

**Report of the SAGE Working Group on
Quality and Use of Immunization and
Surveillance Data**

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List of Abbreviations

AEFI	Adverse events following immunization
AFP	Acute flaccid paralysis
AFR	African Region (WHO)
AMR	American Region (WHO)
CDC	Centers for Disease Control and Prevention (U.S.)
cMYP	Comprehensive multi-year plan
CQI	Continuous quality improvement
CSO	Civil society organization
DHS	Demographic Health Survey
DHIS2	District Health Information System 2
DIP	Data immunization plan
DIT	Data improvement team
DTP	Diphtheria-tetanus-pertussis
DTPCV	Diphtheria-tetanus-pertussis containing vaccine
DQA	Data quality audit
DQR	Data quality review
DQRC	Data quality record card
DQS	Data quality self-assessment
DVDMT	District vaccination data management tool
ECDC	European Centers for Disease Control
EHR	Electronic health record
EIR	Electronic immunization registry
EMR	Eastern Mediterranean Region (WHO)
EPI	Expanded Programme on Immunization
EUR	European region (WHO)
GCC	Global Certification Commission
GIS	Geographic information system
GPEI	Global Polio Eradication Initiative
GVAP	Global Vaccine Action Plan
HBR	Home-based record
HIS	Health information system
HIV	Human immunodeficiency virus
HMIS	Health management information system
ICT	Information and communication technology
IDSR	Integrated disease surveillance and response
IHME	Institute for Health Metrics and Evaluation
IIS	Immunization information system
JRF	WHO/UNICEF Joint reporting form [for immunization data]

JSI	John Snow, Inc.
LGA	Local government area
LIC	Low-income country
LMIC	Low- and middle-income country
LMIS	Logistics management information system
MCV	Measles-containing vaccine
MICS	Multiple Indicator Cluster Survey
MLM	Mid-Level Management (training course)
MNT	Maternal and neonatal tetanus
NCC	National Certification Committee
NGO	Non-government organization
NITAG	National immunization technical advisory group
Non-NT	Non-neonatal tetanus (ages >28 days)
NT	Neonatal tetanus
NVC	National verification committee
OPV	Oral polio vaccine
PAB	Protection at birth (against tetanus)
PAHO	Pan American Health Organization
POLIS	Polio Information System
RCC	Regional certification commission
RI	Routine immunization
SAGE	Strategic Advisory Group of Experts (on immunization)
SDG	Sustainable development goals
SEAR	Southeast Asia Region (WHO)
SMS	Short message service
TB	Tuberculosis
TORs	Terms of reference
TT	Tetanus toxoid
TTCV	Tetanus toxoid containing vaccine
UHC	Universal health coverage
UNICEF	United Nations Children's Fund
V3P	Vaccine Product, Price and Procurement
VF	Verification factor
VPD	Vaccine-preventable disease
WG	Working group
WHO	World Health Organization
WIISE	WHO Immunization Information System
WPR	Western Pacific Region (WHO)
WUENIC	WHO-UNICEF estimates of national immunization coverage
YF	Yellow fever

1. Introduction and Methods

1.1 Background

With the aim of supporting the planning and monitoring of national immunization programmes, the World Health Organization (WHO) and partners encourage countries to collect Expanded Programme on Immunization (EPI) data, including data on vaccine coverage, vaccine-preventable disease (VPD) surveillance, human resources, financing, vaccine and supply chain, service delivery, and safety.

Concerns about the quality of EPI data have been highlighted on the global agenda for more than two decades. In 1998, the Strategic Advisory Group of Experts (SAGE) reviewed analysis of officially reported vaccination coverage data¹ for 217 countries and territories that revealed many issues with internal consistency (20% of countries with >10% difference from one year to next; 15% of countries with >5% difference in vaccine doses given at same age) and lack of concordance with data obtained from other sources (17% of countries with >10% difference) during the period of 1991 to 1996 (1). Accordingly, SAGE recommended that the EPI intensify efforts and add resources to improve the quality and validation of national immunization data in the overall context of national health information systems strengthening (1). These recommendations eventually led to the development of the annual WHO and UNICEF estimates of national immunization coverage (WUENIC) for every country, based on a systematic analysis of data from various sources (2).

In 2007, WHO and partners published the Global Framework for Immunization Monitoring and Surveillance (GFIMS) that defined the necessary types of data and components for health systems to monitor and evaluate immunization programmes (3). In 2011, to enhance country ownership, monitoring and accountability of immunization service delivery under the Global Vaccine Action Plan (GVAP) (2011-2020), SAGE recommended efforts to improve the quality of national and subnational coverage and surveillance data (4). At this time, SAGE acknowledged the important role of the WUENIC estimates, but advised caution in interpreting coverage estimates for performance-based financing. The SAGE also recommended that WHO work towards improving coverage survey methods, developing guidelines for using biomarkers to validate vaccination coverage (e.g., serosurveys), and supporting countries to improve use of surveillance data for monitoring immunization programme performance and decision-making (4). SAGE assessment reports of GVAP implementation in 2013 and 2014 stated that poor data quality was impeding programme improvement, and recommended that improving data quality should be the number one priority for national immunization programmes (5).

Countries and immunization partners have made a number of efforts in recent years to improve the availability, quality, and use of immunization-related data. In 2015, SAGE highlighted that data quality improvement efforts were a major contributing factor in significant programme gains achieved in several countries (5). And, in 2017, Gavi, the Vaccine Alliance established a “Strategic Focus Area” in immunization, surveillance, and safety data (“data SFA”) to allow for synchronized investments by countries and partners in data improvements (Box 1.1) (6).

However, data quality challenges continue to affect monitoring of GVAP, as well as progress in achieving the Sustainable Development Goals (SDGs) and Universal Health Coverage (UHC). Within the last few years, issues with data quality and use have been highlighted in most disease-specific presentations to SAGE (e.g., polio, measles, tetanus, diphtheria). In the 2016 GVAP mid-term assessment, SAGE also highlighted the need to improve VPD surveillance capacity and EPI data quality (5).

These ongoing concerns lead to the establishment of the SAGE Working Group (WG) on the Quality and Use of Global Immunization and Surveillance Data in August 2017. The WG terms of reference are shown in Box 1.2 (7). A *Global Framework to Strengthen Immunization and Surveillance Data for Decision-Making* was developed and reviewed by partners and the SAGE Data WG during the Data Partners Meeting in Cascais during 23–25 October 2017 (8) (Annex 1). A Post-2020 GVAP plan is

¹ Bacillus Calmette–Guérin (BCG), 3rd dose of diphtheria-tetanus-pertussis (DTP3), hepatitis B, measles, 3rd dose of oral poliovirus (OPV3), 2nd or subsequent dose of tetanus toxoid (TT2+), and yellow fever vaccines.

currently under development, and the findings of this WG are relevant for informing data-related strategies in the plan (9).

Box 1.1. Major Immunization Data Partners and Initiatives

Major Immunization Data Partners

WHO — standards, immunization and surveillance data reporting, partner coordination

UNICEF — immunization and surveillance data reporting, logistics and stock management, digital health

Gavi, the Vaccine Alliance — funding for new vaccine introduction, health systems strengthening, targeted country assistance, partner projects on data quality and use through the data Strategic Focus Area (SFA)

Bill & Melinda Gates Foundation (BMGF) — funding and technical support for immunization and surveillance data quality and use

U.S. Centers for Disease Control and Prevention (CDC) — technical support for surveillance, workforce capacity, and evidence generation

European Centers for Disease Control (ECDC) — immunization information systems and surveillance

PATH — digital health, evaluation of new interventions

John Snow Inc. (JSI) — capacity building and design of information systems and tools

Institute for Health Metrics and Evaluation (IHME) — research on disease modeling, data visualization

Major Initiatives Relevant to Immunization Data

BID Initiative (2013–2018) — an initiative led by PATH and funded by BMGF, that was designed in partnership with countries to enhance immunization and health service delivery through improved data collection, quality, and use. The BID Learning Network (BLN) was established to foster continuous learning and information sharing across countries to improve their data and decision-making.

Health Data Collaborative (HDC) — launched in 2016 as a partnership of international agencies, governments, philanthropies, and academics with the goal of strengthening country health information systems to meet the challenge of monitoring the health-related Sustainable Development Goals and boost the development of robust, sustainable national health monitoring systems.

Data Strategic Focus Area (SFA) — established by the Gavi Alliance in 2017 to allow for synchronized investments by countries and partners to improve immunization, surveillance, and safety data.

Box 1.2. Terms of Reference for the SAGE Data Working Group

1. Take stock of data availability and determine if there are unmet immunization monitoring and evaluation data needs at global and regional level, and suggest revisions for reporting processes
2. Review existing and new draft standards and guidance on immunization monitoring and vaccine-preventable disease (VPD) surveillance data to identify gaps, revisions, and areas that require updates
3. Review and assess the current 'state' of immunization and VPD-surveillance data quality and use at country, regional, and global level (including triangulation)
4. (a) Review evidence on factors that may cause and/or limit access to quality and use of immunization and VPD-surveillance data for decision-making at different levels
(b) Review evidence on the effectiveness (including where possible, cost-effectiveness) of interventions for improving access to, improving quality of, or promoting the use of data at national and subnational levels.

5. Review the status of information systems that collect immunization and VPD-surveillance data, the availability of modern information technologies, and their current and potential future role in supporting the collection, management, analysis and use of immunization and surveillance data.
6. Identify knowledge gaps and create a prioritized research agenda.

1.2 Methods

Since its establishment in August 2017, the Data WG met during multiple teleconferences and three face-to-face meetings, including two Data Partners' Meetings (2017 and 2018). During the meetings, WG members outlined the scope of work, plans for completion, and progress, as well as had robust discussions on framing of the topic and recommendations. In addition, teleconferences with partners were conducted to orient the WG about relevant work on the topic and related cross-cutting areas.

Data considered within the scope of this work were vaccine coverage, immunization programme process indicators (e.g., vaccination sessions), vaccine supply, and VPD surveillance data.

1.2.1. Reviews and studies

A range of research methods were used to fulfill the terms of reference of the WG and develop this report. A series of landscape analyses; literature reviews; country case studies on different aspects of immunization and surveillance data and a data triangulation analysis were conducted by the WG members, consultants, or partners (see Box 1.3). It is important to recognize the significant contribution of WHO, UNICEF, Ministries of Health, and partner organizations who worked in close collaboration with the WG to complete the scope of work. Findings from their work are used throughout this report and also included as online Annexes.

Box 1.3. Studies and reviews conducted for this SAGE Data Working Group report (Annexes)

- Landscape analyses of:
 - Data availability, reporting and monitoring needs involving survey of 22 key informants (TOR1)
 - Immunization and surveillance guidance and standards, including survey of informants from six WHO Regional Offices (TOR2)
 - Data quality assessment approaches and indicators (TOR3)
 - Data triangulation use by immunization and other public health programs (TOR3)
 - Evidence gaps and research needs (TOR6)
- Literature and other reviews:
 - Immunization Data: Evidence for Action. A realist review of what works to improve data use for immunization: Evidence from low- and middle-income countries (LMICs) (TOR4b)
 - Scoping review of factors limiting quality of immunization data in LMICs (TOR4a)
 - Literature review of barriers limiting quality of and access to VPD surveillance data (TOR4a)
 - Scoping review of pre- and in-service training on immunization data in LMICs (TOR4a)
 - Literature review of novel approaches for immunization data (TOR5)
 - Literature review of novel methods for polio surveillance & applicability to other VPDs (TOR5)
- Triangulation analysis of tetanus vaccination and surveillance data (TOR3)
- Series of country case studies (various TORs)

The landscape analysis of data availability and monitoring needs involved interviews in person, by phone or by self-administered questionnaire of 22 key informants from all levels of WHO, partner agencies, ministries of health and other experts. Themes from qualitative findings were abstracted and summarized. Staff from the six WHO Regional Offices were also administered a short questionnaire on available guidance and examples of the state of data use in the regions; UNICEF regions were also invited to participate. Separate landscape analyses of data quality assessment approaches and indicators, as well as data triangulation use by EPI and other health programs were also conducted.

The latter was developed into a Global Framework on the Application of Public Health Data Triangulation for Immunization and Surveillance Programs, which is a joint product of the WG with WHO, UNICEF and CDC (*Annex 2*) (10). Evidence gaps and research needs were identified based on review of meeting reports, background documents developed for the WG and key informant interviews; a research agenda was developed based on identified gaps.

The literature reviews included traditional reviews, as well as a “realist review” and several “scoping reviews” on key topics, including barriers to immunization and VPD surveillance data quality and use. Although differing slightly in terms of methodology,² all literature reviews included searches of electronic databases (e.g., Pubmed) to identify relevant published literature. Most also included a search of references from identified articles (“snowballing citations”), as well as consulting with experts to identify other relevant references, including from the grey literature.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology is usually used by the SAGE to critically evaluate evidence for making vaccine recommendations. However, the WG found that the present topic was not amenable to this methodology because the scope of work and questions posed to the WG were broad, and a lot of the related evidence was descriptive in nature. A majority of evidence came from the literature reviews and landscape analyses described in Box 1.3, and the published and grey literature identified therein. Published systematic reviews were used where available. Where there was a paucity of high-quality evidence, the WG employed expert opinion and consensus.

1.2.2 Relevant definitions

Vaccination coverage

Coverage is measured using one or more of the following approaches: (1) administrative-based approaches that utilize individual level vaccination registries (either paper-based or electronic immunization registries [EIRs]), or aggregated summary reports of administrative data to identify the number of vaccinated individuals, or (2) population-based household coverage surveys (11). This report primarily focuses on *administrative* vaccination coverage data since these data are readily available to programmes on a day-to-day basis. Population-based household coverage surveys are also conducted periodically to monitor vaccination coverage (e.g., every 5 years), but not everywhere and not frequently enough to provide information for regular programme management. Readers should be aware that similar data quality concerns and concurrent discussions are taking place around vaccination coverage surveys (see Chapter 2) (12, 13).

Administrative vaccination coverage requires data on a target population or the number of age-eligible children in a defined geographic area during a defined time period (the denominator), as well as data on the number of age-eligible children vaccinated (the numerator) from the same target population as the denominator. By dividing the number of age-eligible vaccinated children by the appropriate target population, programme staff are able to measure the percentage of the target population that has received a specific vaccine dose in a given geographic area during a specific time period.

Vaccine-Preventable Disease (VPD) surveillance

These data provide vital information to help immunization programmes understand the burden and epidemiology of VPDs, to assess vaccination impact, and to inform programme policy and strategy. Specifically, disease surveillance helps establish the VPD burden, thus providing evidence for vaccine introduction, refinement of vaccination schedules and targeting vaccination campaigns. It also helps identify immunity gaps and unreached populations; enables the programme to monitor progress towards disease eradication, elimination and/or control goals; facilitates rapid detection and response to disease events of public health concern; facilitates documentation of short- and long-term effects of

² A realist review is where the question of interest includes how and why complex social interventions work in certain situations, rather than assume they either do or do not work at all. A scoping review is a type of research synthesis that aims to 'map the literature on a particular topic or research area and provide an opportunity to identify key concepts; gaps in the research; and types and sources of evidence to inform practice, policymaking, and research. For more information on types of reviews please see: <https://www.ncbi.nlm.nih.gov/pubmed/26693720>.

vaccination on disease burden and epidemiology, thereby monitoring programme effectiveness and impact; and enables detection of shifts in types or sub-types of organisms causing disease (14).

VPD surveillance data comes from three types of surveillance: 1) passive notification of VPDs from healthcare providers, 2) active surveillance in which public health officers review hospital or clinic discharge data for specific VPDs, or 3) sentinel site surveillance typically occurring at specialized hospitals with high clinical and laboratory capacity. VPDs on lists of notifiable diseases typically have standardized case definitions for detection and reporting to the central public health authority. VPD data are reported through aggregate summary reports or individual-level case investigation forms (“case-based” data). Some diseases have both aggregate and case-based data and may also have additional data on healthcare visits by diagnosis reported through the health information system (14).

Data quality

The definition of data quality for immunization varies but has typically been described in two ways. The first defines quality as the degree to which the data represent the truth of a given reality at a specific point in time. Using this definition, data quality would be reflected by the accuracy of the measurement relative to an absolute truth and precision of the measurement. Because the absolute truth with regard to immunization programme performance and disease burden is usually impossible to know, the first definition is of limited operational use. The second defines data quality as the degree to which data are “fit for the intended purpose.” This definition is arguably the more operationally relevant by combining various functional aspects of data quality and usability. Operational definitions used in this report are summarized in Box 1.4.

Box 1.4. Operational definitions used in this report

- **Data:** Measurement inputs that need to be processed into actionable information before action can be taken or decisions can be made (15).
- **Data availability:** Degree to which data relevant for decision-making can be reliably accessed by relevant persons.
- **Data quality:** Degree to which data are fit for the intended purpose (*see paragraphs below*).
- **Data use:** Degree to which data are actually used for a defined purpose, e.g., programme management, planning, decision-making.
- **Culture of data use:** The customs, dispositions, and behaviors of a particular group or organization to support and encourage the use of evidence, including facts, figures, and statistics, to inform their decision-making (16).
- **Data triangulation:** An approach for critical synthesis of existing data from two or more data sources to address relevant questions for programme planning and decision-making (Annex 2).

For the purpose of this report, the **WG further defined quality data as accurate, precise, relevant, complete, and timely enough for intended purpose** (Box 1.5). This was based on adaptation of a scheme by Bloland and MacNeil (17), after review of several schemes of data quality attributes (17-19) (Annex 3). Since accuracy and precision may be hard to measure, consistency, concurrence, and integrity in the case of evaluations of secondary data quality (i.e., stored data at higher levels), can be considered as proxies for accuracy and precision. It is important to note that implicit in the definition is the fact that data quality is context-specific, and fitness for purpose may vary by place, health system level, over time, or from user to user.

WHO defines public health surveillance as “the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice (20).” Most of the routine data collected for immunization programmes could be considered surveillance data under this broad definition. In 1988, the U.S. Centers for Disease Control and Prevention (CDC) published their first *Guidelines for Evaluating Surveillance Systems*, which has been updated periodically and adapted by WHO (21-23). According to the WHO Guide to Monitoring Communicable Disease Surveillance and Response Systems (2006), “the quality of the surveillance

system is defined by attributes such as completeness, timeliness, usefulness, sensitivity, positive predictive value, specificity, representativeness, simplicity, flexibility, acceptability, and reliability (23).” Since routine data is product of a data collection system, it is probably not surprising that we observe these terms to relate to a mix of system and data quality attributes (under the above definition of data quality as “fit for purpose,” including dimensions of quality and usability).

Box 1.5. Attributes of data quality, as defined as “fit-for-purpose”

- **Accuracy** — Degree of agreement between a given measurement and the actual (or true) value.
 - **Concurrence** (proxy) — Degree of agreement between different methods intended to measure the same construct.
 - **Integrity** (proxy) — Degree to which data, once entered into the official record, are not lost, incorrectly transcribed from one record to another, or otherwise altered from the original, i.e., accuracy of stored/reported data.
- **Precision** — Degree of spread among a series of measurements that is independent of accuracy
 - **Consistency** (proxy) — Degree to which data attributes are free from contradiction and are coherent with other data in a specific context of use, e.g., over time for one indicator or across related indicators.
- **Relevancy** — Degree to which the data collected and reported reflect what is most important to support decision-making and not in excess of what is needed so as to consume scarce resources.
- **Completeness** — Degree to which all relevant data needed for decision-making are recorded and reported and therefore available for use.
- **Timeliness** — Degree to which data are current and available when needed to inform decisions.

