

Evaluating Zindagi Mehfooz- Electronic Immunization Registry and suite of digital health interventions to improve the coverage and timeliness of immunization services : A mixed methods study in Sindh, Pakistan

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Evaluating Zindagi Mehfooz- Electronic Immunization Registry and suite of digital health interventions to improve the coverage and timeliness of immunization services : A mixed methods study in Sindh, Pakistan

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Abstract

Background: Zindagi Mehfooz (Safe Life) Electronic Immunization Registry (ZM-EIR) in Sindh Province, Pakistan is a comprehensive suite of digital health interventions that aims to improve equitable access, timeliness, and coverage of child immunizations through a smartphone-based application (app) for vaccinators, web-based dashboards for supervisors and managers, text message alerts and reminders for caregivers, and a call center. Since its inception in 2012 until August 2022, ZM has scaled across 30 districts of Sindh Province with phased introduction in other areas including the Federal Capital (Islamabad), Khyber Pakhtunkhwa province and Gilgit-Baltistan region and has been used by over 5,000 vaccinators at public and private immunization clinics to enroll over 7 million children.

Objective: This paper summarizes findings from a mixed-methods study of ZM-EIR which assessed vaccinator use of ZM-EIR, provider and caregiver perceptions of ZM-EIR, temporal changes in immunization coverage and timeliness among children 12-23 months, equity, and cost-effectiveness.

Methods: The mixed-methods study included a) Pre-post outcome evaluation using vaccine coverage from the Multiple Indicator Cluster Surveys (MICS) 2014 and 2019; b) In-depth interviews with caregivers, vaccinators, supervisors, and managers; c) Analysis of ZM-EIR system data, and d) costing analysis. Key outcomes of interest were receipt of individual antigens (BCG, Penta I-III, Measles), full immunization (all antigens), and zero dose children defined as a child aged 6 to 23 months that has not received the first dosage of DPT1/Penta. Incremental changes in coverage were input into the Lives Saved Tool (LiST) to model lives saved from 2017-2019.

Results: ZM-EIR implementation in Sindh Province may have contributed to a 10-percentage point increase in the prevalence of fully immunized children (12-23 months), from 5% (95% CI) in 2014 (before implementation) to 15.1% (95% CI) in 2019. Increases in vaccine timeliness were observed for BCG (+8.3%), Penta I (+3.2%), and Measles II (+1.3) vaccines. The prevalence of zero-dose children declined from 38.7% in 2014 to 24.7% in 2019. Incremental changes in coverage are estimated to have saved over 3,000 lives at a cost per life saved of \$1,362 USD per life saved. Stakeholder groups interviewed had favorable impressions of ZM-EIR. However, they highlighted the dual burden of reporting on paper and gender-related barriers of female caregivers not wanting to give their phone numbers to male vaccinators.

Conclusions: ZM-EIR is a promising technology platform that may have contributed to improvements in immunization outcomes through systematic registration of children, alerts and reminders, and effective use of data from defaulter and zero-dose lists. Clinical Trial: The study received IRB approval from the IRD Review Board with number – IRD_IRB_2021_11_001 and is

registered with ISRCTN #23078223.

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Evaluating Zindagi Mehfooz-Electronic Immunization Registry and suite of digital health interventions to improve the coverage and timeliness of immunization services : A mixed methods study in Sindh, Pakistan

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ABSTRACT

Introduction: This paper presents findings from an evaluation of Zindagi Mehfooz, electronic immunization registry (ZM-EIR) and suite of digital health interventions, aimed at improving data availability and use as a contribution among other immunization program interventions to improved immunization outcomes for children 12-23 months in Sindh Province, Pakistan.

Methods: The mixed-methods study included a) Analysis of ZM-EIR system data to identify high- moderate- and low- adoption and compliance sites, b) In-depth interviews with caregivers, vaccinators, supervisors, and managers; and c) Pre-post outcome evaluation using vaccine coverage from the Multiple Indicator Cluster Surveys (MICS) 2014 and 2018-2019. Key outcomes of interest were improved data availability and use and contributions to immunization outcomes, including receipt of individual antigens (BCG, Penta I-III, Measles), full immunization (all antigens), and zero dose children defined as children aged 6 to 23 months that have not received the first dosage of DPT1/Penta.

Results: By registering newborns, providing alerts and reminders, and tracking their immunization completion, ZM-EIR improved data availability and use within the Essential Program for Immunization (EPI) in Sindh, Province. ZM-EIR was well received by EPI administrators, supervisors, vaccinators, and caregivers. The key benefit highlighted by ZM-EIR users is a list of children who missed scheduled vaccines

(defaulters). Through greater availability and use of data, the ZM-EIR implementation as part of a broader package of immunization program strengthening activities in Sindh Province may have contributed to an increase in immunization coverage and timeliness for BCG and decrease in zero-dose children in 2018-2019 from 2014. Additional findings from the study included the dual burden of reporting on paper and gender-related considerations of female caregivers not wanting to give their phone numbers to male vaccinators, creating barriers to greater uptake of ZM-EIR.

Conclusion: ZM-EIR is a promising technology platform that has increased the availability and use of immunization data that may have contributed along with other intensive immunization program investments to improvements in immunization outcomes through systematic registration of children, alerts and reminders, and increased use of data for planning and monitoring by the EPI Program. **What is already known on this topic?**

- Electronic Immunization Registries (EIRs) are designed to improve the collection, analysis, and use of immunization program data to improve efficiency, equity, and coverage of immunization programs.
- There is very little evidence on the effectiveness of EIRs or their contribution to immunization outcomes associated with their adoption and use.

