Introduction

Within global health, it is widely acknowledged that a cornerstone of well-functioning health systems is data of high enough quality to guide decision-making. Yet despite international efforts to improve the quality of health data, including in the immunization field, increasing data use for making decisions remains a challenge, especially at the level of health care delivery.1 There is a need to take stock of the evidence from existing efforts to strengthen immunization data and identify effective and ineffective approaches, as well as any knowledge gaps.

The goal of the Immunization Data: Evidence for Action (IDEA) project is to identify, review, synthesize, and disseminate what works to improve use of immunization data and why it works. To this end, we conducted a realist review with these objectives.

1. Articulate a Theory of Change (TOC) that illustrates key mechanisms and outcomes related to strengthening data use.
2. Synthesize existing evidence (published and unpublished) related to strengthening the use of immunization data, and evidence on strengthening data quality in relation to data use.
3. Provide information and evidence so that various stakeholders may select approaches with the highest potential for improving the use of routine immunization data.

This review was a collaborative effort between PATH and the Pan American Health Organization (PAHO). The review team included health systems researchers with expertise in immunization, measurement and evaluation, and evidence-informed policymaking from PATH's Health Systems Analytics team, as well as immunization and data use experts from PAHO. To ensure the review's relevance for multiple agencies, countries, and decision-making bodies, a steering committee of ten global and regional senior leaders in the areas of immunization, data quality, and use guided the work of the review team.

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Methods

The review sought to answer two principal research questions:

01. What are the most effective interventions to improve the use of data for immunization program and policy decision-making?
02. Why and how do these interventions produce the outcomes that they do?

Realist Review Approach

To answer our research questions, we conducted a realist review of the evidence on what works to improve data use. This approach allowed us to include multiple types of evidence, such as experimental and nonexperimental study designs, grey literature, project evaluations, and reports.

Much of the immunization sector’s knowledge on data quality and use interventions has not been rigorously evaluated or published. In addition to including studies and evaluations that applied scientific research methods or evaluation design in our review, which we referred to as “evidence,” we considered grey literature that did not qualify as a study or evaluation but had strong theoretical plausibility of improving data use, as judged by our TOC. We referred to these records as “promising strategies”: strategies that have not yet proven successful but have potential for future success.

Realist reviews are typically driven by a theoretical understanding of how the context and causal mechanisms interact to produce certain outcomes. By providing explanations for why interventions may or may not work and under what circumstances, realist reviews can lead to more pragmatic, actionable conclusions. The approach also gave us the flexibility to orient our data collection iteratively to fill gaps.

Review Process

The review included eight steps:

01. Develop a TOC based on our analysis of systematic reviews and related literature.
02. Conduct a systematic review of effectiveness (peer-reviewed and grey literature).
03. Review promising strategies to inform why and how the interventions work.
04. Extract and code text data based on the TOC.
05. Conduct a quality assessment of studies and evaluation of effectiveness.
06. Synthesize preliminary data and validate findings with the IDEA steering committee and other immunization stakeholders.
07. Conduct a second round of data collection and review literature on data use interventions in other health sectors.
08. Synthesize the final data and develop an evidence gap map.

To guide the review, we developed a TOC (see Figure 1) based on our analysis of existing health information and data use frameworks and logic models, as well as reviews on topics related to health information system strengthening and evidence-informed decision-making. The TOC framed our hypothesis of the theorized mechanisms and contextual factors that work together to help decision-makers translate data into information and, ultimately, action. In order to be effective, we hypothesized that any intervention must incorporate one or more of these mechanisms: demand, access and availability, quality, skills, structure and process, and communication. We also included behavioral drivers: capability, motivation, and opportunity.

We identified intermediate outcomes as the necessary precursors to data use: data quality and availability; and analysis, synthesis, interpretation, and review of data. The ultimate outcomes of interest are the data use actions, which are based on the World Health Organization’s Global Framework to Strengthen Immunization and Surveillance Data for Decision-making. The TOC guided our analysis of how interventions led to improved data use and, ultimately, to increased immunization coverage.

The review focused on studies, evaluations, reports, and descriptions of interventions to improve use of routine data by an immunization program for service delivery (which excluded surveillance, financial, and human resources data). We excluded documents that were not specific to a particular intervention or where the outcome examined was something other than data use. We considered health care professionals to be the principal users of routine health data and did not examine use of data by recipients of health care services. We primarily focused on interventions implemented in low- and middle-income countries (LMICs); however, in a limited number of cases, we considered relevant publications from high-income countries (n=7). Much of the literature we collected had been published within the last 15 years.

