRs in LMICs in Latin America and the Caribbean. It does give a little insight into the Panama and Honduras experiences.	Panama - PAI software (Visual FoxPro 6.0 and interoperable with other MoH information systems. Honduras - SINOVA (Visual Basic .NET 2010 with an SQL database)	Peer Reviewed Article (Pan America Journal of Public Health)	Panama - developed 2006-2007 Honduras - developed 2009	Does not state the extent they have been scaled up

Mexico & Peru	Improving immunization data quality in Peru and Mexico: Two case studies highlighting challenges and lessons learned (Link)	Trumbo	2018	Case studies were conducted on Mexico and Peru's EIR systems. In Mexico, one of the first EIRs, was discontinued due to poor data registration practices and insufficient funds. Peru's system collected data beyond immunizations to improve health and strengthen health systems. Challenges to implementation and sustainability show the importance of clear governance structures, funding, and incorporating health workers in the process.		Peer Review Article (Vaccine)		
Uruguay	Paper health registries project case study: Uruguay's national immunization program register (Link)	Green	2014	Lessons learned from implementing PNV and transitioning the paper registers into the an EIR.	PNV	Donor Report	1987	Yes

Multi-regions								
Countries	Title and Link	Author/ Organization	Publication Year	Brief Description	EIR Type	Reference Type	Year EIR implemented	Scaled Nationally?
Africa (Zambia & Tanzania) & Asia (Vietnam)	"It doesn't have to be like ripping off a Band-Aid:" Transitioning from paper to digital records (Link)	BID	2018	A high level brief blog that discusses the transition in Tanzania from paper to digital records and highlights the challenges faced by Zambia, Tanzania, and Vietnam.	ImmReg (Vietnam) & ZEIR (Zambia)	Blog Post from BID	Vietnam - 2012	Does not state

Africa (Tanzania) & Asia (Vietnam)	Tanzania & Vietnam forge South-South learning exchange to advance electronic immunization systems (Link)	BID	2018	A brief blog that overviews successes areas of improvement in Tanzania and Vietnam and gives an overview on progress made by each country.	Tanzania - TimR - DHIS2 Vietnam - ImmReg	Press Release	Vietnam - 2012 Tanzania - 2017	Yes
Africa, Asia, & Latin America	Accuracy and quality of immunization information systems in forty-one low income countries. (Link)	Bosch-Capblanch	2009	A data quality audit found that out of 41 countries reviewed, nearly half had scores below 80% and only 9 countries had consistently high scores in the accuracy of information in their IIS. Weaknesses in systems includes inconsistent denominators to establish coverage, poor availability of guidelines, incorrect estimation of vaccine wastage, and lack of feedback on immunization performance.	N/A	Peer Reviewed Article (Tropical Medicine and International Health	N/A	N/A
Africa, Europe, Asia, Latin America, Oceania	Challenges to sustainable immunization systems in Gavi transitioning countries. (Link)	Cernuschi	2018	A review of available literature, of countries transitioning from GAVI, and found that there was a lack of comparative analyses on immunization system performance. From the findings, they recommend development of a more nuanced theory of change toward sustainable immunization programs and measurement of progress in key areas for attention and investment.	N/A	Peer Reviewed Article (Vaccine)	N/A	N/A
Africa and Asia	The catalytic potential of rapid	BID	2019	This press release provides a case study of three countries (Kenya, Pakistan, and Zambia) and the iterations that were made to the EIR systems so additional	OpenSRP	Press Release	Discussions began in: Kenya – 2016	Does not state

	iterative software development (Link)			data points were collected, data was captured accurately, and the new systems were user friendly.			Pakistan – 2016 Zambia - 2014	

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