What this study adds

- Implementation of the Zindagi Mehfooz (ZM) -EIR as part of a broader package of immunization program strengthening activities has improved the availability and use of data, in particular through follow up based on defaulter lists as well as uptake of vaccination services through alerts and reminders to caregivers.
- The ZM-EIR is well received by caregivers, vaccinators, EPI managers, and administrators across Sindh Province, Pakistan for its ability to identify areas of low immunization coverage, facilitate vaccinator supervision, and identify defaulters and zero-dose children.
- ZM-EIR may have contributed to declines in the proportion of zero-dose children, increases in the proportion of fully immunized children, and increases in timeliness for BCG3. However, this may also be the case in other regions in Pakistan.

How might this study affect research, practice, or policy?

- The study contributes to the evidence on the use of electronic immunization registries and more broadly digital health interventions to improve sub-national data availability and use for planning, service delivery, and monitoring of immunization services, contributing to improved immunization coverage. Challenges reported by ZM-EIR users related to dual paper-based reporting and gender barriers offer important lessons for future implementation that include plans for paperless reporting and gender-intentional digital health interventions.

INTRODUCTION

Zindagi Mehfooz (Safe Life) Electronic Immunization Registry (ZM-EIR) is a comprehensive suite of digital health interventions that aims to improve equitable access, timeliness, and coverage of child immunizations through a smartphone-based application (app) for vaccinators, web-based dashboards for supervisors and managers, text message alerts and reminders for caregivers, and a call center. It has been implemented at scale in Sindh Province in Pakistan.

Electronic Immunisation Registries (EIR) are digitized case-based immunization record-keeping systems designed to improve the collection, analysis, and use of immunization program data to improve efficiency, equity, and coverage of immunization programs [1]. A 2015 systematic review of aggregate immunization information systems in high-income settings highlighted the main pathways through which such systems improve immunization outcomes such as coverage despite only one study in Australia measuring such an association [2]. The benefits of aggregate systems align with more recent reviews and studies of EIRs that

record and track data for individual children and generate aggregate data for immunization program monitoring and planning [3]. These benefits include client reminders, client vaccination status, missed vaccinations, and vaccination program management and accountability [2, 3]. Improved access to better data can support evidence-based decisions, planning, and operations for the immunization program, which in turn will lead to better delivery of immunization services [4]. When EIR data are triangulated with other primary health care services, recorded births, and population denominators, EIRs can enable population-level analysis to identify areas where the number of children vaccinated is lower than the target population [1, 5]. In this way, EIRs can improve the identification and reach of ‘zero-dose’ children (i.e. children who have not received a DTP-1 vaccine) and provide targeted service improvements and extended outreach services to those areas and communities. EIRs can also address demand-side challenges by sending automated reminders to caregivers, providing access to educational messages and service-related updates and improving the quality of services at vaccination centers [5].

Because EIRs are intended to support immunization programs with improved data-driven decision-making, the evaluation of data use is also important [6]. Drivers of EIR use include organizational factors (supervision, support, resources, facility type, location, and volume of clients), technical factors (infrastructure, electricity, and internet connectivity), and behavioral factors (training, capacity, and motivation of system users) [6]. A recent study using EIR data to evaluate the timeliness of vaccination systematically found mixed results with the conclusion that the overall reliance of the study on system-level data was insufficient to evaluate its impact on immunization outcomes [7]. A review of the evidence for EIRs reveals a moderate number of process evaluations, few pilot studies, and no large-scale effectiveness studies of EIRs [3].

ZM-EIR is comprised of complementary digital health interventions that satisfy and go beyond the conventional definition of an EIR. ZM-EIR aims to strengthen Expanded Program for Immunization (EPI) service delivery and the broader health system by addressing both supply and demand-side barriers that contribute to sub-optimal utilization of immunization services. On the supply side, it is designed to enable health workers to track immunization history for individual children and assess catch-up immunization schedules; support motivation among health workers by reducing the excessive burden of paperwork and demonstrating the value that quality data can contribute to their workflow [4]; and reduce the occurrence of poor reporting, management, supervision, and monitoring of vaccinators. On the demand side, ZM-EIR is designed to overcome challenges associated with low uptake of immunization services due to a lack of awareness and motivation among parents as well as the inability to remember vaccine appointments.

Pakistan represents one of the six countries in the world with the highest concentration of zero-dose children. In 2012-13, only about half (58.3%) of children aged 12-23 month in Pakistan received all basic vaccinations [8], according to the Pakistan Demographic and Health Survey 2012-13, with marked geographic variation across the country. Sindh Province recorded full immunization coverage of 35% [9] in 2014, according to the Multiple Indicator Survey conducted in 2014. Sindh Province is home to 47.9 million people and was comprised of 28 districts during the timeframe covered by the evaluation with around 1500 fixed immunization centers that conduct outreach activities as well as over 200 private clinics [10]. The provincial capital, Karachi, is Pakistan’s largest capital city and economic hub representing a large urban population. Most childhood vaccines in the district are delivered through the public sector immunization centers or outreach activities, managed by the national EPI Program [10].

As of August 2022, ZM-EIR has scaled to cover all of Sindh Province, including two new districts that were not covered within the evaluation period. ZM-EIR has also been introduced in other areas of Pakistan including the Federal Capital (Islamabad), Khyber Pakhtunkhwa province, and Gilgit-Baltistan region, and has been used by over 5,000 vaccinators at public and private immunization clinics to enroll over 7 million children.

This paper summarizes findings from a mixed-methods evaluation of ZM-EIR implementation in Sindh province of Pakistan. Retrospective evaluations of program implementation are difficult to design and carry out due to the lack of counterfactuals and recall biases. Habicht et al propose ‘adequacy’ as the minimum level of evidence in support of a program’s impact part of an evaluation [9]. We use a range of data sources to

support the hypothesis that the ZM-EIR intervention may have contributed to the outcomes achieved by the immunization program. We show that the ZM intervention activities were implemented adequately, accepted (provider and caregiver perceptions of ZM-EIR), adopted (vaccinator use of ZM-EIR), and may have contributed to improved coverage (changes in antigen coverage) and timeliness.