Although we primarily focused on evidence related to strengthening the use of immunization data, we also examined interventions to strengthen data quality in relation to improving data use. Our TOC recognizes data quality as both a driving mechanism of data use and a measurable intermediate outcome of data use interventions. We therefore included literature on data quality that allowed us to examine these relationships.


FIGURE 1. Theory of Change for supporting data-informed decision-making for immunization programs

<table>
<thead>
<tr>
<th>INTERVENTION MECHANISMS</th>
<th>BEHAVIOR CHANGE COMPONENTS</th>
<th>INTERMEDIATE OUTCOMES</th>
<th>DATA USE ACTIONS</th>
<th>GOALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generate demand for data</td>
<td>Motivation</td>
<td>Capabilities</td>
<td>Data use actions</td>
<td>Communities and health facilities collect and use data to:</td>
</tr>
<tr>
<td>Improve access to data and its availability</td>
<td></td>
<td></td>
<td></td>
<td>• Know their target populations</td>
</tr>
<tr>
<td>Strengthen data quality</td>
<td></td>
<td></td>
<td></td>
<td>• Track coverage and follow up on unvaccinated</td>
</tr>
<tr>
<td>Build data analysis skills and knowledge</td>
<td></td>
<td></td>
<td></td>
<td>• Monitor and respond to outbreaks</td>
</tr>
<tr>
<td>Strengthen decision-making structures and processes, and data use infrastructure</td>
<td></td>
<td></td>
<td></td>
<td>• Manage vaccine supply and cold chain</td>
</tr>
<tr>
<td>Improve communication of data to decision-makers</td>
<td></td>
<td></td>
<td></td>
<td>• Improve data quality</td>
</tr>
</tbody>
</table>

Context: Policies, leadership, and governance around data and information systems; Human resources and continuing professional development; Harmonized and interoperable data systems; Electricity and Internet infrastructure
We searched PubMed, POPLINE, CABI (Centre for Agriculture and Biosciences International) Global Health, and African Journals Online for published evidence. We obtained grey literature by searching vaccine and digital health conference, implementer, and technical agency websites, as well as through targeted outreach to entities such as TechNet-21, the Global Digital Health Forum, BID Learning Network webinars, other key stakeholders, and members of the steering committee to identify projects and interventions. We assessed the quality of records that qualified as evidence using the Mixed Methods Appraisal Tool (MMAT), a checklist for systematic literature reviews.4

We examined the characteristics of the interventions: designs and strategies; targeted types of health care professionals and levels of the health system; implementation settings; and outcomes. We looked at how the interventions functioned and what mechanisms made them successful. We also sought to understand the reasons why interventions did not show evidence of effectiveness.

We presented a synthesis of our preliminary findings to the IDEA steering committee and other immunization stakeholders in May 2018 and identified gaps in the literature. For intervention categories that had limited evidence and were applicable outside of immunization, we expanded the review to include evidence from other health sectors, specifically HIV and maternal and child health. We coded the included records, synthesized the evidence according to outcomes in the TOC, and rated the certainty of evidence.

Assessing Certainty of Evidence

Realist reviews generally do not exclude evidence based on study design or quality. We took this approach but adapted various methods of quality appraisal. We considered certainty of evidence of the evaluated intervention's effect on data quality and use by analyzing (1) design and (2) quality of the included studies, (3) number of studies and their agreement, and (4) context dependence of the evidence. The certainty of evidence rating of high, moderate, low, or very low was a subjective estimation based on these four constructs.

Literature Findings

We initially reviewed 426 documents from published and grey literature and in the second round of data collection reviewed another 123 documents. Ultimately, we included 103 of these documents in the full-text review. We determined that 69 of the articles were research evidence, as they reported results from a study or evaluation, and 34 were promising strategies. Most included literature came from LMICs, although seven pieces of literature were from high-income countries. Africa was the most represented region in the review, and electronic immunization registries were the most reported primary intervention type.

▶ 48% of reports from Africa
▶ 13% from the Americas
▶ 9% from South East Asia
▶ 6% from Western Pacific
▶ 5% from Eastern Mediterranean
▶ 2% from Europe
▶ 17% of reports were not related to a single region

Most documents described projects with multiple intervention components and tended to report on multiple intermediate outcomes and data use actions.

We developed a gap map to visualize all the pieces of evidence and promising strategies included in the review, which illustrates the relatively small number of records pertaining to many data use actions and impact indicators (see Figure 2). Many gaps exist regarding national-level data use actions.