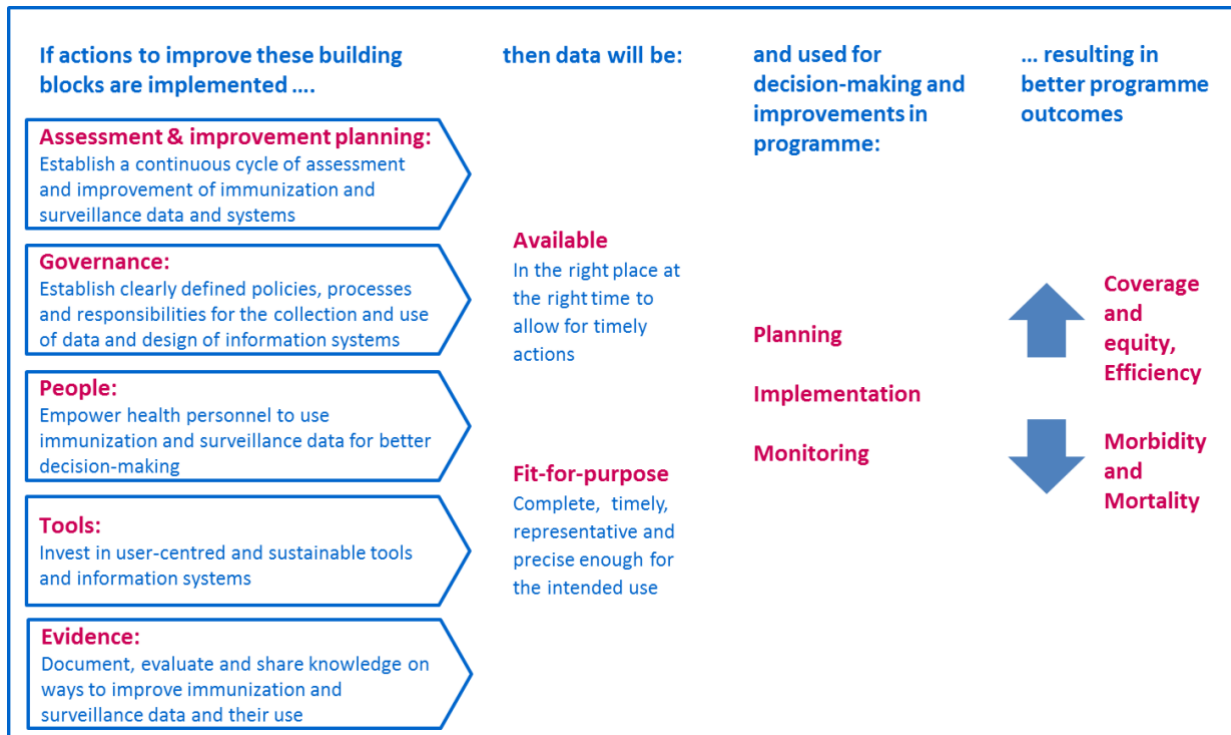
Source: Adapted from Bloland and MacNeil, In Press (as of 11 March 2019)

1.2.3. Frameworks used

WHO has a comprehensive framework for health system strengthening, which includes six “building blocks”: 1) service delivery, 2) health workforce, 3) health information systems, 4) access to essential medical products, vaccines and technologies, 5) financing, and 6) governance and leadership (19).

The structure of this report is based on a simplified theory of change of how to improve EPI data and ultimately immunization programmes and health outcomes, which comes from the *Global Framework to Strengthen Immunization and Surveillance Data for Decision-making* (8) (Figure 1.1) (Annex 1). This framework identifies five pillars required to produce immunization and surveillance data that are “fit-for-the purpose” in programme planning and decision-making. The five pillars are governance, people, tools, processes (data use and continuous improvement), and evidence.

Figure 1.1. Simplified theory of change on how health system inputs lead to improvements in immunization programmes and health outcomes (8)



1.2.4 Orientation to this report

For orientation to this report, the landscape chapter contains the results of the reviews associated with TORs 1, 2, and 3 (landscapes of data availability and reporting process; standards and guidance on immunization and surveillance monitoring; data quality and assessment approaches). The four chapters that follow present key issues relating to the five pillars: governance, people, tools, assessment and improvement planning, and evidence. These chapters generally draw on the results of reviews associated with TOR4a (barriers limiting data quality and use for immunization data quality; VPD surveillance, as well as data access and sharing) and TOR4b (review of what works to improve immunization data use). The Tools chapter summarizes key evidence and results from TOR5 (reviews of immunization information systems and innovative approaches; innovative approaches to polio surveillance). The Assessment and Improvement Planning Chapter includes additional results and evidence from TOR3 (triangulation landscape and data analysis). Country case studies are interspersed throughout the report (Box 1.3 and Annexes).

2. Landscape of immunization and surveillance data availability, quality, use and guidance for countries

Key messages

- A considerable amount and variety of immunization and surveillance data is available nationally, regionally and globally, but they may be inaccessible to those that need them.
- Poor quality immunization-related data still exist, especially in low- and middle-income countries, with inaccuracies in denominators especially of concern.
- The WHO/UNICEF Joint Reporting Form (JRF) on Immunization remains an important tool for global monitoring of immunization programmes, though the increasing time and resources required for countries to complete it was recognized.
- WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) remain a key data source with improved reliability and comparability across countries, relative to reported data.
- Disaggregated coverage and surveillance data (e.g., subnational, individual-level) are increasingly being collected at regional and global levels to meet immunization programme monitoring needs.
- Key data that were missing were data from the private sector, data for monitoring equity, and data pertaining to high-risk groups, including migrant or mobile populations.
- Under development are a global WHO Immunization Information System (WIISE), which will include an electronic JRF (eJRF), and a global comprehensive VPD surveillance strategy that are projected to improve data collection, management, and use.
- Efforts are being made in countries and regions to improve data quality and use, including conducting data quality assessments and developing of electronic immunization registries and web-based surveillance information systems.
- A number of guidance materials addressing immunization monitoring and data quality improvement are available, though awareness and discoverability of these materials needs to improve, and user-friendly, practical guidance is still needed for a number of topics.
- Recent data quality assessment tools showed positive trends in increased country ownership and inclusion of root-cause analysis and data improvement plans.
- More work is needed to define a common lexicon and standard set of indicators to measure data quality and use, as part of comprehensive programme monitoring (see also Chapter 6).

2.1 Data availability and the reporting process

A landscape analysis was conducted to assess data availability and unmet monitoring and evaluation needs at the national, regional and global levels. This involved interviews with 22 key informants, including staff from WHO Headquarters, UNICEF, Gavi, the Bill & Melinda Gates Foundation, the U.S. Centers for Disease Control and Prevention, the International Red Cross, WHO Regional Offices, several WHO country offices, health ministries, and expert consultants. The interviews focused on what data are available and by whom, their relevance for decision-making, what's missing, views on the reporting process, and what could be improved and how. [Annex 4](#) summarizes all the answers collected through the interviews.

2.1.1 Data available at the national level

At the national level, routine coverage data are available, through national health management information systems (HMIS), and in some cases, stand-alone immunization reporting systems (such as the District Vaccination Data Management Tool [DVTMT] in the African Region), and coverage surveys (Multiple Indicator Cluster Surveys [MICS], Demographic Health Surveys [DHS], or stand-alone), and are shared with the regional and global levels. Data from private providers may not be included in routine reporting. Data for monitoring equity usually comes from subpopulation analysis of these periodic surveys, while data for routine monitoring of high-risk populations may not be available in most countries. Coverage data from supplementary immunization activities (SIAs) are available, but may not be well-archived or in a standardized format for use.

VPD surveillance data are collected by integrated systems in place nationally, such as the Integrated Disease Surveillance and Response (IDSR) or Early Warning and Response System (EWARS), and also disease-specific case-based surveillance. Most countries currently have national case-based surveillance for polio (acute flaccid paralysis [AFP]), measles, rubella, and neonatal tetanus. The systematic linkage of laboratory and epidemiological data was identified as a current gap in many countries (24). Adverse Event Following Immunization (AEFI) monitoring systems exist in some form in most countries, though they may not be robust (25).

Beyond epidemiological data on VPDs and immunization coverage, vaccine and supply chain data obtained from logistics management information systems (LMIS), pricing information from the Vaccine Product, Price and Procurement (V3P) project, and cold chain assessments can help monitor the delivery and effectiveness of immunization programmes, including their costs. Other sources of data that may be relevant for monitoring of immunization programmes include reports from outbreak investigation reports, EPI reviews, VPD surveillance reviews, post-vaccine introduction evaluations, data quality assessments, or other reports related to supervision feedback. Most of the qualitative data from these reports (e.g., recommendations) are not stored in a usable format to support use and follow-up for continued improvement.

Data from other programmes (e.g., population statistics, maternal and child health programmes) may also hold relevant immunization or surveillance data, or data on denominators, socio-economic status, and geographic information systems (GIS) (26). These data sources are often used to generate key immunization programme performance indicators – both epidemiologic (e.g., vaccine coverage or disease incidence) and programmatic (e.g., performance indicators for surveillance or logistics systems) – and can be triangulated to improve data quality and create a more comprehensive picture that can inform key strategic decisions. National Immunization Technical Advisory Groups (NITAGs) provide an organizational structure to support this process.

National reporting processes for administrative immunization and VPD surveillance reporting were considered to be functioning well, despite concerns about quality, timeliness and ready availability/access. In addition, guidance on data use for planning and monitoring is not always implemented (27). Due to the regular reporting processes in place, national reports on vaccine coverage and service delivery were available and found to be useful. These have enabled countries to plan efficiently for vaccine supply and logistics and monitor the cold chain. However, immunization and surveillance reporting process were found to be time- and resource-consuming, and there were concerns about the quality of the data. Reporting was not always conducted according to guidelines, and the tools available (forms, hardware and software) were not always optimal to support the reporting process. Other specific quality concerns highlighted by the key informants included AEFI data, and an absence of data for specific high-risk populations including migrants/ mobile populations.

2.1.2 Data availability and the reporting process at the global and regional levels

The WHO/UNICEF Joint Reporting Form (JRF) on Immunization

A key source of immunization data available internationally since 1998 is the JRF, which collects a standard set of immunization, surveillance and other programme data from countries on an annual basis and is coordinated jointly by WHO and UNICEF (Box 2.1). Since 2017, the global form has also collected subnational-level vaccine coverage data for DTP and measles-containing vaccine, with known limitations (28); some regional variations of the JRF collected subnational data before 2017. Data from the country reports are extracted, reviewed for completeness and consistency and queries are sent back to countries to clarify absent information and inconsistencies. The nationally reported immunization performance data are then made publicly available on the WHO website.³ The JRF reporting and validation process has improved over time and the data have become more comprehensive, expanding beyond coverage and surveillance (Box 2.1). In 2018, 100% of the 194 WHO member states submitted 2017 data through the JRF. Plans to switch to an online reporting system (eJRF) are ongoing and are related to the development of WHO Immunization Information System (WIISE), a global level integrated platform for management and visualization of coverage, surveillance and other data that is projected to improve data availability and usefulness (Box 2.2).

Box 2.1. Data collected from national immunization programmes through the WHO/UNICEF Joint Reporting Form (JRF)

- Reported cases of selected VPDs and general information on surveillance systems
- Updates to national immunization schedules
- Source of vaccines and supplies
- School based immunization activities
- Administrative data system derived immunization coverage
- Official government immunization coverage estimates
- Immunization system planning and management indicators
- National immunization advisory mechanism indicators
- Proportion of districts by coverage levels for DTP3 and MCV1
- Subnational (admin 2) level coverage data for DTP3 and MCV1
- Vaccine and supply stock-out information
- Vaccine safety indicators
- Home-based records
- Immunization financing data
- Supplementary immunization activities completed and planned

JRF data are used by WHO and UNICEF to produce estimates of national immunization coverage (WUENIC), which are in turn available to member states and global immunization partners (Box 2.3) (29). Data from the JRF and WUENIC serve as a critical resource for tracking implementation of the Global Vaccine Action Plan (GVAP) and Regional Vaccine Action Plans. Other uses of JRF data include monitoring countries' health situation and assessing health trends, monitoring progress towards the SDGs; and informing VPD burden estimates.

The main reason the JRF was created was to harmonize UNICEF and WHO immunization data collection for global and regional use, and not specifically for use at the country level. As such country programs may perceive the JRF as a burdensome exercise requiring significant time and resources. An assessment at the global level has shown that the JRF is meeting the needs of WHO and UNICEF, in terms of decision-making and programme monitoring (30). Regions can add questions to their regional forms, but must keep the global core. And to ensure its continual relevance, the form is reviewed and revised every two years taking into account data use, needs and feedback from the regions. For example, to further improve the relevance of these data for global immunization programme monitoring, the number of VPD cases by age group will be added to the form, starting in 2019.

³ https://www.who.int/immunization/monitoring_surveillance/en/

Box 2.2. WHO Immunization Information System (WIISE)

Although WHO has been collecting, analysing and reporting immunization programme and vaccine-preventable diseases surveillance data for decades, there has never been an effort to harmonize the processes and workflows across WHO Regional Offices and Headquarters. Different technological solutions were independently developed by each Regional Office to handle data from their respective regions. This has resulted in fragmented systems based on regional priorities that depend on specific individuals for access and support and that may use outdated technologies with limited capacity for analysis, visualization and triangulation. In recognition that this situation was neither efficient nor sustainable, all WHO offices supported the development of a new integrated platform, which gave birth to the WIISE project. The main objectives of the project are to develop a new information system for immunization data hosted at WHO that will:

- Simplify data collection and management processes for Regional Offices, Country Offices and Member States;
- Collect, harmonize, and consolidate various sources of immunization and surveillance data.
- Simplify data management through web-based tools, and automated data transfer and validation checks;
- Produce standard outputs (e.g. graphs, tables, and maps) for more consistent reporting and usability;
- Facilitate in-depth data analyses by easy access to different datasets by internal and external stakeholders; and
- Leverage existing technologies and expertise to maximize the benefits of the project's products to other WHO departments.

Key priorities for information to include in the WIISE platform are measles and rubella surveillance data, the annual JRF, subnational coverage data, data on supplementary immunization activities (SIA), and cross-cutting reference data supporting all programmes.

Box 2.3. WHO and UNICEF estimates of national immunization coverage (WUENIC)

In 1998, following a retrospective analysis of annual vaccination coverage reports from countries that revealed poor data completeness, consistency and concurrency, the SAGE recommended investing resources to improve the completeness, accuracy and precision of the vaccination coverage estimates published by WHO. To address these issues, WHO and UNICEF jointly developed methods that were approved by WHO's Quantitative Immunization and Vaccines Related Research (QUIVER) Advisory Committee, and externally reviewed again in 2009. Following criticism and concerns about a lack of replicability, consistency and transparency of the estimation methods, a WHO and UNICEF Working Group developed WUENIC, a formal system that uses computational logic to determine the data, decisions, and rules used to derive the estimates of national immunization coverage. Following concerns about the absence of a measure of uncertainty in the coverage estimates expressed during the 2009 QUIVER review, the WHO and UNICEF Working Group developed a Grade of Confidence, which was introduced and published alongside the WHO and UNICEF WUENIC estimates for the first time with the 2011 revision (31).

Other sources of global and regional data

In addition to data collected through the JRF, all regional offices collect case-based surveillance data for polio, measles, rubella and neonatal tetanus. Case-based surveillance data for rotavirus, invasive bacterial disease (IBD) are also collected from sentinel sites in selected countries. These data are shared with WHO-HQ, which publishes surveillance reports (weekly for polio, monthly for measles and rubella, quarterly for new vaccines). In 2017, WHO also produced a one-off surveillance supplement that collected information on the status of surveillance systems for a wide range of VPDs, a summary of which was published online (32). Currently, efforts are underway to develop a global strategy for comprehensive VPD surveillance to improve the efficiency and relevance of data collected, as well as use for immunization programme monitoring (Box 2.4).

Box 2.4. Comprehensive vaccine preventable disease (VPD) surveillance

There are considerable challenges and weaknesses with VPD surveillance systems in many countries. These include fragmented or parallel systems, the fact that most data collected are not “fit-for-use,” weak laboratory capacity for most diseases (especially bacterial), and the risk of their losing resources as polio funding diminishes as eradication nears.

A global strategy is being developed to transform the current fragmented VPD surveillance into a more cohesive and comprehensive system. **Comprehensive VPD surveillance is defined as the country, regional and global systems required to meet the minimal recommended standards for surveillance of a set of priority VPDs, with integration of surveillance functions across other diseases where possible.**

Comprehensive surveillance will include more VPDs, based on country priorities, and a mix of nationwide case-based, aggregate, and sentinel site surveillance, based on specific surveillance objectives. In general, more individual-level and laboratory data will be needed. Greater emphasis will be placed on the visualization and use of surveillance data for routine programme monitoring, decision-making and response.

In addition to surveillance data, Regional Offices may collect monthly subnational coverage, but the degree of completeness varies by region. For example, in the WHO African region (AFR), immunization and VPD control programmes use a standardized reporting system across countries in the region. While national-level data remains country-owned, various datasets are shared with the regional office to monitor coverage and disease trends in the Region (Table 2.1) (33). Some of these data are shared with technical and donor organizations (e.g. IHME, U.S. CDC, USAID, BMGF, World Bank, Gavi).

Table 2.1. Type and format of immunization and surveillance databases handled at WHO African Regional Office

Database	Frequency of sharing with WHO	Format of database	Datasets expected per year
Population data	Annually	Excel	47
Routine immunization coverage	Monthly	MS-Access	564
Stock management tool	Weekly	Excel	564
District vaccine data management tool	Weekly	Excel	564
WHO-UNICEF Joint Reporting Form: coverage and incidence data	Annual	Excel	47
SIAs coverage data	Activity related	Excel	Ad hoc
SIAs independent monitoring data	Activity related	Excel	Ad hoc
SIAs lot quality assurance survey data	Activity related	Excel	Ad hoc
AFP/polio surveillance	Weekly	MS-Access	Ad hoc
Measles surveillance	Weekly	MS-Access	2 444
Yellow fever case-based surveillance	Monthly	MS-Access	2 444
Neonatal tetanus surveillance	Monthly	MS-Access	564
Paediatric bacterial meningitis surveillance	Monthly	MS-Access	564
Rotavirus surveillance	Monthly	MS-Access	324
Polio lab data	Weekly	MS-Access	324
Measles rubella national lab data	Monthly	MS-Access	832
Measles rubella regional referral lab data	Quarterly	MS-Access	528
Yellow fever national lab data	Monthly	MS-Access	36
Yellow fever regional reference lab data	Monthly	MS-Access	12
Integrated disease surveillance data	Weekly/monthly	MS-Access/ Excel	564

Source: Poy A et al. Immunization monitoring and vaccine-preventable diseases surveillance data management in the African Region. *African Health Monitor*. 2015; 19: 46-50.

2.2 State of immunization and VPD surveillance data quality

Countries and immunization partners have made a number of efforts in recent years to improve the availability, quality, and use of immunization-related data (5). However, poor quality data still exist in high, middle and low-income countries. Deficiencies in immunization and VPD surveillance data quality are often more pronounced in LMICs, where immunization data needs are greatest in order to be able to target missed populations (34-37) (*Annex 5*). Data issues affect both numerators and denominators used to calculate administrative coverage or disease incidence rates, and also affect surveys. The many possible sources of data quality loss and data use failure for administrative reporting are depicted in Figure 2.1. A summary of suggestions for improving data availability, quality and use from the key informant interviews is shown in Box 2.5, categorized by the pillars of data quality and use described in Chapter 1.

Figure 2.1. Possible sources of data quality loss and data use failure as administrative data progress from primary points of collection to global reporting (17).