METHODS

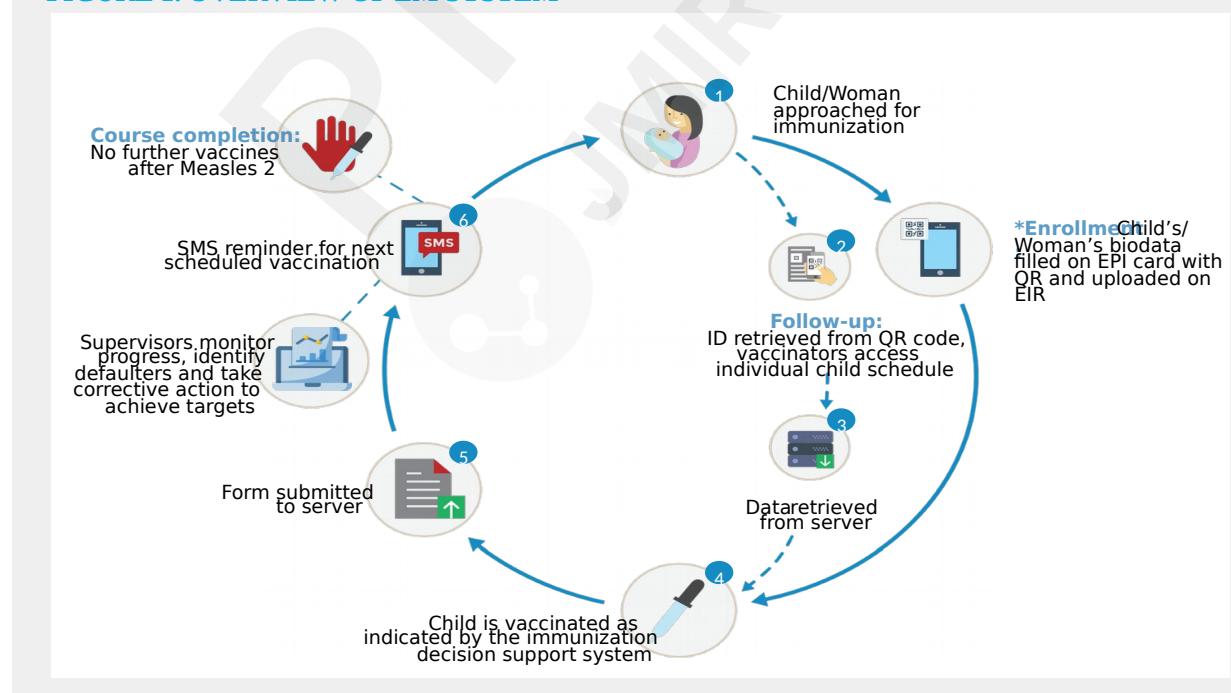
Intervention description

ZM-EIR's functionality centers around a mobile phone-based registry with a suite of complementary interventions. More details and underlying research that has contributed to the development of the intervention over the past decade have been published elsewhere [12-18]. See Figure 1 for a graphical overview of the ZM intervention. While the intervention can capture the immunization of pregnant women, this research study has focused on its use for routine immunization of children.

ZM-EIR functionality

- 1) Web-interface for data visualization
- 2) Mobile based data entry and access for vaccinators
- 3) Geo-spatial data for vaccination events
- 4) 2-way interactive SMS reminders for parents/caregivers
- 5) Call center to answer queries of parents/caregivers
- 6) Offline mode to work in areas of poor connectivity
- 7) Child registry for enrolling newborns or never-vaccinated children
- 8) Immunization decision support system (iDSS) to guide vaccinators on routine and catch-up immunizations
- 9) Defaulter reports for vaccinators
- 10) Gamified videos for training vaccinators
- 11) Artificial intelligence (AI)-based predictive analytics to identify children highly likely to drop out
- 12) AI-based chatbot to address caregiver queries and concerns in real-time
- 13) Global System for Mobile Communications (GSM)-based tracking of vaccinators during work hours
- 14) QR code-based tracking for unique identification of children and women

FIGURE 1. OVERVIEW OF ZM SYSTEM



The ZM mobile Android app is used to capture data for each point of contact between the immunization

service, caregivers and their children. At the time of first enrolment the child's data are entered on the paper EPI card and entered into ZM-EIR. A QR Code is printed and affixed to the paper home-based record and linked to the electronic system by the unique QR code. During follow-up visits, the child's ID is retrieved by scanning the QR code, giving the vaccinator access to an individual child's vaccine schedule. For each vaccination received, the data is entered into the ZM app and linked to the server. All data entered into the ZM app are collated on a central web-based dashboard which supervisors can use to monitor progress, identify defaulters, and take corrective action to achieve targets. The decision-support system uses a built-in algorithm to automatically calculate which vaccine is to be given based on the date of birth of the child and the immunization history. This minimizes the chance of missed immunization and enables the vaccinators to provide age-appropriate and timely immunization. In addition to recording vaccination activities within the ZM intervention, vaccinators were required to document their work in paper-based registers that were then manually tabulated and submitted as part of monthly reporting activities.

To remind caregivers of when they need to next visit the clinic, up to three automatic personalized SMS reminders are sent one day before, on the day of, and six days after the scheduled immunization date (if the child did not make the scheduled appointment). A child is considered to have completed the full course of immunizations after the second dose of measles.