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Evidence presented in the gap map includes studies and evaluations of immunization data use interventions that applied scientific research methods or evaluation design, as well as literature that did not qualify as a study or evaluation but had strong theoretical plausibility of improving data use, as judged by our TOC. We referred to these records as promising strategies, which we define as strategies that have not yet proven successful, but have potential for future success.

Strong, Moderate, and Weak categories apply only to the study quality. Reviewers appraised each study using the Mixed Methods Appraisal Tool (MMAT) checklist, which translates into a percentage score. ‘Strong’-quality studies scored 75-100%; ‘Moderate’-quality studies scored 50-74%; ‘Weak’-quality studies scored 0-49%.

To access the interactive gap map, please visit public.tableau.com/profile/path5412#!/vizhome/IDEAgapmap/FORPUBLICPUBLISH

<table>
<thead>
<tr>
<th>Intermediate Outcome</th>
<th>Data Use Action: Communities &amp; Health Facilities</th>
<th>Data Use Action: Health Districts</th>
<th>Data Use Action: National Program</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Immunization Registries</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Logistics Management Information Systems</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>HMIS</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Decision Support Systems</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Monitoring Charts and Dashboards</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Home-Based Records</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Data Quality Assessments</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Data Review Meetings</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Peer Learning Networks</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Supportive Supervision, Mentorship, and On-the-Job Training</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>Training</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
<tr>
<td>mHealth</td>
<td>Data are analyzed</td>
<td>Data are synthesized</td>
<td>Data are reviewed</td>
<td>Home-based records</td>
</tr>
</tbody>
</table>

The color of a circle indicates the strength and directionality of the evidence:
- Strong quality evidence
- Moderate quality evidence
- Weak quality evidence
- Promising strategy
- Weak quality counterevidence
- Moderate quality counterevidence
- Strong quality counterevidence

The size of a circle indicates the amount of evidence available:
- One piece of evidence reviewed
- Two pieces of evidence reviewed
- Three pieces of evidence reviewed

A blank square on the gap map indicates no evidence from immunization data use interventions was identified.
Categories of Data Use Interventions

We grouped the interventions into ten primary intervention categories, as well as multicomponent interventions (see Table 1). Although not all interventions were digital, we aligned most of the intervention categories with the WHO Classification of Digital Health Interventions.5

<table>
<thead>
<tr>
<th>Intervention Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic immunization registries (EIR)</td>
<td>Store data on administered vaccine doses in computerized, individual-level databases</td>
</tr>
<tr>
<td>Logistics management information systems (LMIS)</td>
<td>Collect data on vaccine inventory and demand to support managing the vaccine supply chain; often computerized</td>
</tr>
<tr>
<td>Health management information systems (HMIS)</td>
<td>Store aggregated health data and can facilitate converting data into useful information for decision-making; we focused on computerized HMIS</td>
</tr>
<tr>
<td>Decision support systems</td>
<td>Help users interpret data and use data for decision-making; include computerized decision support systems (CDSS) and noncomputerized tools (e.g., monitoring charts, dashboards, and home-based records)</td>
</tr>
<tr>
<td>Data quality assessments</td>
<td>Range from interventions that train program managers how to routinely audit data quality to external audits of data quality</td>
</tr>
<tr>
<td>Data review meetings</td>
<td>Employ adult-learning techniques (e.g., peer learning and knowledge sharing) to build skills in data analysis</td>
</tr>
<tr>
<td>Peer learning networks</td>
<td>Connect health workers so they can share information and discuss data; increasingly accessed through social networking platforms online</td>
</tr>
<tr>
<td>Supportive supervision, mentorship, and on-the-job training</td>
<td>Build health workers’ skills, foster performance and motivation, and identify and resolve problems</td>
</tr>
<tr>
<td>Training</td>
<td>Strengthen the capacity of health workers responsible for managing and using data at all levels of the health system through workshops, classroom-based learning, and hands-on approaches</td>
</tr>
<tr>
<td>Multicomponent interventions</td>
<td>Leverage many of the intervention categories but lack a clearly identifiable primary intervention type</td>
</tr>
</tbody>
</table>

TABLE 1.

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Results

We identified data use actions at the community and health facility, district, and national levels and analyzed the effects of interventions on those actions, as well as on intermediate outcomes according to our TOC.