Box 2.5 Suggestions from key informants on ways to improve the availability, quality,

and use of immunization and surveillance data

Data processes, improvement and use

- Focus the global reporting requirements on data that is relevant to both the national level and the regional/global level
- Standardise data from countries and regions (including minimum datasets)
- Routinely analyse multiple data sources/do data triangulation, in particular between data generated by different agencies or sources
- Strengthen denominators at national/subnational levels
- Capture immunization/surveillance data from private providers/ Non-Governmental Organizations (NGOs)/ Civil Society Organizations (CSOs), not just immunization programme data from public facilities
- Use other data sources that include socio-economic data to better measure equity estimation with regards to vaccinations
- Develop and implement monitoring and evaluation frameworks and dedicated activities (e.g., annual regional data meetings)
- Implement data quality improvement plans
- Strengthen JRF data validation
- Create a repository for qualitative data

Tools

- Technological options to facilitate data capture, validation, storage, linkage, and sharing (e.g. data entry platform at health facility level, laboratory/case-based surveillance linkages)
- Data visualization tools with inter-regional dashboard (e.g. WIISE)
- Data repository for data and reports from NITAGs/RITAGs/National Verification Committees (NVCs)
- Guidance for classification of AEFIs, especially when data is lacking for full causality assessment, and sharing of summarized outcomes of classified cases

People

- Capacity development of workers at all levels to collect, analyse and triangulate data
- Demonstrate the value of collecting and using data at all levels to improve staff motivation to create a data driven service delivery

Governance

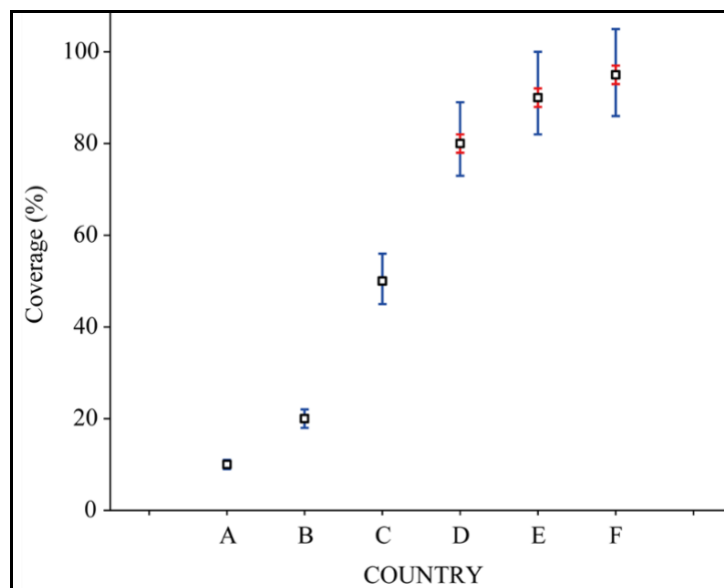
- Guidance on what “fit for purpose” data means at different levels and for different users
- Greater support, coordination and alignment from partners on the ground
- Provide feedback of analysed data to stakeholders
- Share best practice in implementing data management
- Regular data quality monitoring at subnational and national level
- Improve the use of data to make decisions about the programme at all levels
- Rethink incentives, which sometimes become disincentives (35, 38), to report accurate data

2.2.1 The quality of vaccination coverage data

Studies in low- and middle-income countries have shown that officially reported immunization coverage figures are often of poor quality, with coverage rates most commonly over-reported (34, 35, 39-44) but sometimes under-reported (34, 35, 40, 43). A recent review of global coverage raised the issue of the number of subnational areas with coverage >100% in terms of interpretability of the subnational coverage figures used for GVAP monitoring (41). The literature describes data disagreement at all levels of the health system, from facility-level to national reports (41, 45-47), due to problems with both numerators and denominators.

Inaccuracies with denominators, which are critical for microplanning and administrative coverage calculation, have especially been documented in the literature (40, 43-46). For example, one review found that while national denominator figures were updated annually, 87% of districts used the same figure over several years (45). In fact, only 14% of the countries reviewed had an agreed-upon denominator at both the district and national level. A recent global review found 11% of all reporting events (country-years) had substantial (>10%) year-to-year differences in the number of reported live births, as well as BCG coverage rates of more than 100% (43). It is important to highlight that target population estimates at the global and regional levels involve less uncertainty than those at a country and subnational levels, as errors at the country level tend to offset each other when aggregated (48). The accuracy of target population estimates especially affects the precision of vaccination coverage rates in places with high levels of coverage. In fact, as coverage levels approach 100%, errors in target population estimates can mask differences in vaccination coverage rates, resulting in pockets of missed unvaccinated children (49) (Fig. 2.2).

Figure 2.2. The effect of 10% error in target population estimates on estimated immunization coverage rates (49)



In some cases, immunization programmes estimate the number of children in the target population (e.g., surviving infants) based on counts or estimates by local programme staff or health workers. In others, immunization programmes rely on population projections from the latest census data. Changes in fertility, mortality and/or migratory patterns over time create challenges for obtaining robust target population estimates. While complete vital registration would be the most reliable source for denominators, few countries use this, as problems with vital registration systems exist in the majority of the low- and middle-income countries (50, 51). Two-thirds of the countries with the highest mortality rates, which account for 95% of all maternal, newborn and child mortality, lack the vital registration systems necessary to accurately project denominators (52). Use of alternative data sources from other programs and/or good coordination with national bureaus of statistics to improve denominators is rare in countries (53).

Problems with numerators have also been documented in the literature. Studies using the standardized WHO Data Quality Assessment (DQA) tool found that only one-fifth to one-third of countries evaluated had verification factors that suggested consistent immunization numerator data. Meanwhile, one third had VFs in keeping with moderate over-reporting and one third had VFs consistent with considerable over-reporting (45, 46, 54). Another issue with the numerator data at the national level is the completeness of reporting of this data from all vaccination sites, including private providers which may represent a large proportion of health services provided in LICs and MICs (55).

Some countries using electronic immunization registers (EIRs) have reported improved data quality (46, 56), while other countries with EIRs continue to report quality data issues (57, 58). A case study on an EIR from Chile (done for this report) shows the relevance of including vaccination reporting from the private sector and how using numerators that consider the place residence ensured optimal data

quality and ability to locate unvaccinated children (Box 2.6 and Annex 6). Efforts are also ongoing to improve data quality from EIRs through guidance and the development of built-in routines to flag potential problems (59, 60).

Box 2.6. Effect of private sector engagement and place of residence vs place of vaccination on coverage estimates in Chile

Chile began the implementation of its online national Electronic Immunization Registry (RNI in Spanish) in 2010. Its use is mandatory in all public facilities and also in private clinics as per a Ministerial mandate. A total of 2,075 facilities were using RNI in 2018, with 241 (12%) of them being private. In the Metropolitan Region of Santiago, one in four children were vaccinated in private clinics, and some districts had up to 94% of their children vaccinated by the private sector. Also, one in five children were not vaccinated in the same district where they reside. This phenomenon resulted in coverages ranging from 29% to 325% by district when the place of vaccination was used as a denominator, but when coverage was calculated based on the district of residence, the range narrowed to 79% to 140% coverage (Annex 6).

Surveys are often seen as more reliable than administrative coverage estimates, as they do not rely on inaccurate denominators. It is important to note that while being useful for national or regional monitoring, surveys do not typically provide programmatically useful information at the local level (12). Further, not all countries conduct surveys and in those who do, surveys coverage estimates may also be inaccurate as a result of selection, information or other biases. Information bias is especially an issue in determining vaccination status using caretaker's recall when vaccination cards or home-based records (HBRs) are not available (12, 61, 62). Studies looking at the validity of recall have highlighted how it varies in different settings (63-65); the impact of recall bias on survey coverage estimates has been highlighted as a research priority (13). Crucial data like date of birth may be missing, preventing estimation of the timing of children's vaccinations (66). Countries with inaccurate administrative data often tend to have challenges in obtaining accurate survey estimates, as a result of outdated sampling frames, inaccessible areas, or low availability of HBRs (12). An analysis of survey results from countries where a vaccination coverage survey was conducted within one year before or after a DHS or MICS identified several instances where the findings diverged substantially, in terms of coverage estimates and in the percentage of vaccination cards or HBRs seen, leaving decision-makers unsure what to believe or to do (D. Brown, personal communication) (13).

2.2.2 The quality of VPD surveillance data

The literature has also identified quality issues with VPD surveillance data. These include incomplete or delayed routine surveillance reporting, inconsistent use of standardized disease case definitions, a lack of laboratory confirmation, and insufficient completeness of critical information, including absence of documented evidence of vaccination history of cases — all of which can negatively impact the use of surveillance data for decision-making (Annex 7)(67-69). While case-based surveillance data for polio, measles, rubella and new vaccines are routinely analyzed and used at all levels (despite documented challenges in performance monitoring indicators) (70-72), most of the aggregate incidence data collected through national surveillance systems and the JRF are seldom analyzed and of limited use (Box 2.11) (36, 73, 74). This is related in part to doubts about the completeness of the data, but also to the fact that relevant data, such as age-specific incidence and laboratory confirmation, may not be collected or reported, thus limiting the usefulness of available data for immunization programme monitoring (30). Global efforts are also underway to improve surveillance quality (Box 2.4).

2.2.3 Other evidence of data quality: an example of a global analysis

The WG commissioned an analysis of the use of tetanus incidence data reported to the JRF to monitor DTP coverage, including doses provided beyond infancy in light of the shift towards a life-course of vaccination approach. The analysis found substantial data quality issues — both with surveillance and vaccination coverage data — that affected the ability to perform the analysis (Box 2.7). Of the indicators assessed, only WUENIC estimates of DTP3 coverage were available for all countries during 2011–2016. Otherwise, there were large variations in the number of countries reporting immunization and surveillance data across regions and income levels. These findings reflect the challenges inherent in making systematic comparisons at the global level (Annex 5) (37).

Box 2.7. Challenges with the quality of JRF data during a global tetanus triangulation analysis: looking towards monitoring the life-course of vaccination approach

The U.S. CDC conducted an analysis that triangulated data on the immunization schedule for tetanus containing vaccines (TTCV), coverage, and tetanus surveillance — both neonatal and non-neonatal tetanus (in persons aged >28 days) — data collected by WHO from 194 countries. The aim of the analysis was to evaluate the feasibility of using non-neonatal tetanus surveillance data to assess the potential of using the data to monitor the coverage of diphtheria, tetanus, and pertussis containing vaccines (DTPCVs) (Annex 5). As part of the evaluation, challenges were noted with the availability and quality of current immunization and surveillance data, including the following:

- WUENIC had good completeness and seemed more reliable compared to official reported coverage.
- Administrative coverage data differed from survey coverage, especially in LICs and LMICs (but, few surveys were in upper middle-income and high-income countries).
- Data on coverage for booster doses were not generally available (e.g., poor completeness of reporting DTP4 coverage, lack of WUENIC estimates for DPT4, no DTP5 coverage collected).
- Immunization schedule data required substantial cleaning (readjusting of variables) before use.
- Collated data on the timing of TTCV booster introduction or schedule changes were unavailable.
- Variations in how countries interpreted the definition of “total tetanus” cases led to challenges in interpreting the number of non-neonatal tetanus cases.
- Non-neonatal tetanus is under-reported, based on comparing reports of total tetanus cases with neonatal cases, which is a marker of endemic disease.
- Age-specific disease data were only available for AFR and AMR and were of poor quality.
- It was difficult to make country-level epidemiologic interpretations with the existing data.

Based on this analysis, the 2019 JRF (for 2018 data) was revised to enable monitoring of the life-course approach towards tetanus vaccination, including report neonatal and non-neonatal tetanus cases separately (revised from “total tetanus”), and collecting age-specific tetanus incidence data (an example of how data use can lead to improvements in data quality). The WG also recommends that data on booster dose coverage be collected, that a plan is developed for WUENIC estimation of DTPCV booster doses, and that the usability of schedule data is improved.

2.3 Efforts to improve the collection, quality and use of immunization and surveillance data

2.3.1 Standards and guidance on immunization monitoring and surveillance

A key component of the Global Framework to Strengthen Immunization and Surveillance Data for Decision Making is establishing clearly defined standards for the design of information systems and processes for data collection and use (3, 8). Harmonized guidelines and standards are critical to improve the quality, availability and use of immunization-related data. WHO is responsible for developing standards and guidance at the global level and regional levels. Usually, regional guidance should be adapted from global guidance for greatest harmonization. However, a specific region may identify a need for guidance and develop a regional document, which is then used as an impetus and starting point for developing global guidance. In all cases, it is particularly important for country programmes to adapt global and regional guidance to their specific context at the local level, where health workers need relevant training in core competencies (75), as well as tools and procedures to implement good practices on data collecting, reporting and how to use data for making decisions (See Chapter 5: People).

The WG conducted a thorough review of existing (including new) guidance documents and standards that include immunization monitoring and surveillance, as well as an analysis of gaps in global and regional guidance, including what’s missing or needs updating to meet countries’ needs. A list of published core guidance and standards at the global level was compiled, based on an existing list of WHO documents, a CDC landscape analysis of EPI guidance documents conducted in 2017, and supplemented by on-line searches and information gleaned from WG members and WHO EPI staff.

Regional documents were identified from a questionnaire sent to the six WHO Regional Offices. Potential gaps in guidance materials were identified through reviews of publications and meeting reports, the key informant interviews, input from WG members, and personal communications. It should be noted that the review did not examine country guidance materials in any systematic fashion, nor did it assess the appropriateness or completeness of individual guidance documents in addressing all relevant areas. The resulting list of published EPI guidance is included in [Annex 8](#).

The review found that there is actually a lot of existing and newly developed global and regional guidance that is relevant for immunization and surveillance data. These include a number of documents published in the last several years or available online that together represent a major effort by WHO and a step forward towards filling in gaps and improving existing guidance materials (see [Box 2.8](#)). In addition, 11 WHO Position Papers on specific vaccines were published in the past two years that include guidance on monitoring and data, and the WHO Immunological Basis of Immunization Series is currently being revised.

Box 2.8. Key recent WHO global guidance materials with relevance to data quality and use

Published documents:

- [Vaccination Coverage Cluster Surveys Reference Manual \(2018 revision\)](#): improvements in methods for probability-based sampling, minimizing bias, improving data quality since the 2005 version, with related capacity-building tools
- [Surveillance Standards for VPDs \(2018 revision\)](#): enhanced from 2003 version to include overview of surveillance principles, minimal & enhanced standards for 22 diseases (from 11 in 2003), outbreak investigation, discussion of integration
- [Data Quality Review toolkit for health facility data \(2017\)](#): builds on previous EPI data quality assessment methodology with integrated guidance (across HIV, malaria, TB, EPI programs) for conducting a desk review and field assessment
- [Guide for conducting an EPI Review \(2018\)](#): first global guidance that includes best practices, use for programme improvement, and integrating with post-introduction evaluations, VPD surveillance reviews, and data quality assessments
- [Establishing and strengthening immunization in the second year of life \(2YL\) \(2018\)](#): guidance on planning, implementing and monitoring in 2YL, integration, and catch-up vaccination
- [Working Together \(2018\)](#): resource guide on policies and strategies for integrating various health services with immunization throughout life-course
- [Protecting All Against Tetanus \(2019\)](#): Guide to sustaining maternal and neonatal tetanus elimination (MNTE) and broadening tetanus protection for all populations
- [Missed Opportunities for Vaccination \(2017\)](#): comprehensive guidance on planning and implementing a MOV assessment, as well as implementing interventions
- [Engagement of private providers in immunization service delivery \(2017\)](#): guidance for optimal engagement of nongovernmental providers in immunization delivery and surveillance
- [How to Develop a Continuous Improvement Plan \(CIP\) \(2018\)](#): guidance on how to develop a continuous immunization supply chain improvement plan & case for supply chain investments
- Disease-specific guidance on serosurveys, including [dengue \(2017\)](#), and [tetanus \(2018\)](#), measles & rubella (draft), added to existing guidance for [hepatitis B \(2011\)](#)
- [Guidelines for Accurate and Transparent Health Estimates Reporting \(GATHER\) \(2016\)](#): outline recommended documentation for releasing health data
- Capacity-building approaches and [training](#) for improving data quality and use:

- A 2-hour [e-learning](#) module (2015) describes how to monitor immunization coverage, assess data quality, and interpret and use that data for action
- [Immunization Monitoring Academy](#) (2018): comprehensive multi-month distance learning programme requiring participation in lectures, discussion sessions, and projects
- [Survey Scholar](#) (2017–2019): hands-on distance learning on designing, implementing, analyzing and interpreting vaccination coverage survey using the 2018 revised guidance
- [E-learning course on Vaccine Safety Basics](#) (2013): online course on adverse events, pharmacovigilance, and communications related to AEFI and its risks
- [Effective Vaccine Management \(EVM\) system training course](#) (2012): developed by WHO and UNICEF to train immunization staff on conducting EVM assessments

WHO Working Documents:

- Global Framework to Strengthen Immunization and Surveillance Data for Decision-making (2019) (included in Annex 1)
- Handbook on the use, collection, and improvement of immunization data (2019)
- [Analysis and Use of Health Facility Data: Guidance for Immunization Programme Managers \(2018\)](#)
- Application of Public Health Triangulation for Immunization and Surveillance Programs: Framework Document (2019) (included in Annex 2)
- Harmonizing vaccination coverage measures in household surveys: A primer (2018)
- [Standard Competencies Framework for the Immunization Workforce \(2018\)](#)
- [Assessing and Improving the Accuracy of Target Population Estimates for Immunization Coverage \(2015\)](#)

The review also found a number of regional guidance materials related to immunization and surveillance data quality and use that have recently been completed or that address gaps in global guidance (Box 2.9). In addition, there are a number of global guidance documents currently in development and planned for publication in 2019–2020, which the WG urges to be finalized as soon as possible:

- Handbook on the use, collection, and improvement of immunization data
- Guidance on measles & rubella serosurveys
- EPI competency guidelines and tools for use by country programs to assess their immunization programme capacity
- Guidelines on data triangulation for programme planning and decision-making.

Box 2.9. Additional key guidance documents from the WHO regions

Increasing coverage and equity

- AFR: [Reaching Every District \(RED\) guide \(2017\)](#)
- EURO: [Guide to Tailoring Immunization Programmes \(TIP\) \(2013\)](#)

Pre-service and in-service capacity building

- AFR: [EPI Mid-level Managers \(MLM\) course \(2017\)](#)
- AFR: EPI Training Curricula for [Medical Schools \(2015\)](#) and [Nursing/Midwifery schools \(2015\)](#), and an EPI/IMCI interactive training tool for health workers (2016)
- EMR: currently developing Immunization in Practice training and translating MLM into Arabic

Coverage monitoring

- AMR/PAHO: [Tools for coverage monitoring \(2017\)](#)
- WPR: [Improving data quality: Guide for developing countries \(2003\)](#)

Electronic immunization registries (EIR)

- AMR/PAHO: [Electronic Immunization Registries \(EIR\) Guide \(2018\)](#) and draft “[DQS-Plus](#)” for improving data quality and use, and assessing acceptance and functionality of EIRs
- European Centers for Disease Control (ECDC): [Designing and implementing an immunization information system \(2018\)](#)

VPD Surveillance

- SEAR: [VPD Surveillance Guide \(2017\)](#)
- AFR: currently updating the Integrated Disease Surveillance and Response guidelines

Gaps in guidance materials and key emerging issues related to guidance

Despite the considerable number of relevant guidance materials available, a key finding of the review is that people working in immunization and surveillance are often unaware of what materials exist. Management of these materials on websites that are not intuitively organized or easily searchable makes the discovery of documents challenging. Communications about recently published documents through appropriate venues (e.g., EPI managers meetings, BID Learning Network, TechNet-21) may also be insufficient, resulting in low awareness. For example, most key informants noted immunization targets (denominators) as a major issue that needed to be addressed by guidance, but few had ever heard of or used the existing [2015 draft denominator guide](#) that is on the WHO website (Box 2.9). With the ability to publish electronically, which saves printing costs, guidance documents also seem to be growing in length (regularly 200+ pages) and more technically complex. All of these issues may limit their broader use or result in a duplication of efforts.

An analysis by the Working Group of gaps in critical guidance materials did find, however, that guidance was lacking or insufficient at the global or regional levels in a number of technical areas and should be developed (Box 2.10).