Study design

A pre- / post- mixed methods study design measured changes in the proportion of fully immunized children ages 12-23 months from 2014 to 2019. Fully immunized children are those who have received the complete recommended schedule of five antigens by 23 months of age (see Table 1). The vaccine "penta" refers to a diphtheria-tetanus-pertussis-Hib-HepB combination in this context. Additional aims and objectives of the study were assessed through qualitative research (observation and in-depth interviews), secondary data analysis (Multiple Indicator Cluster Surveys (MICS) from 2014 and 2018-2019) as well as comparison between districts and health facilities with high, moderate, and low ZM-EIR compliance (based on data from the platform or app of log-in and entry of child encounter information). The results have been presented in the findings section by study aim and objective. Experimental or quasi-experimental study designs were not feasible as ZM-EIR was implemented throughout Sindh Province and a suitable comparator was not available.

Patient and Public Involvement

There was no patient or public involvement in the design or implementation of the study. Caregivers, health workers, and health administrators were included in the qualitative research component as key informants after providing informed consent. The study received IRB approval from the IRD Review Board with number – IRD_IRB_2021_11_001 and is registered with ISRCTN #23078223.

Data Sources and Analysis

The two sources of quantitative data are the Multiple Indicator Survey conducted across the state of Sindh, Pakistan by UNICEF from 2014 and 2018-2019, and the database of the ZM registry. Details of the MICS survey are provided on the UNICEF website. The indicators across the study aims and objectives are listed in Table 1.

Table 1: Indicators included in Quantitative Analyses

Indicator	Definition	Numerator	Denominator	Data source
Compliance	Vaccinator updates/uploads 1 record per vaccination day	Number of days the vaccinator logged in the ZM app and uploaded/updated at-least one child record	Number of vaccination days for that health center/vaccination center	ZM database
ZM registry coverage		The total number of children receiving any immunization reported in the ZM	Estimated monthly target population of children of Sindh Province that is derived by the EPI program in close working/collaboration with the ZM team	ZM child records database

ZM registry use	The proportion of vaccinators trained to use ZM who upload details for at least 1 client per day in Sindh from 2017 to 2019	Number of days vaccinator logged in the ZM app and uploaded/updated at-least one child record	Number of vaccination days for that health center/vaccination center	ZM vaccination staff database
ZM dashboard use	The number of unique user (Manager/ Supervisor) log-ins to the dashboard	Number of log-ins per district per year		ZM management staff usage dashboard derived from ZM database
Fully immunized	Child has received BCG at birth, OPV 1, 2, and 3, Penta 1, 2, and 3, Pneumococcal 1, 2, and 3, and Measles 1 in 12-23 months old children, then child will be considered as fully immunized	Number of children 12-23 months who received BCG at birth, OPV 1, 2, and 3, Penta 1, 2, and 3, Pneumococcal 1, 2, and 3, and Measles 1	Number of children 12-23 months sample as part of the survey in Sindh province	MICS 2014, 2018-2019
Zero-dose	Child aged 6 to 23 months that has not received the first dosage of DPT1/Penta 1	Number of children who did not receive DPT1/Penta I		MICS 2014, 2018-2019
Timely immunization	Child has received the dose of antigen at the recommended age specified in the EPI schedule	Number of children 12-23 months who received BCG at birth, OPV 1, 2, and 3, Penta 1, 2, and 3, Pneumococcal 1, 2, and 3, and Measles 1 as per the timeliness criteria of the Pakistan / Sindh province EPI program		MICS 2014, 2018-2019

The ZM platform uses multiple sources to register children, including birth cohort registration, the recording of pregnancies and births, the EPI program's estimated targets and the date of enrolment. The current analysis reflects the vaccine-wise coverage for the age group of children ages 12 to 23 months. The registry-based coverage was calculated using the enrolment numbers for each calendar year birth cohort as numerator and the annual targets provided by the EPI (ascertained population based on modelling using birth rates and recent census figures). Furthermore, target population of children is derived based on the enrolment of children at the time of birth through a birth cohort registration and an EPI schedule-based continuum of care mechanism. The numerators were based on aggregate numbers for the different antigens and did not distinguish the age of the child for the receipt of vaccination, which is reflective of immunization data from administrative sources.

We analyzed the MICS survey data using the design considerations for weighting, adjustment of clustering at the level of primary sample units, and strata for survey errors according to guidelines provided by MICS. We present survey design-adjusted estimates of vaccine coverage with 95% Confidence Intervals.

Timeliness was calculated according to the following recommended age schedule. It is worth noting that timeliness for Penta3 does not correct for any minimal interval with previous doses, which makes being untimely almost normal if Penta1 is late already.

Table 2: Timeliness schedule of vaccination

Antigen & dose	Minimum age	Recommended age	Timely
BCG	Birth	0 weeks / 0 days	0-28 days
Penta-1/OPV-1/PCV-1	6 weeks	6 weeks / 42 days	39-70 days
Penta-3/OPV-3/PCV-3	14 weeks	14 weeks / 98 days	95-126 days
Measles-1	6 months	9 months / 274 days	180 -302 days

Study Setting and Qualitative Study Recruitment and Overview

Home to over 221 million people, Pakistan is the fifth most populous country globally. Pakistan is a federation of four provinces, the second most populous of which is Sindh. Sindh is located in south-east Pakistan. The provincial capital, Karachi (population 18 million), contains two of the countries busiest seaports and is Pakistan's largest capital city and economic hub. Sindh's population, like much of Pakistan, is characterized by wide gender (male/female), (urban/rural) geographic and socioeconomic disparities. These considerations have been accounted for as part of the evaluation design and included in the presentation of findings.