### Intermediate Outcomes

**Timely, high-quality data are more available.** Computerized interventions (EIR, LMIS, and HMIS) improved data quality, especially when combined with other data use activities. While evidence suggested that these systems made data more available, inconsistent use undermined this availability. Tools used to digitize paper immunization records and mHealth solutions applied to LMIS interventions helped increase data availability. Countries that conducted repeat data quality assessments or that held data review meetings as part of broader efforts to develop health information infrastructure saw improved data quality. These efforts were more effective when combined with supportive supervision and other forms of feedback, so that health workers developed the skills to address issues.

**Data are analyzed, synthesized, interpreted, and reviewed.** Health workers reported increases in their ability to synthesize and interpret routine data as a result of using computerized systems (EIR, LMIS, HMIS, and CDSS), especially at the district and provincial levels. Simple paper-based monitoring charts and dashboards increased tracking of immunization coverage; these tools are most effective when integrated within established data review and decision-making processes (such as monthly review meetings) and when reinforced through supportive supervision and other forms of feedback. Evidence suggests that peer learning networks increase collaborative data review and problem-solving by health workers.

### Data Use in Communities and Health Facilities

There was little evidence that health facilities used data from computerized data collection and management systems (EIR, LMIS, and HMIS) to make decisions and take action, especially when implemented as stand-alone interventions with no support mechanisms. At this level, improving data quality was often emphasized more than improving data use. Challenges such as additional data-entry burdens, poor infrastructure, and workers’ lack of motivation contributed to inconsistent use. Digitizing paper immunization records helped improve data quality and relieve the burden of manual data entry. Peer learning networks, training, and decision support interventions (monitoring charts) bolstered facility performance. Data quality assessments prompted health facilities to improve data quality, and such improvements in turn generated more data use in facilities.

### Data Use at the District Level

When used consistently, computerized data collection and management systems had more impact on using data to make decisions at the district level than at the facility level, likely as a result of fewer operational challenges. LMIS interventions in particular improved vaccine stock management. Health districts used monitoring charts and dashboards to strengthen facility performance and data quality, but the effect of computerized decision support systems that employed algorithm-based software was uncertain. Data review meetings at the district level increased the use of data to understand and solve issues. Training of district monitoring and evaluation personnel also improved the quality and use of data.

### Data Use at the National Level

There was little evidence on how interventions improved data use by national programs. However, anecdotal evidence suggested that a data quality assessment led to the use of data to inform national vaccine strategies and policies. Evidence also suggested that training contributed to more use of data at the national level to strengthen systems and implement policies. National-level participants in peer learning networks reported becoming more data oriented in their work and making decisions based on data. Peer learning networks are likely most effective when they bring together individuals from across departments and levels of the health system and adopt structured approaches for continuous quality improvement.
**Impact on Overall Immunization Programs**

Few evaluations and studies measured improvements in immunization coverage, equity, and vaccine availability resulting from data use interventions. Among the evaluations and studies that measured overall impact on the immunization program, the results were difficult to attribute to improvements in data use because other interventions were often implemented at the same time.

**Improved coverage:** Some interventions, such as EIRs, contributed to increased vaccination rates, however it was difficult to assess the EIR’s effectiveness in isolation since complementary activities such as text message immunization reminders may have contributed to the improvements.

Decision support systems (monitoring charts) contributed to improvements in coverage in low-performing regions. Data review meetings and supportive supervision also contributed to increases in coverage.

**Improved vaccine availability:** Both use of LMIS and participation in peer learning networks improved vaccine stock management, leading to more consistent stock availability.

**Improved equity:** We found no evaluations that examined whether or how data use interventions led to improvements in immunization equity.

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**Key Findings**

Summarizing across all evidence and promising strategies, and informed by our TOC, we reached the following broad conclusions:

- **(1) Multicomponent interventions were the most prevalent and were often more effective.** Nearly all the interventions we reviewed used more than one strategy. More comprehensive strategies that addressed barriers at various stages of data use were more likely to achieve results.

- **(2) Interventions that took a health systems approach to institutionalizing data use were more likely to succeed and be sustained over the long term.** This occurred by routinely conducting data review meetings, creating national guidelines and protocols on data use, hiring data managers at all levels of the health system, and incorporating training in data use in national curricula.

- **(3) Although we found limited evidence on the effectiveness of health management information systems (HMIS), including electronic immunization registries (EIR), on data use, they remain promising interventions when accompanied by complementary activities.** Transitioning from paper to computerized HMIS across all levels of the health system has made higher-quality data more available to decision-makers. Phasing in computerized systems incrementally after establishing reliable infrastructure and human resource capacity improves their likelihood for success.