Box 2.10. Gaps in guidance materials in immunization monitoring, data quality and use: areas where guidance is lacking, insufficient or out-of-date

- Pre-service EPI training curricula for medical, nursing/midwifery schools (following [AFR example](#)) for not only growing immunization knowledge, but data collection and use skills
- Guidance for improving immunization targets (denominators) and how to deal with migrant populations, e.g., temporary workers, undocumented immigrants, nomads (i.e., revise and finalize global [2015 draft guide](#) to meet user needs), alongside capacity-building activities
- Capacity-building approaches for data analysis and use (see examples of global e-learning and distance learning; global MLM is out-of-date)
- Comprehensive VPD surveillance standards for some regions and most countries (adaptation of global guidance)
- Global guidance on creating electronic information system standards, including minimal data elements, interoperability with other systems, data flow and user access, validation checks:
 - Routine (aggregate) immunization data
 - Electronic immunization registries (following [PAHO example](#))
 - VPD surveillance (aggregate and case-based data)
- Improved guidance on monitoring approaches, including generic indicators that countries can adapt, for the following:
 - Equity and universal health coverage
 - Routine immunization data quality
 - Data quality in EIRs (following the example from the American Immunization Registry Association [AIRA](#))
 - VPD surveillance data quality
- Life-course and special population guidance, such as:

- Introduction guide for Penta/Td boosters (disease burden, school-based programs, monitoring coverage, etc.)
 - Guidance on school entry and adolescent vaccination, school checks, and mandatory vaccination for schools
 - Immunization of pregnant women (whether to vaccinate) and surveillance recommendations (pertussis, flu, vaccines in pipeline) (see [PAHO example](#))
 - Adult and elderly vaccination (influenza, pneumococcal)
- Technical guidance on how to manage, analyse and better use qualitative data for immunization programme improvement (e.g., assessment recommendations, case studies)
 - Recommendations from SAGE on the role of serosurveys for immunization programme monitoring and use in management

These gaps include guidance on effective approaches in building capacity at each level of the health system to strengthen data quality and use. The WG did note a positive trend in including capacity-building approaches as part of guidance roll-out (e.g., coverage survey), as well as efforts to develop e-learning curricula (on coverage monitoring, vaccine safety, logistics management). This is a positive trend that should continue. In particular, the [WHO Immunization Monitoring Academy](#) is potentially a useful modality for sharing guidance on data quality and use, especially if tailored to meet needs at different levels (Box 2.8). However, guidance on mapping of minimum capacity for data collection, use and analysis at each level could be useful to support the development and use of training materials, or to identify strategies to build capacity at various stages (e.g., pre-service, service induction, on-the-job training, leveraging broader data/epidemiology training). Simple guides and practical job aids are still largely lacking on how to use available complementary data to address various questions across all levels of the health system. Overall, guidance should emphasize the analysis and use of data, instead of simply data collection and reporting.

Another area where additional technical guidance is needed is on how to introduce information, technology and communication solutions for data management, including Electronic Immunization Registries (EIRs). The PAHO [EIR guidelines \(2018\)](#) were consistently cited by key informants as an example of good guidance, which could be replicated to include solutions for aggregated data, mHealth applications, and so forth. A [Planning and Information Systems Project \(2013\)](#) toolkit for other information systems exists and may also be helpful. However, national electronic information system standards are still needed that are specific to country contexts. To guide countries in their development, it would be useful to develop global guidance on the process, key issues, and best practices for creating functional standards, and for defining the minimum data elements for immunization information systems, EIRs, and VPD surveillance information systems.

Effective guidance was also felt to be needed to address emerging and increasingly critical issues for data collection and use related to both numerator and denominator. These include coverage monitoring among mobile populations or those living in informal settlements; recording and reporting of doses administered late; the management of data monitoring of vaccines given across multiple age groups and during the life-course; how to monitor and address issues of coverage equity to achieve universal health coverage; and how to effectively manage and use qualitative data generated in assessments or routine monitoring. In summary, while there is a considerable amount of guidance documents available globally or regionally, the awareness and discoverability of these materials among those working in immunization must be increased, guidance in a number of technical areas is still needed, and the guidance developed must be very practical and user-friendly.

2.3.2 Data quality assessment approaches and indicators

Achieving equitable immunization coverage and timely detection of VPDs requires high-quality programme data. GVAP includes a target that states: “All countries [are] to have high quality immunization coverage data by 2020” (76). However, GVAP does not describe what defines “data quality” or when data become “high quality.” Prior attempts to develop a GVAP data quality indicator for assessing and monitoring progress of vaccination coverage proved unsuccessful (76). In addition, prior

work has highlighted challenges with the underlying data GVAP uses for programme performance indicators (41).

Tools for assessing the quality of immunization coverage data

A number of tools to assess the quality of vaccination coverage and VPD surveillance data at the national and local level have been developed since 2000. These tools were developed to enable funding agencies to monitor progress and justify their investments, as well as to assist countries in conducting their own assessments in order to improve data quality. Below is a summary of the main data quality assessment tools developed in recent years, based on a landscape analysis commissioned by the WG. It should be noted that the impact of these assessment approaches on actually improving data quality and use was not systematically reviewed.

- [Data Quality Audit \(DQA\)](#): The DQA was developed in 2000 to enable Gavi to validate country reports of the number of children vaccinated with DTP3 — a measure used for the Alliance’s performance-based grants (77). While the main focus of the tool was to validate number of children vaccinated, it also assessed the quality, efficiency, security and usefulness of the administrative data system at each reporting level to develop practical recommendations for data recording and reporting. However, the tool had several limitations: a) It was not a country-owned or country-led process and as such was not flexible or based on the priorities of country programmes; and b) the methodology is challenged by small sample sizes at the district level, which creates problems with large variation in the measured verification factors of reporting accuracy.
- [Data Quality Self-Assessment \(DQS\)](#): In response to the limitations and critiques of the DQA, WHO developed the DQS in 2005 to assist countries to self-diagnose data quality problems in order to improve their monitoring systems. It is a flexible toolbox of methods intended for use by programme staff that can be adapted to meet their needs in assessing immunization data at the national, provincial, or district levels. The DQS includes a review of data integrity, completeness and timeliness, as well as a self-designed questionnaire for reviewing system quality issues (e.g. availability of home-based records (HBRs), directly-observed recording and reporting practices at health facility level). The tool has been widely and regularly used by countries and its use is now encouraged as part of [EPI reviews](#).
- [Assessing and Improving the Accuracy of Target Population Estimates for Immunization Coverage](#): In 2015, WHO produced a working draft of a guide to facilitate national immunization programmes to assess their target population estimates for vaccination coverage. The assessment includes assessing internal (i.e., trends over time, comparison of target populations across vaccines) and external consistency (i.e., comparison with alternative sources, examining population growth rates and implied mortality rates). As mentioned above, awareness of this tool was noted to be low among key informants, and the extent of use of this tool is unclear. The WG has recommended the guidance to be finalized.
- [Tools for Monitoring the Coverage of Integrated Public Health Interventions](#): In 2017, the Pan American Health Organization (PAHO) published this guide provide health staff at the local, district/municipality and national levels practical methods and tools to facilitate the management, analysis and coverage monitoring of vaccination and deworming interventions. Building on the DQS and other tools described above, the PAHO guide encourages in-depth evaluations of data quality every three to five years, complemented by abbreviated annual assessments and data congruence exercises based on supervisory visits. The guide encourages a focus on data accuracy, timeliness and completeness, as well as an overall evaluation of the recording and reporting system.
- [Data Quality Review \(DQR\)](#): This toolkit, developed by WHO, Gavi, the Global Fund and USAID and published in 2018, uses a unified approach to data quality across many disease control programs (including TB, malaria, HIV and EPI) to assess data quality at the health facility level. It builds upon a health facility [Data Quality Report Card \(DQRC\)](#) tool developed by WHO in 2015, as well as other data quality assessment tools (e.g., DQA and DQS), and takes into account best practices and lessons learned from many countries. The DQR framework includes: 1) routine and periodic reviews of data quality built into a set of checks of the health information system as part of a continuous feedback cycle; 2) annual independent assessments to identify reporting system gaps as well as the credibility of health facility reported data during the prior year; and 3) periodic in-depth reviews of data quality for specific programmes. The toolkit includes a desk review module

that assesses: 1) data completeness, 2) timeliness, and 3) internal and external consistency. A module to validate data integrity in the field and assess the system is also included. Related guidance on routine Analysis and Use of Health Facility Data has been developed along with a module for the District Health Information System 2 (DHIS2) that includes data quality (11).

- **Handbook on the use, collection, and improvement of immunization data:** WHO has also recently developed a working draft of this handbook to provide practical assistance to country-level decision-makers who want to: a) decide what data are needed for programme improvements and decision-making; b) develop tools and systems to collect and analyze immunization data; and c) assess the quality of data produced by their immunization recording and reporting system and implement improvement plans to address gaps within the system. Building on the DQR, the Handbook proposes a review of the design and organization of the information system, a desk review of data produced by the information system, a field review to verify reported data from source documents at the health facility and district level, and to perform a root-cause analysis to tailor recommendations and feed into a data improvement plan.

Recent data quality assessment tools showed positive trends in increased country ownership (DQS) and inclusion of root-cause analysis and data improvement plans (Data Handbook). However, it remains unclear as to how well these tools fit the data quality needs of country programmes and at what levels (8). In many situations, data quality assessment measures for data collection, analysis and use appear to remain a “tick-box” exercise to satisfy those at the international level demanding attention to data quality. However, periodic data quality assessments can be important to ensure that the methods, tools and indicators used, as well as accompanying visualization dashboards, fit the needs of national immunization programmes and are institutionalized and sustainable. Outcomes of assessments should feed into planning and improvement cycles. Summaries of DQA results suggest improvements in some aspects of data quality in some countries (45, 46), but whether these improvements persisted over time is unknown.

Approaches for assessing the quality of VPD surveillance data

While not receiving as much attention as data quality for vaccination coverage monitoring, standardized approaches to evaluating and monitoring VPD surveillance systems have existed since the 1980s (14, 21, 23, 78, 79). All VPD surveillance evaluation tools have been regional and disease specific (e.g., AFP, measles), until the publication in 2017 of the first global guidance on conducting EPI and integrated VPD surveillance reviews (78). Methodologies that have been used to assess surveillance data quality include capture-recapture (80, 81), reviewing facility registers for “missed cases,” and comparing aggregate reporting from health facilities with case-based reporting systems (14, 82). Box 2.11 describes a recent example of validating the quality of reported surveillance data in Uganda.

Similarly, disease surveillance performance indicators have been used routinely to monitor polio incidence since the 1980s and measles since the 1990s. Indicators specific to each VPD were included in the 2018 revision of the *WHO Surveillance Standards for VPDs*, but generally include completeness and timeliness of reporting, sensitivity (a surveillance-specific proxy measure for accuracy), representativeness (geographic completeness) of case detection, and adequacy of case investigation and laboratory confirmation to inform decision-making (14). These indicators have served as the basis for a strong monitoring and accountability framework for the global elimination and eradication programs (70, 83, 84).

Box 2.11. High tetanus burden or surveillance reporting error?

Globally, reporting of non-neonatal tetanus (non-NT) to the through [the Joint Reporting Form \(JRF\)](#) has generally been weak (74). In 2011, Uganda established a District Health Information System version 2 (DHIS2) platform that includes weekly reports of neonatal tetanus (NT) and other notifiable diseases sent by short message service (SMS) and monthly reports of both NT and non-NT (aged >28 days). In Uganda, infants and reproductive-age women are given tetanus toxoid-containing vaccines (TTCV), but the schedule does not include the three WHO-recommended TTCV booster doses (85). In 2013–2015, a small cluster of non-NT cases, associated with male circumcision for HIV prevention, helped highlight that Uganda had one of the world’s highest reported incidences rates of non-NT (74), which has a case-fatality rate (CFR) approaching 100% without medical intervention.

To evaluate whether reported data reflected Uganda’s true tetanus disease burden, the Ministry of Health in 2017, in collaboration with the Field Epidemiology Training Program, U.S. CDC and WHO, conducted a medical records review of 26 facilities across the country’s four regions. The investigation confirmed that the non-NT burden was high, but likely over-reported. The vast majority of cases were identified from inpatient registers of referral hospitals; 81% were among males and the reported CFR was 54%. Data entry errors of conditions adjacent to “tetanus” on the reporting form were observed in multiple cases. In addition, more than 4,000 tetanus *vaccine doses* were recorded as tetanus *cases* at a single health center in Kampala (an error that was corrected in the DHIS2 database) (86). The results of this investigation were used in developing the first global standards for non-NT surveillance (14).

Indicators of immunization and surveillance data quality

A systematic review of data quality assessment methods for public health information systems found that completeness, timeliness and accuracy were the most commonly used attributes of data quality, among a total of 49 attributes (87). Another review specific to immunization data quality noted that a wide variety of data quality attributes and indicators had been used and attempted to systematize a limited defined set of attributes that were operationally relevant for monitoring (17) (Box 2.2). Similarly, the review completed for the WG identified many versions of data quality measures for immunization coverage, denominators, and surveillance related to the same attributes, but was not exhaustive (Annex 9).

Though many measures exist, it could also be said that the same analysis approaches and indicators to assess immunization and surveillance data quality have more or less been in use since the beginning of this discussion with the SAGE in 1998 (see 1.1 Background). Moreover, use of a handful of key indicators has generally coalesced as various guidance has evolved, and publications have been informed by the guidance. Efforts by the GVAP WG to develop data quality indicators for immunization coverage presented to the SAGE in October 2015 largely focused on a composite indicator that included the following: (i) completeness of reporting, (ii) internal consistency of the administrative coverage numerator, (iii) internal consistency of the administrative coverage denominator, and (iv) external consistency of administrative coverage with other data sources. The composite indicator was rejected because of issues of interpretability for monitoring. In the absence of global indicators, Gavi established their own holistic monitoring framework for implementation of their data strategy that includes indicators for data availability, quality and use in Gavi-supported countries (Box 2.12).

Box 2.12. Gavi, the Vaccine Alliance efforts to improve data quality and use

Beginning in 2014, funding proposals submitted to Gavi required countries to address data quality in four ways:

1. conduct an annual desk review;
2. conduct periodic (i.e., at least once every five years) in-depth system performance assessment that includes a desk and field review;
3. conduct a national vaccination coverage survey at least once every five years; and
4. develop a data improvement plan.

In 2016, the Gavi Secretariat launched a new strategy for 2016–2020 with ambitious goals and targets. To monitor progress against these goals, Gavi relies on a set of performance indicators to track the number and percentage of Gavi-eligible countries that:

- have conducted a nationally representative household survey within the prior five years;
- have less than a 10%-point difference between reported national administrative vaccination coverage for DTP3 and the estimated vaccination coverage from the most recent nationally representative household survey;
- have available subnational vaccination coverage data;
- report national administrative DTP3 coverage of >100%;
- have $\geq 10\%$ of their districts reporting administrative DTP3 coverage of >100%;
- have <10% discrepancy between country-reported target population estimates and those from the UN Population Division; and
- demonstrate the use of data to guide the targeting and tailoring of their activities.

Gavi's efforts to emphasize data availability, quality and data use as critical components of national immunization programme monitoring and evaluation is promising. Further work is needed to evaluate the quality of country efforts and the actual impact of the new focus on data availability, quality, and use in Gavi funding proposals.

While the focus has been on measuring data quality, measures of data *use* are generally lacking. This is despite the strong global interest in creating a “culture of data use” centered around continuous improvement. Gavi has included a data use measure among their monitoring indicators (Box 2.12). The use of VPD surveillance data often includes follow-up case investigation and public health response activities (14). NITAGs may use immunization and surveillance data to develop evidence-based policy recommendations (Box 3.2). There is some evidence from the literature that the data quality improves as data use increases (88). Increased immunization programme performance has also been noted to coincide with increased data quality and use (5, 83, 84, 89). While these relationships have been demonstrated in the field of healthcare quality improvement, further work to examine the relationship between data quality, data use, and immunization programme improvement would be useful. However, developing a common lexicon of definitions, attributes and indicators of data quality is needed first.

The WG proposes that a panel of indicators (with 1–2 “key indicators”) relating to key data quality and use attributes, similar to what exists for surveillance performance monitoring, be developed for use in routine monitoring of immunization data quality alongside coverage and equity monitoring. The WG's perspective is that composite indicators are of limited value because of they can obscure issues with the individual components of the composite indicator. The indicators identified in Annex 9 can be used as a starting point to creating such a panel, recognizing that the indicators identified do not cover all attributes of data quality (e.g., relevancy,⁴ which is rarely, if ever, evaluated using measures).

⁴ Degree to which the data collected and reported reflect what is most important to support decision-making and not in excess of what is needed so as to consume scarce resources.

2.3.3 Recent examples of regional and national efforts to improve data quality

Improvements in the area of data quality and use have recently been highlighted by the SAGE, the GVAP SAGE Working Group, Gavi and the WHO regions. In the 2016 GVAP progress report, the collection of district-level coverage data for the WHO-UNICEF JRF was highlighted, as were two countries (Mexico and Uganda) that took decisive steps to improve data quality (5). Box 2.13 highlights different initiatives to improve data quality and use across the regions. Boxes 2.14 and 2.15 highlight efforts to improve vaccination coverage in China and India, respectively. Other country case studies are included in the Annexes.

Box 2.13. Recent WHO Regional efforts to improve immunization data quality and use

African: Support of immunization monitoring within District Health Information System 2 (DHIS2), a tool widely used in the Region, including piloting of a Data Quality module

Americas: Work on Electronic Immunization Registries (EIR), particularly the [Regional guide](#) and the [Data Quality Self-assessment \(DQS\)-Plus](#) assessment tool including EIRs

Eastern Mediterranean: Quarterly feedback to countries with an analysis of subnational level immunization data, which countries have appreciated

European: Prioritization of immunization data use for action exemplified through formation of a new “Immunization and Surveillance Data Team” in the Regional Office

South-east Asian: Push to develop comprehensive [VPD surveillance standards](#) in 2017, ahead of the global guidance

Western Pacific: Support of web-based information systems for surveillance that allow direct integration of epidemiological and laboratory data (e.g., measles and rubella)

Box 2.14. Efforts to improve vaccination data quality in China

In China, the country programme recognized that despite high coverage, poor data quality was preventing identification of measles immunity gaps, resulting in barriers to achieving measles elimination. After soliciting and undergoing a consultative assessment process with support from WHO and the US CDC in 2017, China is starting to implement the recommendations, including improving coverage monitoring methods, including disaggregating by residential status, triangulating surveillance data to identify immunity gaps, assessing the utility of different target population ascertainment methods, and planning to conduct coverage surveys (Annex 10).

Box 2.15. Improving state and national official coverage estimates in India

In 2014, the Government of India and its partners conducted a data review process similar to that used by WHO and UNICEF at the global level (see Box 2.3). Vaccination coverage data from 1) administrative reports, 2) coverage surveys and 3) rapid monitoring were used to estimate state coverage (39). In more than half of estimates, the official coverage was based on a survey estimated coverage value or an interpolation from a survey estimated coverage value. Only about 10% of estimates were based solely on administrative coverage. While estimates of coverage are subject to limitations of the underlying data, the resultant state and national level official vaccination coverage estimates produced through the process were felt to be improved over previous official coverage estimates based only on administrative coverage. Reports suggest that the Government of India has repeated the data review and estimate production exercise at least once since the original exercise (Annex 11). Similar triangulation exercises were done, with WHO and UNICEF support, in Indonesia (2017), Ethiopia (2017) and Pakistan (2018).

Box 2.16. Immunization data quality improvement activities in Nigeria

The Nigeria EPI programme faces several challenges, including insufficient health workforce, insufficient cold chain capacity, weak supply chain, issues with demand for immunization (lack of awareness, distrust, and social-culture norms), and poor routine immunization (RI) data quality. For example, administrative coverage rates calculated using denominators based on census projections routinely exceed 100%. Historically, large discrepancies have existed in the coverage estimates from DHS or MICS and EPI surveys. The Nigeria EPI programme has recently undertaken many efforts to improve data quality, including:

- Pilots to improve denominators through triangulating different potential data sources: a) satellite imagery/geographic information system information, b) house-to-house enumeration of children younger than 15 years, and c) micro-census enumerations.
- The government collaborated with MICS on a national immunization coverage survey (MICS/NICS) in 2016 and has preferentially used these results compared to questionable administrative coverage data.
- The web-based software District Health Information System, version 2 (DHIS2) was adopted in 2013 as the Health Management Information System (NHIMS). An RI Module was launched in 2014, and is currently present in all 36 states of Nigeria with more than 67,000 health care professionals, local government area (LGA) officers and state officials trained, and 774 laptops provided. This Module serves as the only platform for reporting RI data in the country from December 2018.
- A DHIS2 RI dashboard was developed to support improved accountability and use of data for action down to the health facility levels. The dashboard includes indicators for: data reporting, coverage and drop-out rates, RI vaccination sessions, supportive supervision visits, vaccine management and logistics, cold chain functionality, and RI funding disbursed to HFs.
- Workforce capacity support for data improvement occurs through the on-the-job mentoring and supportive supervision of a network of 266 Nigeria Stop Transmission of Polio (NSTOP) officers assigned to high-risk states and LGAs ([Annex 12](#)).