Qualitative data collection was conducted in three districts in Sindh, selected for the High, Medium and Low immunization coverage rates according to the analysis of ZM-EIR system data. Direct observations of immunization services were conducted for one day per facility in six health facilities and three district offices. Within each district, two health facilities were selected based on high and low ZM-EIR compliance. At each health facility, two vaccinators and two caregivers (one male and one female) who were attending the facility for their child's immunization were interviewed. The selection was based on their availability and consent to participate during the field visit days. For each district, the managing supervisor as well as the District Field Coordinators and EPI managers were also interviewed to capture views of the leadership as along with vaccinators and clients. The District Field Coordinator then facilitated contact with health facilities to be included in the sample. The health facilities provided introductions to the vaccinators and the vaccinators provided introductions to caregivers to participate in the study. A structured discussion guide was used to conduct the interviews, led by a researcher with experience in qualitative methods. In total, qualitative data were collected from caregivers of children <2 years (n=12), vaccinators (n=12), supervisors (n=3), district-level EPI managers (n=7), provincial EPI managers (n=2), and ZM-EIR implementation and data teams (N=4). The interviews were audio-recorded and transcribed for qualitative analysis. Direct observations of immunization services were also conducted for one day per facility in six health facilities and three district offices.

As guided by the Consolidated Criteria for Reporting Qualitative Research, the research team was comprised of a Pakistani female Principal Investigator and health systems researchers trained in qualitative methods with master degrees in public health and over ten years of experience. There was no previous relationship with the study participants. District field supervisors facilitated contact with health facilities and health facilities facilitated contact with caregivers. The sampling was purposive to ensure that all key stakeholder groups engaged in using and/or having data captured within ZM-EIR, namely EPI Managers, District Health Officers, EPI Supervisors, Vaccinators, and Caregivers were included in the sample. Interviews were conducted face to face either in offices/ places of work or health facilities, and informed consent was obtained prior to interviews. There were no refusals and no non-participants were present at the time of the interviews. Content

analysis was conducted using a framework developed through the content captured within the in-depth interviews. Interview guides were developed and tested prior to data collection. There were no repeat interviews. Saturation was achieved through the structured sampling and interviews conducted. Interviews were approximately thirty minutes in length. They were audio recorded and field notes captured. Excel was used to organize data by the themes for ease in synthesis of findings and reporting. Thematic analysis was conducted using Grounded Theory through a two-step process: 1) iterative debriefs conducted concurrently with data collection and 2) through coding of transcripts and generating sub-themes and themes. A theoretical framework based on these themes and sub-themes was then developed in line with the research study objectives and used to analyze and present findings.

RESULTS

ZM-EIR reach and use by providers

Vaccination staff training on ZM-EIR started in Quarter 3 of 2017 as part of a district-wide planning with the Sindh Provincial Department of Health. Data on the proportion of vaccination staff trained on the system out of the total were not available. However, of the 1307 staff members nominated for training, all (100%) were trained across 52 batches between September and December of 2017. Training batch sizes ranged from 12-40 participants per training.

Sindh Provincial EPI defines compliance with the ZM-EIR system by vaccinators as one upload or update for at least one client per vaccination day. Compliance estimates include instances in which a vaccinator may be present at the health facility, but no child is brought in for vaccination. Findings suggest that across 27 districts that were active during the timeframe covered by the research study, compliance rates ranged from 46% to 85%. The average compliance increased from 40% in 2018 to 57% in 2019. Data is available in Supplemental Material.

Trends in compliance were assessed based on demographic characteristics of vaccinators. Compliance and usage during 2017-2019 was slightly higher among urban vaccination staff compared to their rural counterparts. Compliance among female vaccinators was higher as compared to males even though the proportion of females in the vaccination staff is only 15%. There was a gradual increase of compliance in all age-groups during 2017 to 2019. Younger age groups (less than 40 years of age) showed improvement from 40% in 2017 to 49% in 2019 with the highest proportional increase observed for those aged 26-30 years (49%) and those aged 18-25 years (47%). More modest increase was found for vaccinators in higher age groups with the 51–55-year group showing only 28% increase.

Stakeholder perceptions of ZM-EIR

Stakeholder perceptions of ZM-EIR were assessed for each set of functions within the ZM-EIR suite of digital health interventions, including the perceived benefits and challenges of use to improve immunization service delivery (Box 2). Overall, all stakeholder groups interviewed had a favorable impression of ZM-EIR and the associated suite of interventions. Provincial managers felt that the real-time access to vaccination data facilitated longitudinal monitoring of vaccination coverage over time and across geographic areas. They further noted that expansion of ZM-EIR would allow this to occur across the country as it would enable the provinces to see and evaluate each other's coverage. ZM-EIR was thought to provide a blueprint of what a national repository of EPI records could look like and further be a mechanism for improving supply monitoring and fraud prevention. As the primary end-users of ZM-EIR, vaccinators expressed their satisfaction with ZM-EIR features, specifically the use of automatic lists generated of those who may have missed a scheduled vaccine dose and/or have not received any vaccines (defaulter and zero-dose lists).

Box 2: Key Informant General Perceptions of ZM-EIR

Caregiver Perceptions

‘... it is very helpful. Otherwise, we are busy with our work and forget about it. When we receive a message then we know we have to get the child vaccinated soon.’

The caregivers who used the call center, called it, ‘*good in every way*’. According to them, these have been proved useful in gaining information about the availability of the vaccination teams, discussing any symptoms caused by the vaccination, and asking for a second dose.

Vaccinator Supervision

...‘wherever he (vaccinator) goes, we monitor it through Google Maps When we visit a vaccinator, it is a surprise visit. We do not call them. We just follow them on mobile and visit them on field.’