- **(4) Computerized logistics management information systems (LMIS) have made higher-quality data more available to decision-makers to improve supply chain management, especially at district levels and higher.** Although implementing computerized LMIS as a single intervention improves data quality and use, even greater gains were made when other data use activities complemented the LMIS.

- **(5) There is a dynamic, cyclical relationship between data quality and data use.** Although results of this review confirm that data quality is a necessary precursor to data use, we found limited evidence that single-component interventions increased data quality and improved data use. Conversely, we found stronger evidence that data quality improved as a result of increased use of data. More data use generated demand for higher-quality data, which in turn drove actions to improve data quality; as data quality improved, users were able to better trust the data, thus reinforcing data use.
Discussion

The state of the evidence around what works to improve data use is still nascent. Few data use interventions have been rigorously studied or evaluated. We found more evidence on intermediate outcomes within our TOC, such as improved data quality and availability, but less evidence on what works to support decision-making informed by data, particularly at the facility level. More emphasis on building skills and a culture of data use at the facility level may have a greater effect, but this should be tested in future research.

Many of the HIS interventions pointed to challenges with operational barriers and administrative burdens on health workers. Health workers’ concerns about sustainability and data loss also limited their acceptance of these systems. We propose additional research and suggest considering the human transaction costs associated with the intervention, as well as any potential unintended consequences for service delivery.

We recommend that data use interventions be designed to address multiple mechanisms in the TOC. Implementers should define the specific data use actions that the intervention will reinforce. Monitoring and evaluation strategies should measure whether data are being used as defined by the data use actions. To strengthen data use throughout the health system, national guidelines for data collection, analysis, and use should be developed and effective support, tools, and training provided to health workers at the facility and district levels. Especially at the facility level, efforts to improve data quality should be balanced with strategies to improve data use. To reduce administrative burdens, health facilities should be equipped with sufficient human resources, including dedicated staff to perform data-related tasks.

Both monitoring and evaluation of interventions could be strengthened: monitoring primarily through better indicator definitions and evaluation through more appropriate evaluation designs. There is a need to develop better measures for assessing data use in decision-making to better understand the effectiveness of these interventions. Measuring data use is possible but requires a firm understanding of the mechanisms that drive data use behaviors and actions and how the use of data may change health outcomes. Evaluations should consider the cost-effectiveness of interventions. Supplementing long-term evaluations with iterative approaches to improving effectiveness of interventions will enable problems and their solutions to be identified more quickly.

Strengths of the Review

The strengths of this review were its inclusiveness and methodological flexibility, afforded by the realist review approach, its focus on data use interventions in LMICs, and its emphasis on understanding how the interventions functioned, what made them successful, for whom, and under what conditions. A majority of the evidence we reviewed was from the non-peer-reviewed literature; although of lesser quality, it provided important evidence and learnings that more traditional systematic reviews would overlook.

Limitations of the Review

Several factors limited this review. Our findings relied on what the literature reported, which sometimes did not thoroughly describe the factors that contributed to an intervention’s success or failure and may have caused us to miss important contextual considerations. We likely missed some interventions, especially in regions where English is not the dominant language. Our focus on routine immunization data helped contain the scope of the review but risks further isolating immunization programs or missing lessons from surveillance, financial, and human resource data use interventions that were excluded from the review. Although we expanded the review to include literature from other health sectors, these efforts likely failed to capture all the available evidence. Few studies and evaluations analyzed cost-effectiveness, so we were unable to examine the cost-effectiveness of interventions included in this review. Likewise, we did not find any examination of the outcomes of data use interventions over the long term, which makes it challenging to determine how to ensure lasting results.
Conclusion

By synthesizing the evidence and learnings from 69 studies and evaluations and the promising strategies from 34 papers, this review contributes to our understanding of what interventions improve the quality and use of routine immunization data and why. Although presented primarily through the lens of using data to make decisions in immunization programs, our findings are relevant for other health sectors. The evidence on the most effective practices detailed in this review will help program implementers, policymakers, and funders choose approaches with the highest potential for improving vaccine coverage and equity. We anticipate that these findings will also be of interest to researchers and evaluators to prioritize gaps in the existing knowledge. However, the state of the evidence does not lend itself to recommending which specific interventions or packages of interventions are most effective. Improving immunization data use greatly depends on designing a package of interventions that is theoretically sound and contextually driven, addresses technical and behavioral barriers, and can be sustained outside a project setting.