3. Governance: Leadership, Policies, and Standards to Maximize the Data Quality and Use

Key messages

- The generation and use of data, including immunization and VPD surveillance data, needs to be an integral part of a country-owned health system, rather than a separate, often donor-financed project (especially in LICs). Strong leadership and political will on the part of national governments are critical to developing efficient and effective information systems.
- Generating data that is of high-quality requires developing and implementing national policies and standards that govern all stages of data generation and use (from selection of variables to methods of data collection, analysis, reporting, storage/archiving and sharing).
- Often the costs and amount of personnel time required for data collection, management and reporting activities are overlooked or under-estimated. Adequate resourcing of data-related activities is critical for obtaining quality data that are relevant for use.
- Articulating clear roles, responsibilities, deliverable at all levels, along with frameworks for monitoring serves as the basis for monitoring and accountability towards programme improvement.
- Good coordination and collaboration across areas and organizations is necessary to avoid the common problems of fragmented information systems (e.g., disease-specific) and inefficiencies related to lack of data sharing or non-interoperable systems.
- Governments need to have plans, policies (including legal frameworks) and mechanisms in place for the sharing of immunization and VPD data — both within countries and across borders — to enable decision-making and effective public health responses.

3.1 The importance of governance in maximizing data quality and use

Developing strong information systems for immunization and VPD surveillance data involves a wide range of activities and functions by government decision-makers, programme managers and other key stakeholders. Policies, processes, and organizational structures must be put in place to provide EPI managers and frontline workers with the authority and skills necessary to collect high quality data and make use of data for action (75, 90). Standards and operating procedures for data and information systems must be developed; sufficient resources allocated for data collection and analysis, as well as for data quality improvements; and transparent and effective accountability mechanisms established for the collection, use and distribution of data (91-93). Good governance related to immunization and surveillance data also requires that governments, international organizations and partners share a common vision, set of strategies, and framework for monitoring and evaluation, as well as collaborate and coordinate on activities to improve data and use (94). Regulations and agreements governing the sharing of data that also take privacy and security concerns into account are also critical.

Different sources of information were reviewed to develop this chapter, including literature reviews; frameworks, approaches and tools on governance and; and global, regional and country experiences and lessons learned gleaned from expert interviews and the published and grey literature. Below is a summary of the findings for different critical elements that are required for good governance of immunization and surveillance data.

3.2 Leadership, ownership, political will

Strengthening immunization data quality and use is a long-term process requiring evidence-based decisions that must be owned by countries down to frontline where data is collected. To be successful, immunization monitoring and VPD surveillance systems must have political support; clearly defined objectives and scope; infrastructure; sustained human, technological and financial resources; and a transparent and closely monitored plan, with timelines and responsibilities (60, 95). The process must be resilient to changes of administration, so that new authorities remain committed to the data systems and plans for improvement in place. Systematic progress reports of data improvements should be provided to track progress against the plan of activities and budget and to make adjustments, as needed.

An information system for immunization must meet the needs of decision-makers, while at the same time, be useful and accepted by health workers at all levels, and particularly at the local level, it should facilitate their work, not slow them down. The systems should also allow for effective feedback mechanisms, so that health workers at the lowest level feel empowered to use the data to improve programme performance and to contribute to strengthening the system at their level (8).

Effective leadership and organizational culture have been cited as factors influencing the successful implementation of functional health information systems (96-103). Lorenzi et al., (98) argue that people and organizational factors have been overlooked in the implementation of health information systems, and maintain that these factors determine the success or failure of these systems, especially a sense of ownership and the qualities of the leadership. They highlight three domains that should be further researched in terms of their impact on information systems: *motivation, culture and leadership*.

The lack of political commitment to improve the use and quality of data has been reported as a reason for the failure of immunization information systems in many settings, as a result of a lack of policies, regulations and prioritization, such as a dedicated budget for surveillance or allocation of funds for implementation (104) (Annex 7) (69). Mexico's experience with its PROVAC electronic immunization registry is an example of the challenges of governance and sustainability of the immunization information systems, as well as the demonstrated political will of the government in making necessary improvements that resulted in reductions in reported coverage rates (Box 3.1) (105).

Box 3.1 Lessons learned from the immunization information system in Mexico (PROVAC)

Mexico's PROVAC was one of the world's first Electronic Immunization Registries (EIR), used between 1991 and 2013. PROVAC allowed recording of the immunization status for children and pregnant women and the calculation of coverage rates. Use of an open-source and open-access programme allowed the generation of multiple versions of the same program, which led to the system becoming fragmented and obsolete over time (105). This was likely also related to the original PROVAC not being flexible enough to adapt to the rapidly changing immunization schedule, insufficient resources devoted to the maintenance of the system, and inadequate monitoring of the data being produced. Reported coverage levels were high, but numerator data could not be confirmed, and denominators used for immunization monitoring had not been validated against data from the National Statistics Office.

In 2013–2014, Mexico acknowledged the poor quality of its vaccination data, stopped using PROVAC, and developed a plan to create an improved EIR. This involved modernizing the information system, revising local and regional population estimates, and returning to use of the administrative method to calculate coverage. These efforts to improve the accuracy of coverage data resulted in a decline in reported vaccination coverage levels (e.g., from 99% to 83% for DPT3) and were consequently recognized globally as an example of transparency and accountability.

Currently, Mexico has made significant progress with its new EIR and in implementing "[la cartilla electrónica de vacunación](#)", a vaccination home-based record. The record includes a chip that saves the user's vaccination history electronically, along with the traditionally hand-written data. The transition has been difficult due to challenges in coordinating public and private immunization service providers and multiple health insurance mechanisms, but the country is committed to moving towards an improved EIR.

3.3 Coordination and collaboration

In today's public health system, immunization data are produced and used by many different institutions, including ministries of health, national statistics offices, the private sector, NGOs, CSOs, donors and stakeholders. Thus, in many places, health information systems have evolved in a haphazard and fragmented way as a result of administrative, economic, legal or donor pressures. Coordination between different health facilities and across health programmes are necessary for there to be complete, accurate and timely information to support decision-making. For example, the lack of coordination, data harmonization and communication between different units involved in VPD surveillance can result in a lack of agreement between epidemiologic and laboratory databases or between aggregate and case-based surveillance databases, thus negatively impacting data quality (106). Lack of engagement of private providers to report immunization and surveillance data can result in data that is incomplete and not representative of the country (Annex 7); this has already been highlighted by SAGE (69, 107).

To strengthen health systems, including immunization and surveillance information systems, partners and related initiatives must coordinate their technical assistance with the government and each other. This is especially true in low and middle-income countries with weaker health systems, where multiple partners provide technical, operational and financial support for health systems strengthening (108). The [Health Data Collaborative](#) (HDC) is an example of collaboration among multiple global health partners — international agencies, governments, philanthropies, donors and academics — working together to empower countries to strengthen the availability, quality and use of health data for local decision-making. The HDC is not a fund, but rather a partnership that aligns countries, donors and other partners to make investments in the most efficient and effective way (109).

It is also critical that national organizations be identified to support the immunization program, such as universities and schools of public health, professional associations and group of experts. Experience with national immunization technical advisory groups (NITAG) demonstrates how the participation of group of national experts from a range of disciplines and organizations can improve the process of synthesizing evidence and making decisions (Box 3.2).

Box 3.2. Coordinating bodies for data use and decision-making on the national and regional levels

[National Immunization Technical Advisory Groups \(NITAGs\)](#) are multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to decision-makers and programme managers on policy issues related to immunization and vaccines. The Global Vaccine Action Plan calls for all country to establish or have access to a NITAG by 2020. Regional Immunization Technical Advisory Groups also provide advice on regional policies and strategies, ranging from vaccine research and development, to immunization service delivery and disease surveillance, and linkages with other health interventions (110).

The Global Certification Commission (GCC), Regional Certification Commissions (RCCs), and National Certification Committees (NCCs) provide a framework to assist the Global Polio Eradication Initiative (GPEI) in independently certifying and maintaining polio eradication in a standardized, ongoing, and credible manner. Members meet regularly to comprehensively review population immunity, surveillance, laboratory, and other data to assess polio status in the country (NCC), region (RCC), or globally (GCC) (111).

Similarly, for measles and rubella, National Verification Committees (NVCs) at the country level gather, analyze, and validate national data, and submit the necessary documentation to the Regional Verification Commission (RVC). RVCs are comprised of independent experts tasked with reviewing annual progress toward measles and rubella elimination for each country or area in the region (111).

Malawi's experience with the Malawi Health Data Collaborative (MHDC) demonstrates how a collaborative approach between development partners and the government can successfully align country needs and partner support. The Collaborative was launched in 2015 to improve real-time data and align reporting requirements, including harmonizing health indicators. When this experience started, health facilities were reporting on hundreds of different indicators and using 16 related electronic systems — only two of which routinely exchanged information — resulting in a fragmented information system. The reporting rate for most programmes was below 80% and the timeliness of

reporting was below 65%. A country plan was developed to align government and partner investments in health information systems, using the District Health Information System (DHIS 2) as the common reporting platform. However, despite the successes of the MHDC approach, fragmentation of the system still exists, often caused by development partners introducing systems that are duplicative or are siloed by programmatic area or geographic location. High-level leadership within the Ministry will be critical to ensure harmonization and streamlining of health data and reporting systems from all partners (112) (*See also Tools Chapter*).

3.4 The role of data in ensuring accountability of immunization programmes

Good governance requires evidence-based policies that inform decision-making on issues related to public health by upholding the key governance principles of fairness, accountability, transparency and participation (113). As funding for global health has grown during the past years, it has become increasingly clear that data quality and use is key to monitor progress and allocate the resources needed to achieve the expected results (114).

The use of results-based financing mechanisms by major global donors has created further demand for timely and reliable data for decision-making (56). This is particularly relevant in the low-income countries facing the biggest challenges with data quality, particularly coverage data. In the era of global initiatives and funding opportunities that are target- and performance-based, there are concerns about the possibilities for perverse effects encouraging over-reporting, for instance, of vaccination coverage data. Furthermore, SAGE, in 2011, noting the issues related to the accuracy of coverage figures, cautioned against their use for performance-based financing (4). This approach can create a strong argument for not focusing entirely on achieving absolute targets as funding criteria but also on improvement, in terms of both programme performance and the quality of the data.

In order to hold immunization and disease surveillance programmes accountable, the roles and responsibilities of health workers at all levels of the system concerning the collection, analysis, review and use of immunization and surveillance data should be clearly defined in their terms of reference. The WG has developed a basic framework defining roles and responsibilities for data quality and use from the local (facility) level all the way to the national, regional and global level (Figure 4.1 in *Workforce chapter*). Articulating clear expectations for job duties and deliverables can serve as a basis for monitoring and accountability. The introduction of an accountability framework in the polio eradication programme in Nigeria and Ethiopia resulted in improved staff performance and overall indicators for AFP surveillance (83, 84). Lessons learned from these experiences have the potential to benefit other disease programs and potentially immunization monitoring in general.

3.5 Resource allocation for generating and improving immunization and surveillance data

It is critical that accurate estimates be made of the resources needed for implementing activities related to immunization and VPD surveillance data and funding any gaps identified in order to ensure sufficient financing for these activities. Adequate resources are needed to cover the costs of personnel dealing with data collection, analysis and reporting at all levels; electronic information systems (e.g., computers, servers) and their maintenance; data review meetings; and communications. High-quality VPD surveillance systems require sufficient investments in personnel, laboratories (including equipment, reagents, test kits and other supplies), and logistics and communications for field investigations, as well as sample transport (115). A lack of funds for these critical resources can result in data that is of poor quality and limited use (104), as found in a systematic review of the implementation of the Integrated Disease Surveillance and Response (IDSR) (67). The comprehensive multi-year plans (cMYP) that countries prepare for their immunization programmes can be used to advocate for funding these critical operational costs (116).

The costs of personnel involved in data activities — in terms of the number of staff needed to adequately manage information systems and the amount of time health workers spend on data collection and reporting — can especially be overlooked or under-estimated, particularly as information systems are expanded and improved. A five-country study by WHO showed that health workers in LMIC setting spend a third of their time on data recording and monthly reporting processes at the primary care level (A. Siyam, WHO, personal communication); similar findings have been confirmed in other studies

(117). As countries expand and upgrade their information systems (e.g., as a result of new vaccine introduction), the impact of these changes on the number of staff required and their workload needs to be considered in human resource planning. England has recognized this problem and now requires that the additional work-burden on staff and related costs be assessed before any changes in immunization data collection requirements be implemented (Box 3.3).

Box 3.3. Assessing the data-related burden on the workforce in England

In England, *NHS Digital* is the government organization that, among other responsibilities, provides the National Health System (NHS) with information, data and IT systems. Part of its mandate is to offer data standards assurance services (DSAS) that ensure that any new data collection or changes to existing data collection comply with data standards and have a legal basis, and that the benefits of the changes outweigh any additional burden on the system. To ensure that is the case, when changes to immunization data requirements occur – with recent examples including the introduction of new vaccines and the move to collect facility-level rather than district-level data – the immunization team at the national level must re-assess the implications of these changes on the health workforce. This assessment includes estimating the staff time required at both at the local level where data collection and reporting occurs, and at the central level, where data management, analysis and dissemination takes place, as well as associated costs. The DSAS then examines the request and the resulting analysis and determines whether the additional burden on staff resulting from the new requirements is acceptable in relation to their benefits.

3.6 Establishing standards for data collection, analysis, management, use and storage/archiving

Functional and efficient data systems that are useful for programme monitoring and decision-making require the development of standards for all aspects of data management, including standards (e.g., what variables to include and how to name them), and detailed procedures for collecting, processing, preserving, using/reusing, sharing, and disposing of data (118). Such management strategies and standards must address not only immunization and VPD data collected in the public sector but in all sectors, i.e., the private sector, NGOs, etc. Standards must not only exist, but also must be used (e.g., through sufficient training and incentives for health workers).

These standards are especially critical when immunization information systems are being integrated into, or need to interoperate with, broader health management information system, which GVAP recognizes as important to increase the efficiency and effectiveness of data systems (e.g., to avoid errors by having to enter the same data in different systems and reducing the burden on health workers). This integration can be accomplished by developing an integrated electronic health management information system (HMIS) that includes the required elements for monitoring immunization data, or alternatively, through electronic data exchange protocols between different systems following interoperability standards. There are several documents available, such as the WHO Health Metrics Network Framework, that outline global standards for health statistics and indicate how they can be integrated into country health information systems (119). Standards for electronic information system allow for the accurate and consistent exchange of data across various health programmes and departments and different geographical areas. Failure to adopt electronic information standards could result in collecting data that is not fit-for-purpose or challenges to share data across different information systems and/or different levels. An experience with electronic system standardization at the regional level is described in Box 3.4 (*See also Tools Chapter 5*).

Box 3.4. The European Surveillance System (TESSy)

The European Centre for Disease Prevention and Control (ECDC) collects, analyses and disseminates surveillance data for 52 diseases from 31 countries. In 1998, the European Commission formalized disease surveillance networks previously funded as pilot projects. As a result, these informal networks grew and were standardized, and specific reporting meta-datasets were adopted and eventually incorporated into a single system — [The European Surveillance System \(TESSy\)](#). Access to TESSy data are restricted by EU data protection laws. However, member states have interpreted EU legislation on processing personal data in different ways, resulting in countries transferring different types of data to ECDC. This has made the standardization of surveillance data collection difficult. The solution has been to allow ‘mandatory’ and ‘voluntary’ variables to be reported, as well as the reporting of aggregate data in some instances.

Since the system was built gradually and upon existing networks, flexibility when harmonizing different pieces of national legislation has been essential, even at the expense of the ability to standardize. Even though it was not possible to involve all countries at the onset, the EU legal framework is capable of change as new needs and technologies arise, and agreements can be updated to reflect such developments (120).

Numerous assessments in many countries, however, have reported a lack of standards, guidelines and other tools for immunization and VPD surveillance data systems. Murray et al. reported that data collection tools for immunization coverage were not standardized, limiting comparisons within and across countries, and making assessments of trends in coverage challenging (38). Other studies report a lack of VPD surveillance standards, including for case definitions, methods for case detection, active case searches, case investigation, and response ([Annex 5 and 7](#)) (37, 69). As described in Chapter 2 (Section 2.3.1), WHO has made a major effort in the past few years to fill in existing gaps in needed guidance materials by publishing a series of global guidance and standards, as well as regional tools, such as the Integrated Disease Surveillance and Response (IDSR) guidelines for Africa.

Another issue is that standards may need to be assessed and modified as the epidemiologic situation and disease control goals and targets change. A salient example is how polio surveillance standards had to be adapted once regions were certified as having been polio-free. This is because post-certification surveillance requires very sensitive surveillance systems to detect the presence of poliovirus of any kind, such as wild poliovirus, Sabin, or vaccine-derived (VDPV); on the latter, further differentiation is needed as to identify whether the VDPV is circulating or Immunodeficiency-related or ambiguous ([Annex 13](#)) (121).

Archiving historical immunization data and ensuring these data are incorporated into new information systems is essential to monitor epidemiological trends of VPDs, since current population immunity is largely the result of vaccine coverage in birth cohorts vaccinated in the past. Nevertheless, data archiving is often an overlooked aspect of data management in electronic immunization registries (EIRs), even in high-income countries (122). In the United Kingdom (UK), for instance, immunization registers discard records once an individual reaches the age of 18. Some countries have recognized this as an important problem; Australia, for example, has recently moved to life-long immunization records (123).

Data security is also becoming an emerging issue, as EIRs which contain individual patient records, are increasingly introduced. Planning for data security requires a professional ethics officer who is responsible for protecting identifiable data, which are often collected without individual consent. Preserving confidentiality of individual-level data is critical because societies can sometimes respond to persons with infectious diseases in stigmatizing and discriminatory ways (124). Similar principles need to be followed when private sector data is shared within the country.

3.7 Data sharing policies and agreements

Sharing routine public health surveillance data enables regional collaboration, capacity strengthening, insight into public health system performance and ultimately better control of infectious diseases (125). This is true between levels of the health system within individual countries, between countries at the regional level, as well as at the global level. Nonetheless, despite examples of success, sharing public

health surveillance data beyond national borders is still not the norm. A systematic review by van Panhuis et al (2014) identified five types of barriers to local, national and international health information systems sharing surveillance data (106):

- **Technical barriers**, including a lack of or inadequate data collection and preservation, restrictive data formats, lack of meta-analysis and standards, and language barriers (106, 126);
- **Motivational barriers**, including institutional or personal factors that limit data sharing, such as the presence or lack of incentives, lack of trust between data providers and users, and a lack of resources and time needed to share data;
- **Economic barriers**, which include the potential negative economic effects of reporting disease outbreaks.
- **Political barriers**, such as a concern for potential negative consequences of high reported disease incidence or outbreaks, bureaucratic hurdles, a lack of political will to promote a culture of data sharing, and a lack of trust (104, 127); and
- **Legal and ethical barriers**, including various legal instruments that restrict data sharing, such as data ownership and copyright laws, often resulting from mandates to protect individual and community privacy (126, 128).

An expert consultation tasked with finding solutions to overcome these barriers to sharing public health surveillance data defined seven key principle to achieve this: 1) building trust, 2) articulating the value of sharing data, 3) planning for data sharing, 4) achieving quality data, 5) understanding the legal context, 6) creating data-sharing agreements, and 7) monitoring and evaluation. To be successful, data sharing agreements do not always need to be formalized. In fact, evidence suggests that such agreements are unnecessary if informal arrangements can accomplish the goal of sharing as long as the rights, interests, needs and expectations of stakeholders are taken into account (124).

The legal implications of sharing routine surveillance and immunization data vary based on geographic level, the type of institutions involved (e.g., private vs public), the type of data, the level of public health threat, and other contextual factors. Legal restrictions with sharing data across borders mainly relate to disaggregated data containing confidential or personal information. Aggregated VPD surveillance or vaccine coverage data shared with WHO through the JRF, for example, are not subject to complex legal regulations. Legal instruments exist where there are urgent public health imperatives to sharing information, both at the regional level (129) and globally through the International Health Regulations (130). Legal barriers to data sharing are uncommon, but may be cited when the obstacles are more political or motivational in nature (120). Data-sharing agreements can help resolve differences or ambiguities in law and are most successful when the context is defined as precisely as possible, supported by local knowledge, and when relevant laws and regulations are taken into account. In some instances, an agreement that is not legally binding may be more suitable than using legal means.