Manual (Paper-based) Data Capture

‘These graphs depict which vaccinators have complied [based on required vaccinations for the day], and which are still non-compliant.’
‘our people in the field write in the book, on the card, and all that writing is very difficult. It would be better if we just use ZM-EIR, and only one thing stays.’

“if they had owned it properly, it would end. The vaccinators who work honestly in the field ask us to put an end to the manual data capture work so they can continue working with ZM only.’

‘all their registers will cease to be used, and all their data will be done on ZM. That will be their daily register and stock register. Work is being done on this, and I think in one or two months they may become paper-free’

Registry coverage

From 2017 to 2019, the ZM-EIR immunization registry enrolled nearly 5.4 million children and 1.9 million married women of reproductive age group (women aged 15-49 years).

Gender-related barriers to registry uptake Gender was identified to play a significant role in ZM-EIR uptake by caregivers owing to its embeddedness within the local, rural contexts. There is often a clear distinction between caregiver’s interaction with male vaccinators and that with female vaccinators. One key informant emphasized the need for lady health workers who can bond with female caregivers (who are usually more responsible for taking care of their children than male caregivers) to resolve any resistance or anxieties regarding vaccinations to further expand immunization efforts. A female caregiver shared that *‘the female health worker can come inside the house, and we [caregiver] know her so it’s good that a female health worker comes. If a man comes then it is quite difficult’*.

ZM-EIR Data Use

The provincial managers shared that the ZM-EIR intervention provides defaulter and zero dose lists which help them meet their target and improve performance. It enables those who are supervising to encourage the vaccinators to bridge the gaps in the coverage of immunization targets. The data is viewed as reliable due to the feature allowing the system to operate in both offline and on-line modalities and the use of the platform is not dependent on the availability of internet services. This data is then communicated to other responsible representatives at the district and provincial levels. Among the stakeholders who can access the data reports and dashboards, the role of supervisors has been seen to be relatively limited compared to others. The supervisor’s overall responsibilities include monitoring and providing support to vaccinators, checking vaccination stock, and planning and conducting field visits. For their limited use of ZM-EIR app to monitor the activities of vaccinators in their respective district areas, it was stated that newer and younger supervisors can use the app comfortably while older supervisors have found the app difficult and less engaging.

Coordinators and supervisors also suggested that the latter should be given access to a separate app to monitor the vaccinators so that they do not have to rely on the district managers for the data.

Observation of data entry and use - Among the health facilities observed, half of the facilities observed were clean, organized, and relatively well-maintained. The other half were seen as unclean, ‘cluttered’, and with ‘broken furniture’. The number of rooms in a health facility ranges from two to seven. All the health facilities provide vaccination and other health services. Most of the health facilities had two vaccinators present at the facility. Of these one in each facility used ZM-EIR for registration and defaulter lists. In all six facilities, it was reported by vaccinators that when the caregivers would bring their child for vaccination, they did not use ZM-EIR for registration in real-time but they recorded information in the paper-based register system and later entered it into the electronic app. Only four out of six facilities had electricity, one being backed by a solar power system. Network connectivity was limited in all facilities which also hindered the use of ZM-EIR in real-time. All district offices observed had one supervisor on-site with access to a computer / laptop in the office which enables access to web-based ZM-EIR dashboards. The supervisors reported to engage in daily monitoring of the vaccinators whereby they track the vaccinators’ attendance, location, and registration. No other use of ZM-EIR was reported or observed.

Key Informant Views of ZM-EIR Data Use by Key Stakeholder Group

District Coordinators and Managers	Field and	<i>‘when we have their attendance in the morning, the supervisors call right then to ask why this vaccinator isn’t marked present, tell their timing and all. So, we talk to them daily’.</i>
Supervisors		<i>‘I can also see everything about defaulter children and why we can’t cover them.’</i> <i>‘[supervisors] do monitoring by checking their vaccines, by checking their temperature in the monitoring. We check the graph and record to check whether they are taking records or not. We also check whether they [vaccinators] use ZM or not. This is our work’</i> <i>‘we can’t tell if it is useful for the supervisors. Because we don’t know where the vaccinators are. We should be able to check their work through it, even as a guest or monitors.’</i>
Vaccinators		<i>‘all supervisors are old-aged. If we make them use it, they won’t be able to. They can’t even see the dashboard, because those poor people aren’t used to it since the start’</i> <i>‘the vaccinators are scared because when their defaulters increase, their UC goes into categorization B or C. So they are working on the coverage of defaulters because with ZM we are getting proper data now. Since the defaulters are being covered to keep their UCs up, that means vaccinations are happening timely’.</i>

Vaccination coverage and timeliness

The vaccine-wise coverage across this evaluation’s time frame of consideration (2017-2019) reflects that since its inception for scale-up in the province and phase-wise implementation in all districts; increases were observed for all vaccines¹. Findings suggest that improvements in coverage were achieved for BCG (+10.1%), Penta 1 (+8.8%), Penta 3 (+7.4%), and Measles 1 (+5.5%) vaccines. Vaccination timeliness was assessed by antigen by comparing the proportion of children 12-23 months immunized across MICS surveys in 2014 and 2018-2019. Findings suggest that improvements in timeliness were achieved for BCG (+10.0%), Penta 1 (+3.1%), Penta 3 (+2.0%), and Measles 1 I (+0.7%) vaccines. However, only the improvement in timeliness

¹ The EPI program in Sindh had Measles I as the last vaccine as per the child vaccination schedule till 2018. Subsequently Measles II has been added as made part of the EPI schedule, however, given the evaluation’s considered time frame of 2017-2019, the quantitative analyses focused on Measles I.

for BCG was statistically significant.