3.8 Conclusions

A number of policies, processes, standards and mechanisms need to be established to improve the access to quality and useful of immunization and surveillance data. The quality and use of these data will only improve if countries and all immunization stakeholders agree to a common vision and set of strategies, and collaborate more closely on activities to improve immunization-related data. Partners should collaborate on the assessment, planning and implementation of plans to strengthen data quality and use, and align their support, investments and activities to national plans and strategies to avoid parallel or fragmented information systems and data collection efforts. Communication and information sharing between different health facilities and across different programs and partners are crucial for the availability of complete, accurate and timely information to support decision-making. Achieving these goals requires the development and implementation of data standards and clear processes – for all steps involved in data generation, from data collection to analysis, reporting and use. At a national level, policymakers must address the fragmentation of health information systems, and encourage data sharing between the public and private sector, NGOs and anyone providing vaccines, or who potentially can identify a VPD case. Legislation, policies, and accreditation/certification protocols should guarantee data security in order to prevent loss of data and protect confidentiality protection, but data sharing agreements are also needed to support effective public health decisions and responses.

4. People: Building Workforce Capacity in the Generation and Use of Immunization Data

Key messages

- Health workers often lack the necessary skills, competencies, and time, to perform immunization data-related tasks adequately.
- Addressing the issues around inadequate skills in quality data collection and use requires a systematic approach and a dedicated effort by governments to provide continuous and effective competency-based training.
- Continuous training involves the inclusion of data-related competencies in pre-service training for health professionals, as well as on-going in-service training, supportive supervision and feedback to health workers — all placing a focus on data quality and use.
- There is evidence that current pre-service training does not adequately prepare health workers with the necessary skills and competencies to collect, analyse and use data, in part due to the lack of skills in this area among most instructors at professional training institutes.
- Studies show that, despite the necessity of in-service training in data-related skills, most in-service training has not made substantial differences in improving the skills and practices of health workers in the generation, management and use of data.
- Systematic reviews show that multi-faceted approaches to capacity building, e.g., mentorship, feedback, group-problem solving, are more effective than single strategies
- Supervisors should make review, assessment and feedback regarding data a critical part of their supervisory visits and be capable and trained to do so.
- Good leadership and an adequate culture of data demand and use are also vital for people to engage in improving data quality and use.

4.1 The importance of the health workforce in ensuring data quality and use

Equipping health workers at the local level with the necessary data skills is especially critical, since there is no data quality without high quality data at the local level. Capacity-building of health workers in data collection, management, and analysis has been shown to be key to improving the quality and use of immunization and VPD data. The scoping review of the barriers limiting the quality of immunization data in LMICs highlighted the lack of capacity-building of health workers in data management and use as a key factor limiting data quality (Annex 14). Further, issues with workforce capacity were identified more frequently than all other issues, in just over 80% of the references included in the review of barriers limiting VPD surveillance data quality (Annex 7) (69). Therefore, in order to sustain investments in improving data quality in most LMICs, it is essential to increase health workers' competencies and motivation in collecting, analysing, reporting and using data.

Besides the lack of data-related competencies, another key issue affecting data quality and timeliness is that front-line healthcare workers who are responsible for completing data registers and immunization monitoring charts and for compiling monthly statistics and other data-related tasks have multiple responsibilities – with clinical care being the priority. This can result in their not completing routine data collection until many days after an event (e.g., an immunization session), if at all (131-133) and in otherwise limiting the time available for and allocated to data collection, analysis and reporting, impacting data quality (134, 135).

The focus on technology – rather than on the people who drive information systems – has often led to the development and implementation of complex health management information systems, or new electronic tools. However, these still require human resources and capability. Persistent challenges

identified with these systems include inadequate human resources, insufficient capacity of Health Information System (HIS) staff at all levels, high staff attrition rates, inadequate training, unstandardized job descriptions, limited HIS development planning and the lack of an established health information career path and accredited training programmes (136).

Interventions to address skill shortages, such as in-service mentoring and training tailored to meet the needs of information personnel, and adequate supervision for data-related tasks, are needed. If adequate resources are not channelled into developing a cadre of qualified and skilled health information personnel, these skill shortages will continue, and issues around poor data quality will continue to be a recurring problem. Continuous capacity-building in immunization data-related tasks, such as data collection, analysis, interpretation, synthesis and use, and efforts to improve data quality should be strengthened at all levels of the health system, ideally with the guidance of frameworks, such as the minimum health information competencies framework (137).

Below we highlight key elements required in the preparation and utilization of health workers in order to generate and use high-quality immunization and VPD surveillance data.

4.2 Defining and assessing competencies in data collection, analysis and use

Issues around the competencies of health workers related to immunization data management tasks have been widely documented. Competency can be defined as a combination of knowledge, skills and abilities needed to perform a specific task in a given context (117). Competencies can be gained through experience, pre- and in-service training, and the assistance of mentors and preceptors (138). As part of the *Standard Immunization Competencies* project, WHO has developed an immunization competency framework that defines the roles and responsibilities of health workers at all levels, including monitoring and evaluation (75, 139). This framework can be used to assist immunization programmes to develop or revise policies related to their workforce, including hiring, staff development, and human-resource planning. In April 2017, SAGE emphasized the “importance of looking at functions and competencies from a health-system perspective so that all the immunization functions are adequately addressed...” and suggested “creating tools to assist countries in different aspects of immunization human resources management including: staff turnover and rotation policies, performance evaluations, and design of training (140).”

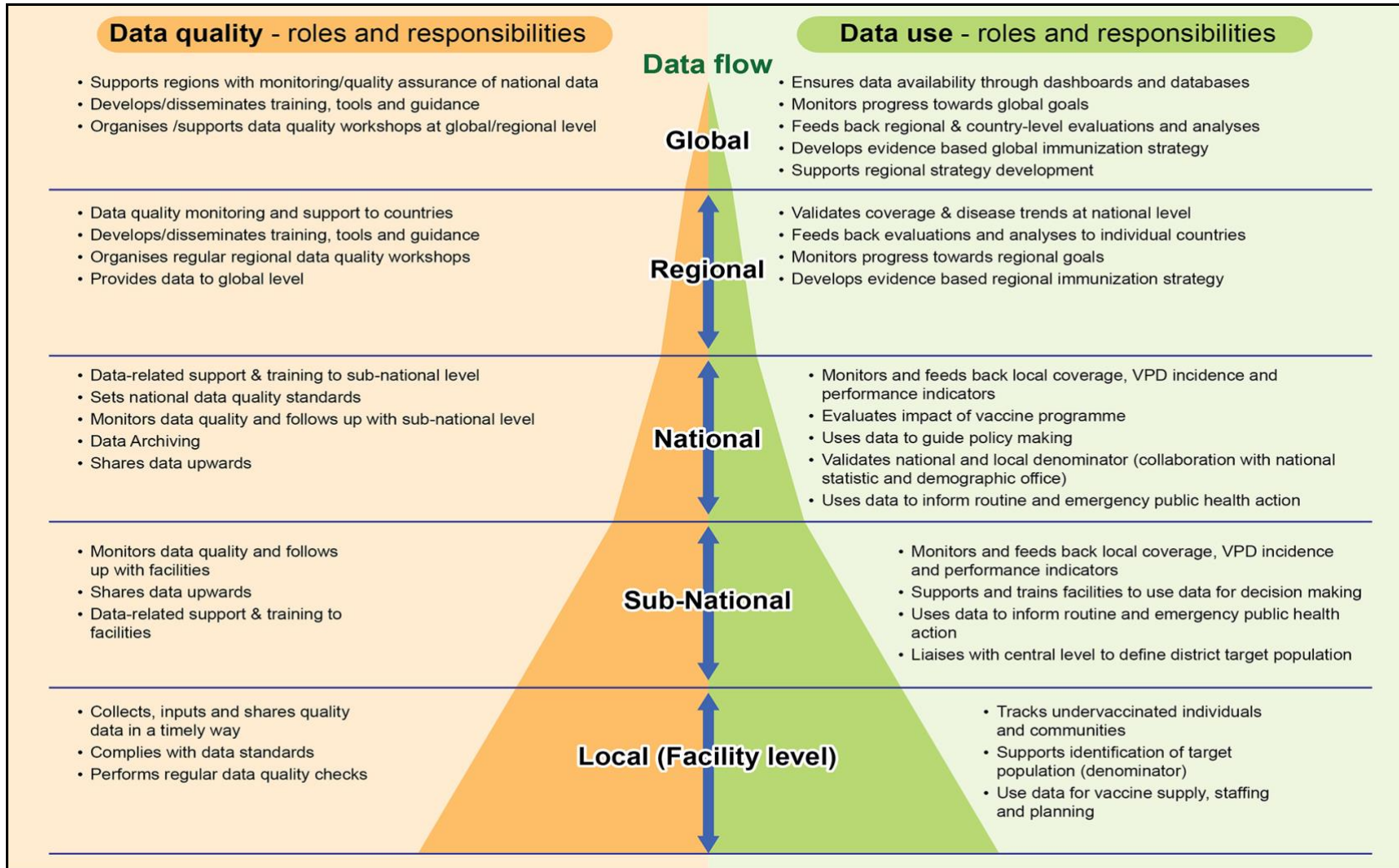
The WG further attempted to define data quality and use roles and responsibilities for the different levels (Fig. 4.1). Interventions to address issues around data quality and insufficient skills sets, including plans to hire new staff, should be focused on elements of these competency frameworks.

4.3 Pre-service training in data generation and use

Findings from the scoping review of pre- and in-service immunization data training show that both are essential for the development of health worker skills in collecting, managing, analysing and using immunization data at all levels of the health system (*Annex 15*) (141). However, the evidence also shows that current pre-service training often does not adequately prepare health workers, especially clinicians, with these necessary skills and competencies. More importantly, training institutions are not adequately equipped to provide health personnel with data-related skills, as most tutors and clinical instructors at these institutes often lack sufficient skills and knowledge in this area themselves. For example, continuous learning and development programmes are often missing to increase educators’ knowledge and improve current skills (142-144).

Inadequate capacity due to a lack of relevant training in data collection processes has been widely documented (136, 145-147). Deficiencies in numeracy skills among health workers involved with data collection at both the facility and district levels has particularly been highlighted (148-150), and is attributed partly to the lack of numeracy skills among nurses when they are in training (151-153). Studies conducted in Australia and the UK found that nurses lacked the necessary numeracy skills to solve basic mathematical problems needed to perform daily clinical functions, such as drug administration and compiling statistics from patient records, let alone the skills required to adequately manage, interpret and use EPI data. The Australian study found that mathematics is not a prerequisite for entry into the nursing degree programme, nor are nursing students trained in numeracy during their nursing training (152). These nurses required additional in-service training to be able to effectively carryout EPI data management tasks.

Figure 4.1. Framework of immunization data roles and responsibilities developed by the SAGE Data WG



There are a number of recommended curricula available world-wide for pre-service training of health professionals that include modules on the collection, analysis, management, and use of immunization data. These include the “EPI Prototype Curriculum for doctors and nursing/midwifery schools” in the WHO African Region (154, 155) and the Mid-Level Management Course for EPI managers (156), which has been recommended for use both for pre-service training and for certifying professionals for practice (157).

4.4 In-service training

In-service training is a regular process to refresh and update skills, competence and knowledge in key areas. Given that pre-service training often does not adequately prepare health professionals to collect, analyse and use data, in-service training is critical to equip them with these skills and competencies.

As part of an effort to improve data demand and use, a “logic model for strengthening the use of health data in decision making” has been proposed (158). Among the eight interventions suggested is the ability to build the capacity of both data producers and users in core competencies around the use of data, such as the ability to analyse, interpret and synthesise data, and skills to disseminate information. However, one of the reasons cited in the literature for poor data quality is the issue of staff attrition (136, 159, 160); shortages in health information staff has been identified as a major problem affecting data quality and use (161). Cristofari et al also observed the double-edged effects that in-service and on-the-job training have on the health information system. On the one hand, training ensures the capacity of frontline staff to effectively perform their tasks while, on the other hand, it increases their market value and the opportunity to opt for better paying positions, thereby causing staff attrition. These challenges could be addressed if staff are well motivated, have a defined career advancement path and are given sufficient incentives to stay on the job (161).

Most in-service training of healthcare workers on health information-related tasks has not made substantial differences in skills acquisition and practices (136, 162). It is unclear why, in spite of the resources invested in training, health workers still lack the skills to effectively perform data-related tasks. This raises the question of why additional in-service training seems unable to upgrade the competencies of health personnel. Addressing the issues around inadequate skills therefore requires a systematic approach and a dedicated effort by governments. Rohde et al. (162) advocate for a structured approach to training, which takes into account “adjustments in nursing and medical curricula at the undergraduate level,” to include core competencies for data collection and use. In addition, they advocate for a postgraduate qualification in health information systems that would include the latest information on trends in health information systems.

Factors that can improve the effectiveness of the training include the use of adult-learning techniques, such as more interactive and participatory than traditional didactic teaching, the content and structure of the training, and the environment in which it is given. As noted in Chapter 2, the WHO Immunization Monitoring Academy, a new distance learning approach to providing opportunities for public health professionals globally, might serve as a helpful model for how online learning coupled with group discussion sessions could be used to upgrade the quality of the in service training, minimize the need for taking front line staff away from their posts and galvanize their interest in learning. Issues around language of the modules and the online discussion groups are resolvable with proper planning and resources.

4.5 Supportive Supervision

An important and often neglected aspect of workforce development in the area of the EPI data management is supportive supervision, which is an approach to supervision promoting mentorship, joint problem-solving and communication between supervisors and supervisees. Supportive supervision is a vital determinant of health information system performance, given that it not only provides a platform for in-service training, but also provides key opportunities to identify bottlenecks in implementing interventions designed to improve data quality and use, such

as through data quality self-assessments (DQSs) and the development of data improvement plans (DIPs) (see *Chapter 6 on Assessment and Improvement Planning*).

Despite its importance, supervision of front-line workers at the health facility level is often inadequate, since the logistic and financial support for supervisory visits are not readily available in many settings, and even where structures exist only a handful of facilities receive good-quality supervision (145, 146). The frequency and quality of supervision can substantially affect data quality. Ferguson et al. give an example of where weaknesses in training and supervision given to clinic staff involved in implementing a maternal and child health programme at the facility level led to data inaccuracies and substantial overestimation of the programme's coverage (146). Rowe et al. (2010) identified several issues related to the incompetency of the supervisors, including inadequate managerial skills, lack of leadership and poor coordination (163). Other issues raised included an ineffective management team, a lack of motivation and an increasing supervisory workload.

When staff have adequate supervision and receive regular feedback regarding their outputs, chances are they will pay more attention to their job. Therefore, supervisors should be capable, motivated and given the necessary support to adequately carry out their supervisory activities. These activities should be structured around providing hands-on support to health workers for specific deliverables or outcomes, especially when it comes to checking for data quality, rather than just randomly checking a few folders that may not reflect the true nature of what is happening at the facility (Box 4.1).

Box 4.1 The impact of instructive monitoring fields visits on immunization data quality and use in the Kingdom of Bahrain

Bahrain's immunization programme has achieved >95% coverage for all vaccines in the childhood schedule for the past 20 years, according to WUENIC data. To help sustain this high performance, the Ministry of Health began conducting "instructive monitoring field visits" in 1996. These visits, which are conducted randomly in all health facilities — both public and private — were first focused on evaluating cold chain and vaccine management practices, but expanded to other aspects involved in immunization in 2009 (164). These include the recording and registration of vaccinations administered, coverage data (including numerators, denominators, targets), VPD reporting, data quality and accuracy, the use of data for decision-making, vaccine stock outs, adverse events following immunization, defaulters tracing, and vaccine wastage.

Feedback to health staff is given instantly, including positive reinforcement for their achievements and progress. Health workers are also given the opportunity to express their needs and to make suggestions for improvements, which are reported up the chain to the national EPI programme and to the NITAG.

These visits have reportedly improved vaccine management, reduced avoidable programmatic errors related to adverse events, and according to data quality self-assessments (DQS), improved the quality and accuracy of data. In addition, they have increased ownership, accountability, and empowerment on the part of health workers in using data for planning and decision-making. This has been achieved in the context of strong political commitments, overall health system strengthening and integration with other services for life course vaccination (164, 165).

4.6 Feedback

EPI data are often forwarded by front-line health workers to higher levels in the system without adequate or timely feedback from senior management to enable staff to identify areas requiring improvement. Timely feedback is a crucial part of the supervisory process, and is important for enhancing data quality, especially when audits using standardized feedback tools are conducted (136, 166, 167) (Box 4.1).

However, feedback is often not provided to staff at the facility level. Studies by English et al. and Muschel have attributed poor data quality and insufficient skills in analysing, interpreting and using data to a lack of feedback mechanisms between the different levels of the health system (136, 167). Mphatswe et al. also showed that a feedback training intervention could be used to improve the quality of routinely collected data in South Africa (168).

4.7 Implementing effective, multi-faceted interventions

The realist review of what works to improve immunization data use found that no single intervention is sufficient to improve data use (87). The most common and effective interventions found in the literature are those that use more than one strategy. Rowe et al, 2018 (169) report that training combined with supervision or group problem-solving proved more effective in improving health worker competence and performance than single strategies. These adult learning principles have been shown in a wide range of other health care areas to improve training outcomes. The development of national guidelines and curricula on the use of health data, and the recruitment of dedicated and skilled data managers at all levels of the health systems were identified by the Immunization data: Evidence for Action (IDEA) review as effective measures to strengthen the data-use culture in the health system. They found evidence to show that without human resource capacity, interventions such as implementing a computerized health information system is likely to be unsuccessful in improving data quality and use (88). JSI has a 5-component framework called BRICKS (Building Routine Immunization Capacity, Knowledge and Skills) for capacity-building on what's already in place (Box 4.2) (170).

In another systematic review by Vasan et al. a combination of in-service training, mentoring, and supportive supervision were identified as important interventions in improving the capabilities of health workers (171). This has been a consistent focus of different capacity-building interventions supported by the U.S. CDC for increasing health worker skills in the processing and use of data, including the Stop Transmission of Polio (STOP) teams, Immunization and Surveillance Data Specialists (ISDS), Data Improvement Teams (DIT), and Strengthening Technical Assistance for Routine Immunization Training (START) (Box 4.3). Mentorship and supportive supervision were common denominators in all of these interventions (172).

4.2 BRICKS (Building Routine Immunization Capacity, Knowledge and Skills)

BRICKS is a framework from JSI based on the capacity building systems, tools, guidelines and policies that already exist in countries. Its five components are considered together as a package: 1) EPI core competencies, 2) situation assessment, 3) supportive supervision, 4) review meetings and 5) applied training. This framework is not “one size fits all” and some of the components may have more emphasis than others, depending on the analysis and situation of each one of the countries. The goal is “not to develop new tools” or “change” systems, but rather “to strengthen what is in place in a way that incorporates modern principles of performance and quality improvement and is ideally affordable and able to be sustained by the country” (170).

Box 4.3 The use of Data Improvement Teams in Uganda

The Uganda National Expanded Programme on Immunization (UNEPI) has worked alongside its partners to implement a variety of data quality assessment and improvement activities across the country. A strategy using Data Improvement Teams (DITs) began in 2014 with the aim of improving the management, collection, analysis and use of administrative vaccination data, and ultimately data quality and service delivery in health facilities and districts (122). DIT teams are each composed of a district-level biostatistician, a surveillance officer and/or EPI focal point, as well as university students. Teams are trained to implement rapid assessments of immunization data quality and use at health facilities and districts, and to provide on-the-job training and mentorship to district and health facility staff on recording, reporting, analyzing and using administrative vaccination data.

In Round 1 of the DIT strategy (2014-2016), the teams reached all districts and 89% of all health facilities in the country at least once. During this round, the teams learned that many health facilities did not know the target population for routine infant immunization in their catchment areas, and there was wide variation in the display of vaccination data in health facilities and in the appropriate use of data recording tools. Following Round 1 and the training activities that it entailed, some improvement in collection and management practices for administrative vaccination data was seen, as well as in the timeliness and completeness of data at the district level (122). The total cost of Round 1 was US\$575,275 over the three-year period, which is 0.5%-1.6% of the estimated operational cost of implementing UNEPI over the same period (K. Ward, manuscript submitted).

Round 2 of the DIT strategy (2017-2019) aims to revisit health facilities to assess progress on recommendations made during the first-round visits and provide further on-the-job training and mentorship.