Table 3: Vaccination Coverage and Timeliness in Sindh Province between 2017-18 and 2014 (MICS)

	2018-19			2014			Increase
	Prevalence	[95% CI]		Prevalence	[95% CI]		
BCG received	80.2%	78.4%	81.9%	70.1%	67.2%	72.9%	10.1%
Penta1 received	72.5%	70.3%	74.6%	63.7%	60.7%	66.7%	8.8%
Penta3 received	50.6%	48.2%	53.1%	43.2%	40.0%	46.4%	7.4%
Measles1 received	54.4%	52.1%	56.8%	48.9%	45.9%	51.9%	5.5%
BCG timely	33.7%	31.6%	35.7%	23.7%	21.0%	26.4%	10.0%
Penta1 timely	22.7%	20.8%	24.5%	19.5%	17.0%	22.1%	3.1%
Penta3 timely	12.3%	10.9%	13.8%	10.4%	8.4%	12.3%	2.0%
Measles1 timely	11.7%	10.3%	13.1%	11.0%	9.1%	12.9%	0.7%

Additional analyses were conducted to compare increases in immunization coverage in Sindh Province with Punjab, which implemented a different EIR as part of its EPI Program. This analysis indicates increases in immunization coverage, making increases in immunization coverage and timeliness difficult to attribute to the ZM intervention.

Table 4: Vaccination Coverage in Sindh and Punjab Provinces between 2017-18 and 2014 (MICS)

	Sindh			Punjab		
	2014	2018-19	% Increase	2014	2017-18	% Increase
BCG	77.4	82.4	5.0	93.1	94.8	1.7
Penta1	70.7	75.1	4.4	85.7	92.7	7.0
Penta3	55.3	57.6	2.3	73.3	87.3	14.0
Measles 1	58.6	62.7	4.1	77.8	82.7	4.9

Key Informant Views of ZM-EIR Relationship to Immunization Coverage and Equity

Immunization Program Performance *‘...in what [performance] category are [2] UCs, i.e., whether [they] are in red, green, blue, or yellow . . . every UC-wise, every vaccinator-wise, every town-wise, every district-wise, we are getting all the data’.*

Immunization Coverage *‘Because of ZM, the EPI office has found out that we have 114 vaccinators. If only 67 vaccinators out of them are working, they ask your district where the rest of your vaccinators are. They ask us to enroll them, assign them a field, and send them to work. So now I*

have over a hundred vaccinators enrolled, and they work themselves after returning. Coverage will thus ultimately increase’.

Immunization Equity

‘in outreach, more female children are being vaccinated because they find it easy that they can get the immunization service at their doorstep . . . we can see [in defaulters list] that more females might be lagging behind as a result of this, there is catch-up, and we do see better coverage among the female population’.

**Immunization
Timeliness**

‘. . . three SMS reminders are sent so it’s not that you only get one SMS reminder for the child’s appointment day . . . there are these three different time points as a constant nudge to the caregiver to bring the child for immunization at the time that he is required to show up’.

From a ground level perspective, vaccinators shared that the selection of local people for authority positions in rural governments has increased the trust of people in government, leading local caregivers to trust health authorities and their immunization efforts. In general, the vaccinators also believe that there has been an increase in awareness coupled with an increase in diseases which has had a concurrent effect on improved vaccination rates among rural communities.

Managers shared that timeliness of immunization may be due to the decision-support system built within the app. While the SMS reminders as a ZM-EIR feature are more caregiver-oriented, the decision-support system within the app integrated as an explicit function is more vaccinator-oriented. In the instances where vaccinators haven’t had substantive training, the vaccinator is likely to get confused about which vaccine to give the child at a specific time.

Zero-dose

The prevalence of zero-dose children 6-23 months, defined as not receiving at least one dose of Pentavalent, went down from 36.3% to 28.5% at 95% CI between 2014 and 2019. Relative decreases in Punjab make attribution to the ZM intervention difficult to ascertain.

DISCUSSION

This external evaluation of the ZM-EIR and the associated suite of digital health interventions for childhood immunization in Sindh, Pakistan highlights important insights and recommendations across stakeholder groups related to the benefits of an EIR, namely the availability and use of data through alerts and reminders to caregivers, identification of defaulters, supervision of vaccinators, and overall management of vaccination program activities [2].

Qualitative findings support this assertion; indicating that, overall, stakeholders interviewed had a favorable impression of the ZM-EIR suite of interventions and the perceived benefits of ZM defaulter lists on improved immunization coverage as well as decreased percentage of zero-dose children. Several suggestions and areas for improvement were made by key informants to address some of the challenges experienced by users of ZM-EIR.

Firstly, gender dynamics, gender segregation (male vaccinators / female caregivers), education, literacy, and cultural norms impacted access and use by vaccinators and the ability to make direct contact with caregivers. Although their numbers are lower, female vaccinators have higher compliance with the ZM-EIR system than their male counterparts. Power, trust, and relationships were noted to present challenges between vaccinators and clients of the opposite gender. The implementation of ZM-EIR brings to the fore the deep-rooted gender

inequities in society that need to be addressed through relevant policy measures to leverage the full potential of the intervention. In addition, gender analyses and planning at the start of future ZM-EIR intervention planning may also help identify strategies to help overcome this gap. These deeply embedded gendered preferences related to vaccination experiences reinforce the need to incorporate cultural and gender considerations when designing digital health interventions.

Secondly, we noted reliance on double record-keeping which respondents recommended phasing out to reduce the data-entry burden (double requirement to complete both paper and mobile data entry) for field vaccinators and facility staff. Paper-based reporting is a requirement for health program audits. This has led to prioritization of paper reporting over the consistent use of ZM-EIR for reporting. Our study found the perception that ZM-EIR uptake is hindered by physical record-keeping with a recommendation to transition to paperless reporting.

While changes in immunization coverage across all antigens, timeliness for BCG, and the reduction in zero-dose children cannot be attributed wholly to the ZM-EIR program, study findings are a promising indication that data availability and use from EIRs can support improvements in child health outcomes such as vaccination, possibly through better tracking of clients and availability of data. Small pilot studies in countries like Viet Nam and Bangladesh with immunization programs rolling out EIRs report improvements in key immunization program milestones such as timeliness of immunization (vaccinations delivered on time according to established schedule recommendations), a reduction in vaccination schedule drop-outs and an improved ability for vaccinators to identify and follow-up with defaulters [3, 19-22]. Similar to this evaluation, health workers using EIR systems report that they use the data to identify defaulters, coverage disparities and vaccine stock levels; and that they have more confidence to take action based on these data analyses [3]. However, this is the first known study of this degree of comprehensiveness, scale, and rigor to evaluate the availability and use of data of an EIR and the potential for associated effects on immunization outcomes. In addition to the inclusion of standard EIR features (as illustrated in Table 8) [3], ZM-EIR includes AI-based predictive analytics to identify children more likely to drop out; automated SMS reminders, call center, and AI chatbot for caregiver questions, concerns, and complaints. The suite of interventions also includes geospatial data for vaccination events - geospatial data to track each child's immunization progress, real-time tracking of vaccinators with GIS tracking to improve monitoring and accountability, simultaneous supervision of multiple teams, monitor attendance and mobility of field staff, as well as gamified videos and training for vaccinators.

Table 3 Comparison of ZM and ideal EIR characteristics and functionalities

Features of Zindagi Mehfooz -EIR (ZM-EIR)	Ideal requirements of EIR [20]
ZM-EIR is a registry to enroll all newborns or never-vaccinated children with a unique ID / QR code assigned to each woman and child; a web-interface allows data visualization, mobile-based data entry and access for vaccinators	Registration and search features: Enrolment at birth, Client management, Unique and unequivocal ID
Registration includes all relevant demographic and location data of patient and facility with geo-location ; barcoded vaccine vials linked with vaccine record; Offline mode for areas with low mobile/data coverage [not linked to other health areas]	Patient records: Individual demographic data, Vaccine event data, Nonroutine (campaign and outreach) vaccine events, and linkages to other health areas
Immunization decision support system guides vaccinators on routine and catch-up immunizations; Defaulter reports for vaccinators; Interactive SMS reminders for parents/caregivers	Vaccination monitoring and follow-up: Clinical decision support, Identification of under-vaccinated children/missed vaccination, Reminder and recall messages
Vaccinators are registered within the system and assigned to a health facility registered to a district management unit.	Health facility registration and management
Vaccine stock is tracked through number and type of vaccinations given by vaccinator, facility, and district.	Stock management
Geospatial analysis to map pockets of under-vaccinated children with exact location to enable follow-up with refusal households; Call center for complaints and adverse events following immunization (AEFI) reporting	Data and reporting: Data aggregation at different geographic and administrative levels, Adverse event reporting
Follows industry standards for data security and privacy platform	Other system requirements: Data exchange

interoperable with DHIS2 and Government's EPI-MIS deployed at full scale in all districts of Sindh Province by over 3,096 vaccinators at 1,694 public and private sector immunization clinics to enroll 3.8 million children and 1.3 million women with 31 million immunization visits recorded (as of 2021).	and interoperability, Offline capability, Alignment with international standards, Data privacy and security, Scalability and capacity, Usability
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Limitations of the study

The study is a retrospective one with a small sample of qualitative interviews and information bias due to recall cannot be excluded. Stakeholders may also have expressed a positive view of the program due to reasons of social desirability. The MICS survey estimates show similar changes in Pakistan's Punjab Province which was not a target of the ZM intervention. But since immunization has been at the forefront of public health issues in Pakistan, similar programs were likely in place in the Punjab province. These provide challenges in the attribution of effects to programs such as ZM. ZM did not act in isolation but would have been greatly affected by the presence of other health system strengthening activities including improvements in supply chain logistics, training and supervision of providers, and demand generation activities targeting immunizations. The increase in immunization coverage may also be attributed to more structural factors e.g. public trust in government.

CONCLUSION

This study contributes to the evidence base of the added value of increased data availability and use through the implementation of EIRs in LMICs as part of broader EPI interventions. It aligns to key benefits identified in other studies of immunization information systems and EIRs, namely alerts and reminders, missed vaccination, supervision and oversight of vaccinators, and management and accountability. Study methods included a retrospective analysis system-generated data, qualitative stakeholder interviews, and an assessment of potential contributions to improvements in immunization coverage and timeliness and reduction in the number of zero-dose children. Findings suggest that ZM-EIR is a promising technology platform that may have contributed to improvements in the coverage and timeliness of BCG as well as the reduction of zero-dose children as part of a broader package of immunization interventions in Sindh Province, Pakistan from 2017-2019.

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Data Availability: A Comprehensive Report of all quantitative and qualitative data analyses conducted as part of the study has been included as Supplementary Material.

Competing interests: The core study team was independent of funders. Mubarak Taighoon Shah, Danya Arif, Siddiqi, and Subhash Chandir, employed by IRD, the implementer of ZM-EIR, contributed to the research design and implementation, and review of study findings. Riswana Soundardjee from Gavi, which funded the implementation and evaluation of ZM-EIR provided high-level review and inputs in the design, implementation, and review of study findings.

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Supplementary Files

Untitled.

URL: <http://asset.jmir.pub/assets/607c0fd1dbcb1368f88cd22b8f391cb5.pdf>

CONSORT (or other) checklists

COREQ Checklist for Qualitative Data.

URL: <http://asset.jmir.pub/assets/41d18b83d5da5972ce5821dbcc950989.pdf>