4.8 Conclusion

This chapter has highlighted the importance of identifying the competencies needed and increasing the skills and knowledge of health workers — especially at the local level — in generating and using data to improve immunization programmes. Too often, development of new electronic tools is the default solution for what may really be a workforce capacity issue. Using a multi-intervention approach seems to be the most useful strategy to improve the quality of reporting, analysis and use of EPI data at the health facility and district level. Several interventions have been outlined and can be instituted, such as including data management and use in the pre-service training of health professionals (e.g., nurses); and reinforcing and refreshing data-related skills on a periodic basis through a combination of effective in-service training using adult learning techniques, supportive supervision, and regular feedback to health workers. All of these actions require strong leadership and a culture of data demand and use.

5. Tools: Information Systems and the Risks and Benefits of Novel Approaches

Key messages

- There is a proliferation of immunization and VPD surveillance information and communication technology tools. However, most never go beyond pilot phase.
- There is evidence that some of these tools improve data quality and use, including their accuracy, completeness and timeliness (e.g., real-time data). However, rigorous evaluation around their effectiveness and cost-effectiveness is often lacking.
- Innovative approaches are not magic bullets. Success depends on their addressing a well-defined problem and in having the infrastructure (e.g., connectivity), governance structure, sustainable financing, health worker training and other critical elements in place to be ready to implement the new technology.
- Immunization and surveillance information systems and tools that are integrated or aligned with broader health information systems (e.g., the national HMIS), while responding to individual user requirements, are more likely to achieve the support of political leaders and be more sustainable than stand-alone or fragmented systems.
- Innovations are more likely to improve data use if combined with other interventions (e.g., a dashboard, health worker training and a feedback mechanism on data generated).
- More guidance on when and how to scale up innovations is needed.

Data quality issues are largely caused by data recording errors at the facility level. Therefore, tools that are intuitive and user-friendly can potentially improve data quality and efficiency. Advances in information and communication technology (ICT) have led to a multitude of tools developed to address deficiencies in data quality, availability and use. Use of these tools are collectively referred to as “e-Health,” defined as “the cost-effective and safe use of information and communication technologies in support of health and health-related areas” (173).

While some of tools, including health management information systems, such as DHIS2, have been rapidly scaled up and are now in use in many countries globally, many of the e-Health tools do not go beyond the pilot stage, wasting financial and human resources. The reasons include over-enthusiasm for adopting technological innovations without defining what problem they seek to address, a lack of rigorous evaluation of the tools, as well as insufficient consideration of critical factors that are pre-requisites for the successful implementation of new technologies. These include the governance structures and procedures needed to support the new technology, the human resource needs to operate and use it, its integration with existing systems, infrastructure requirements (e.g., hardware and connectivity) and its financial sustainability.

This chapter describes the types of e-Health approaches that have the potential to improve the quality and use of immunization and VPD surveillance data, as well as the factors that contribute to their success and their potential limitations. A table summarizing these technologies, including their main features, advantages and limitations, can be found in [Annex 16](#). This chapter is based on the following sources of information:

- Two evidence reviews of: 1) novel approaches to measuring vaccine coverage ([Annex 17](#)) and 2) novel approaches to polio surveillance ([Annex 13](#));
- The grey literature, which was identified by WG members and interviews with experts, since many innovative approaches may not yet have been formally described in the literature; and

- The PATH/PAHO [IDEA report](#) (87) which reviews which ICT approaches have evidence for increased use of data and increased data quality, as well as their limitations (Precis as an Annex in Yellow Book).

5.1 Electronic Information Systems

Health information systems (HIS) have four key functions: 1) data generation, 2) compilation, 3) analysis and synthesis, and 4) communication and use. Their purpose is to convert data into information for health-related decision-making (174). The use of HIS for immunization and surveillance is arguably the technological innovation that has been adopted the most by national health programmes for routine use.

Vaccine and VPD surveillance data can be collected as part of a stand-alone system, such as an immunization information system (IIS) or an Electronic Immunization Registry (EIR), or as part of an integrated HIS, such as the DHIS2 platform – an open-source software that many African countries are using as their health management information system (see Box 5.1). While the terms IIS and EIRs are often used interchangeably, EIRs are narrower in scope and can be defined as a collection of individual-level electronic immunization records compiled in a database, which can be part of an IIS (175). Increasingly integrated HIS are being used to contain coverage and VPD surveillance data versus setting up a stand-alone EIRs or IISs. However, the experience with this has been mixed.

An integrated approach recognizes the similarities in data requirements across health programmes, is theoretically more resource efficient, and facilitates the linking of data across programmes and across health facilities, thus enabling monitoring along the continuum of care. DHIS2 can also improve data use (e.g., at the district level), especially when used in conjunction with tools and activities that support the use of data, such as dashboards, feedback, and regular supervision (88). However, the implementation of HIS alone may not lead to improved data use at the local level (88). One key factor is that immunization modules within these systems are often not developed specifically to meet the needs of immunization programmes. As a result, such modules are often used infrequently by health facility staff or used in parallel with existing paper-based systems, thus increasing the burden of data collection on facility staff (176).

In contrast, IIS are developed specifically for immunization programmes and may therefore be more fit-for-purpose than integrated HIS systems. However, there are two main issues that have arisen with their use. The first is the risk of developing non-interoperable parallel information systems, which are not sustainable in the long-run. To effectively link and sustain IIS with other information systems requires protocols on how data are shared and protected Error! Reference source not found.(176) and the establishment of information standards, including minimum information datasets and interoperability frameworks, as discussed in Chapter 3. Global standards for immunization information systems have not yet been developed (176), although there have been regional attempts to develop a set of standards (175).

The second, an issue with IIS, and particularly with EIRs, is the challenge in linking these registries with data from different sources to create accurate estimates of vaccination coverage. These sources include civil registration systems to estimate the entire target population (denominators) and not just those using healthcare services, which would strengthen health inequalities (58). They also include a range of providers of vaccination services beyond the typical public health facilities — such as private facilities, pharmacies, and schools — to ensure that all vaccinations provided are included in the numerator. This issue has not been resolved even in high-income settings.

Regardless of the approach used, both integrated and immunization-specific information systems have the potential to improve data completeness, timeliness, integrity and efficiency, especially when implemented at the subnational level.

Electronic immunization registries (EIRs) facilitate coverage monitoring in terms of particularity, timeliness and accuracy. In 2016, WHO's Immunization and vaccines related implementation

research advisory committee (IVIR-AC) reviewed the status of EIRs, and recommended “that research and implementation of EIRs should be prioritized and that WHO should find ways of making financial and human resources available [to work on this topic]” (177). Examples of EIR adoption have highlighted sustainable funding, health worker support and capacity building, and clear governance structures as major contributors to the successful implementation of these systems (105). The PAHO guide to EIR implementation expands upon these “readiness” factors, which are relevant to all regions (60).

Though few studies exist, there is evidence of moderate certainty that EIRs can improve data use at the district level when used consistently, and more mixed evidence that they improve data use at the health-facility level (88). The effectiveness of EIRs in improving data use is highly dependent on their function and design, as well as the completeness and accuracy of the data they contain (88). Thus, the quality of the data is still a function of the collection and recording of the data at the facility level, and therefore switching from paper records to an EIR, IIS or HIS in itself does not guarantee better data quality or use.

Box 5.1. The use of District Health Information System version 2 (DHIS2) in the African Region

DHIS2 is an open-source software platform for health information systems, which as of early 2019, is in use at various levels in 67 countries, including most countries in the WHO African Region (178). There has been robust support for reporting of HIV/AIDS, malaria, and TB programme data through the platform. However, immunization programmes have been late adopters of the platform, and until recently, only a subset of DHIS2-using countries used the platform for immunization programme data and an even smaller number for VPD surveillance data. Many countries appreciate the approach that DHIS2 takes, including the fact that it is open-source, is able to support integration across programs, and is being maintained by a cadre of skilled, local technicians trained by the Health Information Systems Program (HISP) in South Africa. Some countries have demonstrated strong leadership in deciding that DHIS2 will be the only HIS platform to be used in the country.

According to a recent assessment reported by the WHO African Regional Office (AFRO), 14 countries had EPI data integrated into DHIS2 and were using the data, while an additional 13 countries have also integrated EPI data into the system but were not using these data. Generally, this was a result of insufficient involvement of EPI staff in defining the minimal indicators and functionality required for immunization programme monitoring and/or lack of trust in the data. A few countries have struggled with challenges caused by the switch to the new system, resulting in a lack of or incomplete reporting. These challenges include an increased burden by having to enter data into two systems during the transition period, and technical issues in implementing DHIS2 while not maintaining the old system in parallel during the transition.

Recently, AFRO, in collaboration with WHO headquarters, provided support for the development and roll-out an immunization monitoring module within DHIS2, which includes dashboards to display analyses of indicators and assess data quality. The Regional Office is currently developing an updated DHIS2 platform for comprehensive VPD surveillance that will allow reporting of both case-based and aggregated surveillance data, as part of the Regional investment strategy in VPD surveillance.

Box 5.2 Lessons learned in incorporating immunization data in the SmartCare electronic health record in Zambia

SmartCare, an integrated electronic health record (EHR) system primarily used for antenatal care and HIV treatment, is now in use in one-third of all health facilities in Zambia. In 2011, a SmartCare module was launched that includes digital vaccination records. The system runs on desktop computers and mobile apps are also now available.

A 2016 evaluation revealed that out of 103 facilities included in the review, only two were using the SmartCare vaccination module. Reasons identified for the low use of the module included the lack of a continuous supply of electricity, low acceptability among health staff (half the facilities had previously used pilot EHRs that were discontinued, sometimes causing loss of client data), poor system design, and incomplete data for reporting, leading to parallel collection of paper and electronic data and thus increased workloads). Other lessons learned included:

- Vaccination information systems must be suitable for the infrastructure and clinic workflow;
- Negative experiences with discontinued EHRs can cause frontline staff to be skeptical of electronic data systems;
- Health records should not be fully transitioned to an electronic system without a clear plan for data migration, data back-up, and their long-term sustainability;
- The perspectives of frontline staff and a thorough understanding of vaccine-specific needs are crucial to the successful system design, implementation and evaluation of vaccination information systems; and
- Staff motivation to use a vaccination information system will be improved if they use the data, perceive that the system eases their administrative burden, and improves client care.

Source: A. King and K. Clarke, personal communication

Box 5.3 Development of web-based tools to report linked epidemiologic and laboratory surveillance data in the Western Pacific Region (WPR)

The Measles and Rubella Surveillance Reporting System (MRSRS) is a web-based system developed by the WHO Regional Office for WPR in response to requests from Member States to integrate measles and rubella epidemiological and laboratory surveillance data on a single platform.

Each time a case investigation record is completed for a suspected case for which specimens have been collected, the reference laboratory receives an automated email notification. The laboratory then records data about the specimens received and test results in the system. Once this occurs, the national surveillance focal points receive a notification, enabling them to complete the final case classification. The system has a set of required core variables; additional non-core variables; built-in validation checks; and standard reports for the distribution of cases by final classification, time, place and person, as well as for surveillance performance indicators.

MRSRS was first adopted nation-wide in Cambodia in 2013 and later expanded to Lao PDR and Mongolia. In addition, Vietnam is piloting a version that enables data entry at the subnational level, as well as data verification and validation at the national level. The system has been customized to meet countries' specific needs, including the possibility for a laboratory to initiate a case record when specimens are received before epidemiological data are entered in the system.

Based on the success of the MRSRS, similar systems have been developed for the surveillance of rotavirus (the RVSRS) and AFP/polio (the PASRS), which are currently being used in several countries. A system for invasive bacterial disease surveillance (IBVPDSS) has also been piloted in one country.

Box 5.4. Integration of VPD surveillance into broader communicable disease surveillance system in Vietnam

The Vietnamese Ministry of Health established a web-based electronic system (“Circular 54”) in July 2016 to serve as a single platform for case-based reporting of 42 communicable diseases, including all VPDs, in order to reduce parallel reporting for single diseases. The system, which has been implemented nationwide at all health facilities, is part of a broader process of digitalizing health sector data. It relies on dedicated focal points at each health facility, thus enabling the timely entry of data on newly identified cases. District and provincial level staff can access the system daily to check for new cases and initiate case investigations, as needed. National scale-up of the system has been undertaken through training of all users, with a focus on data entry, access to data and automatically generated alerts, and the use of dashboards, which are being developed to facilitate the description of cases by time, place and person and more easily identify disease outbreaks.

Some processes are still in transition and some weaknesses were observed during a VPD surveillance review conducted in November 2017. First, some processes, roles and responsibilities were not clearly defined especially regarding who should complete detailed case investigation forms, collect specimens for case confirmation, and classify cases (e.g., from suspected to confirmed) upon receipt of lab results. In addition, doctors and surveillance staff were not trained on new case definitions, the purpose of reporting suspected cases for some VPDs, nor in data analysis – resulting in missed cases. Other limitations of the system at present include the limited participation of the private sector and other government sectors providing health services (e.g., the military, education) and the fact that the system includes only core data elements, thus requiring district and provincial staff to still maintain an Excel line-list to record detailed information for AFP and measles cases.

The Circular 54 system offers a sustainable platform for the successful integration of VPDs, the expansion of case-based reporting to all VPDs, a reduced workload due to less parallel reporting, and improved timeliness of reporting. However, VPD surveillance would benefit from the development of clear implementation guidelines and SOPs, additional training on case definitions and case investigation, and the participation of private and non-health government sectors in the system (Annex 18).

5.2 Digitizing paper-based data

Interventions that used innovative technologies, such as scanning or image capture, to digitize paper-based immunization or surveillance data are designed to address the challenges associated with manual data entry at the point of service or at higher levels (e.g., district). As shown in Box 5.5, these technologies can potentially improve data integrity, accuracy, timeliness and especially, completeness (179, 180). In some instances, they can also eliminate the need to transport paper records.

Box 5.5. Using Smart Paper Technology to digitize immunization data in low-resource settings

The Swedish-based Shifo Foundation has developed [Smart Paper](#) — a hybrid paper-digital technology designed with in the aim of strengthening data quality and use in under-served areas. Smart Paper was developed based on [lessons learned](#) from experiences with the failed mHealth pilots in several developing country settings and could not be scaled up, due to infrastructure limitations, lack of sustainability with existing government budgets (i.e., high maintenance costs), and weak technical support available.

Smart Paper enables health workers to register children and other patients using a unique ID and capture their health data on Smart Paper Forms (regular A4 paper), which replace registers, tally sheets, and monthly reporting forms. Each month the Smart Paper Forms are scanned to generate electronic individual immunization registry entries, HMIS reports and LMIS reports. The technology integrates these data with those in other systems, such as DHIS2 and the District Vaccination Data Management Tool (DVDMT). The system also automatically provides real-time indicators and dashboards for action at the facility, district and national levels, sends reminder SMS messages to individuals, and generates stock request reports. All health workers receive their own performance feedback via SMS.

The Smart Paper technology has been piloted in Afghanistan, Uganda and The Gambia, and external evaluations in each country have shown that it generates high-quality data (based on the WHO data quality review toolkit), is cost-effective, and reduces the time spent by frontline health workers on paperwork by 60%-73% per fully immunized child. Scale up is likely in Afghanistan, The Gambia and Uganda. Further independent evaluation would be helpful.

5.3 Decision support tools (dashboards)

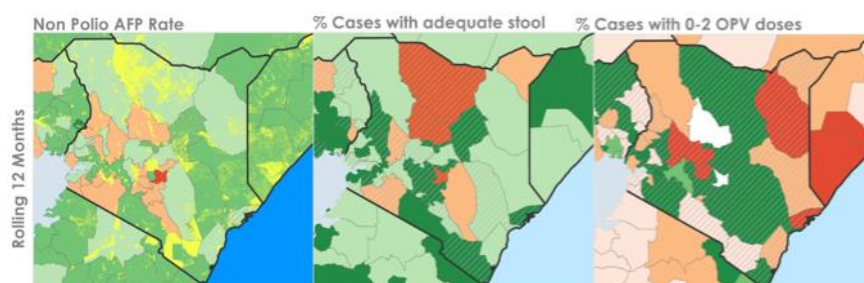
Decision support tools, such as dashboards, are being used at the country, regional and global levels to synthesize and present immunization and VPD surveillance data in a visual format (through maps, charts and tables) for programme managers and decision-makers. By bringing together data on immunization activities, surveillance data, laboratory data, location data and administration data under a single platform, dashboards can improve the efficiency of immunization and surveillance monitoring, as well as its precision (e.g., through data triangulation). At the national and subnational levels, there is evidence of moderate certainty that data dashboards (either stand-alone or integrated into HIS) can also improve the use of data by helping users synthesize disparate pieces of data and translate them into information that is useful for decision making (88).

Examples of such tools currently in use globally are the Polio Information System (POLIS) (Box 5.6) and the WHO Immunization Information System (WIISE) that is currently in development (Box 2.2 in Chapter 2). At the WHO regional level, dashboards have been used to monitor data quality, as well as immunization programme performance, and, more recently, the performance of logistics systems, such as cold chain and vaccine stock availability (89). Factors that contributed to the successful use of an immunization dashboard in several African countries included the standardization of data requirements across countries, and capacity-building workshops that were focused on the use of the dashboard (89).

Box 5.6. Polio Information system (POLIS)

POLIS is a tool for managing and presenting data on polio immunization and surveillance activities that is managed by WHO and has been fully functional since 2014. The system brings together data on immunization activities (routine and campaign), surveillance data (case-based and environmental), laboratory data (from the Global Polio Laboratory Network), geolocation data (GIS) and administrative data. These data — which come in various formats from multiple sources and data systems within each country — are collated and quality checked at the regional level before being sent to WHO in Geneva, where they are consolidated and harmonized in POLIS. The platform includes a dashboard that displays the data in maps and charts that can be used at the country and subnational level to monitor progress against indicators. Global polio bulletins are also automatically generated from POLIS data. The group developing the WIISE system has been collaborating with the POLIS team to learn from their experience and to create synergies where possible.

Example of a risk assessment for vaccine-derived polio virus transmission on the POLIS dashboard:



5.4 Logistics management information systems (LMIS)

Computerized LMISs can overcome the challenges of paper-based systems by standardizing data collection, allowing for vaccine tracking in real time, transmitting data quickly throughout the system for accurate vaccine forecasting and stock management, reducing errors, and automating reporting (181). There is some evidence that these systems can improve data use at the district level and above, as well as enhance the analysis, synthesis, interpretation, and review of data and assessments of data quality (88). LMIS interventions were most effective when they were combined with other data use activities such as dashboards (88).

Digitally-enabled supply chains allow all stakeholders, including manufacturers, distributors, NGOs, country officials and local health workers, to track the exact path vaccines take from the factory all the way to delivery, thus enabling the use of such data to monitor the number of doses that are administered. Additional technological innovations such as the use of block-chain — an incorruptible digital ledger that can be programmed to track individual vaccine doses from manufacturing to administration — also have the potential to increase data security and integrity, improve transparency and traceability along the system (182), and improve interoperability across immunization data systems (183). These initiatives are very recent and the evidence that they improve data quality is not yet available.

5.5 mHealth

While most commonly used in immunization to send SMS messages as reminders about vaccination sessions or appointments, mobile phone-based technologies (“mHealth”) have also been used for real-time data collection and monitoring of programme activities (Annex 17). When used to collect and report VPD surveillance data in real-time (including geolocation data), mHealth apps have the potential to improve the completeness, timeliness and precision of the data, as well as their integrity, since the data are only entered once. However, these systems can

also lead to the over-reporting of cases and a high proportion of false positive cases, which have to be followed-up, resulting in increased workload. This is especially true when used as part of community-based reporting (i.e., by unskilled informants) and/or there are incentives to report cases (Annex 13) (184).

Mobile applications can also be used to track health workers in the field and to supervise surveillance and immunization activities, as well as the management of the cold chain (e.g., using checklists). Such tools can improve data accuracy by, for example, ensuring adherence to case definitions during data collection, and can improve the completeness and timeliness of the data by reminding health workers to report (185). In addition, mHealth apps have been used to simplify the management of logistics data, such as in tracking vaccine stock levels and informing users of stockouts or low stocks at all levels of the system. There was evidence that the data generated from the e-VIN system used in rural parts of India informed actions and reduced periods of vaccine stockouts (186).

5.6 Media-based approaches

The main example of a media-based approach identified in the review is the AVADAR programme in Africa. The intervention involves sending videos to health workers and community informants on a weekly basis to remind them about case definitions and the type of cases to report as AFP and to send in their reports (see Box 5.7) (187). A similar approach could be considered for immunization activities to remind health workers about how to collect and report data, for example. The additional burden generated by applying this approach to VPD surveillance, as a result of over-reporting of cases, would not be seen for immunization data.

Box 5.7. AVADAR (Auto-Visual AFP Detection and Reporting)

AVADAR has been used in selected districts in 10 countries, including Liberia, Nigeria and the Lake Chad countries, to support the reporting of acute flaccid paralysis (AFP) by health workers and community informants.

The AVADAR application is installed on android-enabled mobile devices. A [30-second video](#) of a child with AFP is included in the app. A weekly reminder, including the video, is sent out to the community informants, who are asked to submit a “No” report or to report a case. Positive reports are investigated by a disease surveillance officer, who sends an investigation report by mobile phone, which goes to a database. The data can be viewed in real-time on a dashboard, or collated and presented to decision-makers.

The system has been very helpful in increasing the sensitivity of polio surveillance in remote and high-risk areas (187). At the same time, this increased sensitivity of suspected AFP cases has also led to increased reporting of cases that are not acute or flaccid. Since all reported cases have to be investigated, the high rate of false reports has resulted in a markedly increased workload for polio workers. AVADAR is also too expensive to use extensively beyond high-risk settings. Thus, while the extra workload and costs are acceptable during the last mile of the polio eradication programme, these factors would have to be weighed carefully when considering whether to apply this technology for the surveillance of other diseases.

5.7 Geospatial-based technologies

Geospatial technologies have been used in immunization programmes in two main ways: 1) to estimate better denominators, including migrating populations; and 2) in planning and monitoring immunizations and surveillance activities, including microplanning. Satellite imagery, geo-positioning and mobile phone call records have all been used on an experimental basis to estimate population size and the rate of migration at the local level (Annex 13) (184, 188-190). This reportedly has led to more accurate and precise population data, and even to population estimates in areas where no estimates previously existed. Processing such data requires a trained workforce, however “mapathons” are increasingly used, where volunteers are asked to

identify individual structures (e.g., houses vs. schools or businesses) on satellite images, using a GIS application. This results in a detailed picture of individual structures, making it possible to estimate population size in that area by using an assumed number of residents per structure (Annex 19).

GIS technologies have also been used to improve microplanning, identify missed or poorly covered settlements, more efficiently divide the workload among field vaccination teams, and track vaccination or surveillance teams (191). These uses of GIS can result in data that are more complete and accurate. More impact and economic studies of GIS technologies are needed to determine feasibility of broader programme use.

5.8 Predictive analytics

Predictive analytics in the context of immunization programmes can be described as the use of mathematical algorithms to estimate current and future patterns of vaccine coverage or VPD incidence. Such approaches have been proposed to estimate vaccine coverage in “coldspots” (192), reveal differences in coverage in large administrative areas and across administrative borders (192), or predict defaulters at the individual level (193). However, there is a disconnect between academia where the methodologies are being rapidly improved and refined, and country immunization and disease control programs who have been slower to adopt such tools (190). Such caution may be justified, as there is not much existing evidence of the public health impact and cost-effectiveness of predictive analytic methods. In addition, current algorithms may lack sufficient resolution and positive predictive value to be relevant for routine practice (193).

The use of “big data” for predictive analytics has also been explored in the field of disease surveillance, with mixed results. Consensus has not been reached on whether predictive approaches add value to traditional surveillance methods, or even that they are accurate or representative enough to inform public health action (194). Nevertheless, event-based surveillance based on big data mining is slowly becoming more common in the surveillance landscape (195) and there is some evidence that they can detect public health events earlier than traditional surveillance systems (196). When predictive analytics algorithms are combined with machine learning, the accuracy and precision, and consequently the usefulness, of these methods will increase with time and as increasing volumes of data are processed by these algorithms (Subash Chandir, personal communication). As their use is increasingly considered in routine immunization and surveillance programmes, predictive algorithms should be evaluated not only for the accuracy, precision and timeliness, but also for their added public health value, their cost-effectiveness, and their affordability and sustainability.

5.9 Conclusions

New technologies can have a positive impact on the quality and use of immunization and surveillance data, including their accuracy, completeness and timeliness (e.g. through real-time reporting). However, these interventions are not magic bullets, and are unlikely to be adopted by countries in the long-term or to lead to long-lasting data improvements unless other factors and conditions are in place (Table 5.1). These factors, identified repeatedly by different stakeholders and in guidance documents (60, 197), include sustainable financing, such as earmarked funding; interoperability with other health information systems; the flexibility to adapt to future needs; and their development within a broader national eHealth strategy (60). These factors, in turn, require the existence of strong governance structures to ensure that there is political will to adopt these technologies, the inclusion of key stakeholders and partners in developing and implementing them, and a sustainability plan (Annex 17). Thus, innovative technologies that are not integrated in the healthcare system and that do not take into consideration the infrastructure, human and material resources required to make them functional or the political climate they’re operating in are unlikely to succeed or to go beyond the pilot stage. Innovative approaches are also more likely to lead to improved data use when they include multiple components, when they address a specific need, and when they are considered within a whole systems approach.

Table 5.1. Factors determining the success of innovative technologies for collecting, analyzing and reporting surveillance and immunization data

Factors	Examples
Governance	Leadership, political will, legal framework (e.g. data protection)
Integration/ Interoperability	Data linkage potential, use of consistent data standards, integration of EIR in HIS
Capacity	Human resources (training, workforce), material resources (computers, phones)
Sustainability	Including financial sustainability, e-health strategy
Infrastructure	internet, electricity, technical support structures including effective troubleshooting, security (to store devices safely)

Adapted from the WHO (197) and PAHO (60) guidance documents, and A. Poy, personal communication

Rigorous evaluation of these tools is not systematically done and is essential because the outcome is not always obvious. Where evaluations have been done, they have shown that, for example, mobile-based reporting does not always improve timeliness, or that the implementation of a health management information system does not systematically lead to improved data use (88). In some of the polio examples, for a range of reasons, innovative approaches had low uptake by frontline workers and only made a small contribution to the number of reported cases. This required them to run in parallel with traditional data collection methods, thus further overburdening the already over-burdened frontline health staff ([Annex 13](#)) (184).

There are gaps in the existing literature in key areas, such as how to best integrate routine immunization data into an HMIS or how to identify key indicators that would assist in measuring the effect of a technological innovation on vaccination coverage rates. And although guidance exists on how to evaluate digital health interventions, there is an increasing need for real-life evidence, as well as guidance, on how and when to scale up innovations to ensure a sustained long-term benefit on data quality and use. The sharing of both best practices and challenges with less successful innovations would also assist in improving the overall global community's understanding of appropriate technologies to explore within the appropriate context.

6. Assessment and Improvement Planning: Data Use for Continuous Quality Improvement

Key messages

- New approaches to monitor the performance of EPI programmes are needed as coverage improves and programs shift their focus to life-course of vaccination, equity in service delivery, and disease elimination goals (e.g., measles). This includes new approaches to assessing numerators and denominators.
- The use of data has been shown to improve their quality.
- Better use can be made of existing information to supplement and validate administrative coverage data, such as VPD surveillance data; vaccine supply data; and rapid coverage monitoring data, as collected during activities such as supervisory visits and outbreak response.
- Opportunities should be found for greater coordination between EPI and other programmes and interventions for collecting data, as part of health systems strengthening.
- Data triangulation is helpful for synthesizing existing evidence across data sources and reaching deeper understanding of issues, and should become the default for public health analysis.
- Assessments of data quality and subsequent improvement efforts are most effective if conducted on an on-going basis, versus periodically, – down to the lowest level – as part of a Continuous Quality Improvement (CQI) approach.
- Such assessment should examine the root causes of poor data quality and use and inform the development of a data improvement plan, which are currently often not based on evidence.
- To assist countries in shifting from periodic to routine monitoring of data quality, standard data quality monitoring indicators and global guidance on routine data validation are needed.

Using data enables vaccination of the last child, appropriate responses to disease risk, more efficient allocation of resources, and accountability at all levels. Discussion around data quality and use needs to start from the key objectives in order to determine what data and what degree of data quality are required (“fit for purpose”). Historically, the approach to immunization data quality has been focused on detection of errors and assessing the scope and extent of the problem (the “what?”), rather than on performing an analysis of the root causes of data problems (the “why?”) that would feed into an overall cycle of improvement. Ideally, assessment of data quality should be a continuous process rather than episodic evaluations conducted every few years. And, as mentioned in earlier chapters, the quality of immunization data can only be improved significantly if the health systems organization and structure are taken into account, using a whole systems approach.

The findings of this chapter are based largely on the landscape analysis of data quality assessment approaches and indicators, the Data Triangulation Framework, and example of data triangulation analysis, and case studies (see online Annexes). The purpose of this chapter is to highlight how approaches to assessing data quality can become routine, how data analysis practices might be improved at all levels, and how use of data should feed into broader efforts to improve the immunization programme and the larger health system. The limitations of this review were that the data quality indicators and approaches to continuous quality improvement were not reviewed systematically.

6.1 Monitoring coverage as performance improves and the focus shifts towards an equity and life-course approach

The Decade of Vaccine's GVAP established ambitious goals for national and subnational immunization coverage, which require high-quality data to track progress towards success and reach all of the children left-out or dropped-out of the immunization system. In addition, the costs of the immunization programme and demands of monitoring of evaluation are increasing as the number of available vaccines continues to expand. The introduction of new vaccines and a shift towards life-course vaccination targeting older age groups (e.g., school-age, adolescents, pregnant women, elderly) have increased the complexity of accurately monitoring coverage. Ensuring transparency and accountability regarding the appropriate use of resources and evidence-based decision-making around employing cost-effective strategies — all of which require high-quality data — are perhaps more critical than ever.

Maintaining accuracy as coverage increases

As seen in Chapter 2, high-quality coverage estimates are more difficult to measure through administrative measures as coverage increases (49). The effects of errors in target population estimates are amplified as the coverage level increases and can conceal differences in vaccination coverage across areas and over time (Figure 2.2). Even if national population targets for immunization remain relatively stable, the accuracy of population estimates has been noted to decrease when data are disaggregated (48). Few LMICs have birth and civil registries for obtaining high-quality immunization targets and census estimates may be outdated or inaccurate due to political reasons (50, 51). Some of these issues may be addressed through better cross-unit coordination, advocacy or work-around solutions (53). Geospatial modeling of population denominators for administrative areas also shows promise, but further field validation is needed (198).

Migrants and other high-risk groups may be left out of population target estimates and require different approaches to estimate denominators and monitor coverage. Developing approaches to track coverage not only based on place of vaccination and but place of residence (or inside and outside catchment) may be helpful in this regard (Box 2.6). Tracking individual-level vaccination status through EIRs may be the gold standard, but may not be practical for every setting. Improving the design and functionality of paper-based registers (e.g., to track residence inside and outside catchment areas) and improving use/retention of home-based records should be more feasible. New approaches like electronic dashboards and automated analysis, Smart Paper (Box 5.5) are hybrid paper-digital solutions that show promise for addressing the demand for individual level tracking, while addressing the current limitations for eHealth at the peripheral levels. Continued innovation and stewardship in this area is needed.

Monitoring equity in vaccination coverage

While one can measure inequalities, the goal is to monitor equity in immunization, i.e., the fair reach of vaccines to all. Several global analyses of immunization inequalities have been published (199). However, to date, monitoring equity has often been equated with measuring differences in survey coverage across sub-populations (200). The Health Equity Assessment Toolkit ([HEAT](#)) is a software package that allows analysis and visualization of vaccination coverage by different dimensions of inequality (e.g., education, economic status, subnational region) (201). The software is available as an online or stand-alone version, and either comes preloaded with many years of survey data (from the DHS and MICS), or with the ability to upload and analyze other data. Interactive country profiles that contain these data are also available on the [WHO Global Health Observatory Health Equity Monitor](#) website (202). A limitation is that these surveys occur only approximately every five years and only in some LMICs.

A 2017 systematic review highlighted that existing approaches to monitoring equity towards achieving the SDGs have been sub-optimal in identifying and reducing gaps in immunization coverage for vulnerable groups or minorities, or by attributes such as education, specific religious

groups, or sexual orientation (200). The [Equity Reference Group \(ERG\) for Immunization](#) has written several discussion papers on how equity might be monitored by immunization programs, but associated guidance has not yet been developed. Triangulation of quantitative and qualitative data to validate or put information in context (e.g., surveys of caretakers or healthcare workers to identify reasons for non-vaccination), is also relevant for addressing coverage and equity issues (203). The collection and use of individual level vaccination data (i.e., EIR) can serve as the gold standard for identifying and targeting under-vaccinated groups (Box 6.1).

Box 6.1. Using routine immunization data to tackle inequalities in vaccine coverage in England

Public Health England (PHE), the executive agency of England's Department of Health, is responsible for collecting and reporting vaccine coverage for vaccines offered in the national vaccination schedule. PHE uses two Immunization information systems to monitor the vaccination programme across the life-course: 1) the Child Health Information Systems, which are local electronic registers of all children up to age 18 residing in an area, including migrants, and 2) data automatically extracted from electronic medical records from over 95% primary care health centres.

In addition to estimating vaccine coverage down to the facility level in real-time, these two systems record additional variables that enable PHE to describe vaccination inequalities in terms of geography, ethnicity, gender, co-morbidities, or socio-economic deprivation. The data have allowed the agency to identify and locate groups that are less likely to initiate and/or complete vaccine courses. Ultimately, these data led to changes in national and local strategies in order to improve coverage, such as vaccination catch-up campaigns for susceptible birth cohorts, and local vaccination efforts targeting specific under-vaccinated groups. These studies also inform the national immunization programme's Equity Impact Assessment, a comprehensive analysis of inequalities, and with recommendations on how to reduce them.

Measuring performance of life-course vaccination

Shifting towards a life-course approach of vaccination poses complex challenges in monitoring coverage for multi-dose vaccinations given beyond the first year of life. For administrative coverage data, issues arise with both accurately estimating denominators and accurately counting numerators (e.g., for doses received late). With coverage surveys, there are challenges in standardizing target age groups to assess vaccination coverage and in collecting accurate vaccination histories. For example, measuring TT vaccination coverage among pregnant women with at least two doses (TT2+) or protection at birth (PAB) rates has been long known to be a challenge due to poor retention of home-based records (vaccination cards), in addition to the lack of documentation of tetanus-containing vaccine doses received during childhood or through campaigns. The introduction of the second dose of measles, or measles-rubella, vaccine, HPV and other vaccines in pregnancy have also acutely highlighted the challenges in monitoring coverage associated with new age vaccination platforms and has resulted in many lessons learned. The challenges of estimating coverage beyond infancy will also need to be addressed with the upcoming support from Gavi for a DPT booster dose (85, 204).

Accurately assessing population immunity resulting from multiple-dose vaccination schedules poses another challenge, even for well-performing programmes. For example, TT2+ and PAB coverage rates are known to underestimate population immunity, especially as vaccination programmes improve (14). For this reason, the SAGE suggested in October 2016 that serosurveys could be useful (205). Routine serosurveillance programmes are common in higher-income settings (206-209), and a case has been made for greater use of serosurveys in LMICs to aid decision-making (12, 210). In settings with weak surveillance or unreliable vaccination coverage, or that rely heavily on vaccination campaigns, serosurveillance could potentially play an important role in deciding what interventions should be taken to improve population immunity. For example, repeated poliovirus serosurveys in Nigeria have been used to evaluate the effectiveness of campaigns and to guide programme interventions (211-214). Serosurveys have

also been useful in assessing the level of population immunity required for measles elimination (215, 216). However, questions remain about the role, usefulness and priority of serosurveys relative to other programme priorities, such as vaccination, especially given the various technical limitations with these studies (Box 6.2 and Annex 20) (215, 217, 218).

Box 6.2. The use of serosurveillance to guide immunization policies and strategies

Serosurveys provide an objective biological measure to estimate population immunity and monitor risk for VPDs. Serological data are increasingly desired to guide immunization policy and strategy — from support of vaccine introductions (e.g., rubella) to the verification of disease elimination (e.g., hepatitis B). In 2011, the SAGE recommended that WHO develop guidelines for collecting, analyzing and interpreting biomarkers to validate vaccination coverage and to support research (4).

Since then, serosurveys have been used in an increasingly number of different contexts. Disease-specific guidance on serosurveys for [dengue \(2017\)](#), [tetanus \(2018\)](#), and measles and rubella (in draft) has been added to the existing guidelines for [hepatitis B \(2011\)](#). Methods to reduce the costs of the surveys have also been explored. These include combining their implementation in the field with other surveys, and “multiplex laboratory testing”, which allows simultaneous detection of antibodies to multiple antigens in a single sample (219). However, the question of how useful serosurveys are as a tool to monitor immunization programmes and their relative importance in different contexts, especially in resource-limited settings, remains. The Working Group proposes that, going forward, SAGE provides a position on the role of serosurveys in monitoring immunization programmes across different VPDs and epidemiological situations (Annex 20).

6.2 Routine monitoring of data quality as part of a more robust programme monitoring approach

Monitoring progress, and allocating the resources needed to achieve immunization objectives, hinges on the use of high-quality data (114). The use of results-based financing mechanisms by major donors has created further demands for timely and reliable data for decision-making (56), though SAGE, in 2011, already warned against use of coverage data for performance based financing (4). It has also created the possibility of a perverse incentive to report over-estimated vaccination coverage data, especially in low-income countries with serious data quality challenges. This situation creates a case for shifting away from focusing exclusively on using targets as a basis for funding to a focus on improvement — both in terms of performance and data quality.

Monitoring data quality is crucial to support accountability and transparency (113) of the immunization programme, and helps in interpreting surveillance or coverage data and putting them in context. As discussed in Chapter 2, recent guidance documents (e.g., DQR, Handbook) outline helpful analysis approaches like examining trends in numerator and denominator separately, and assessing internal and external consistency. These guidance documents and other publications propose also possible indicators of data quality. However, there still lacks a robust framework for ongoing monitoring of data quality or a set of standard performance indicators for use at different levels (*Chapter 2.3.2*).

With the increasing use of electronic information systems, there are more opportunities to perform automated data validation checks and analyses to improve data quality and use. WHO/EURO recently developed a JRF data validation process (Box 6.3), and discussions are underway at the global level to incorporate automated JRF data validation checks and data analyses into the new WIISE platform. In AFR, automated analyses of immunization coverage and data quality were incorporated into DHIS2 monitoring dashboards for broad use in the Region (11). However, data validation checks are not used systematically, but are instead incorporated on an *ad-hoc* basis from country to country. The American Immunization Registry Association (AIRA) has issued guidance around data quality validations for to be added to EIRs in use in U.S. jurisdictions (19). An example of data validation checks from England is included in

Box 6.4 (Annex 21). It would be useful to develop guidance for countries in incorporating validation checks for immunization and surveillance data, as part of guidance on developing electronic information systems standards (Chapter 2.3. 1).

Box 6.3 WHO Europe Regional Office (EURO) annual review of immunization data reported through the JRF

Beginning in 2017, the EURO Immunization and Surveillance Data Team began to implement a series of quality checks on data submitted by countries for region-specific questions on the Joint Reporting Form. Data quality checks focus on the completeness of reported data; a comparison of the expected versus actual field data type (e.g., character vs. numeric); a check of the range of reported data against expected values; as well as an internal consistency check of reported data values for similar questions within the same country JRF. They also include consistency checks of reported values against recalculated values (e.g., 85% coverage is reported, but recalculating the coverage using the reported numerator and denominator data yields a different value). At present, the data quality checks are confined to a given JRF in a given year from a given country. Moving forward, the aim is to allow for time-series checks for reported data for region-specific questions.

Box 6.4 How England assures the quality of vaccination coverage data

Public Health England is responsible for collecting and reporting coverage for vaccines offered in the national vaccination schedule. The quality assurance process for the data collected by its immunization information systems include both systematic manual and automated validation checks, as well as *ad hoc* analyses. When data fail validation checks, those providing the data are systematically queried. The data are then either corrected, notated with explanations for the validation failure or, in rare instances where the quality is too low, not published or delayed (Annex 21).

Automated validation checks examples

- Denominator is \geq numerator
- Coverage change within +/- 5% compared with previous quarter
- Denominator change within +/- 10% compared with previous quarter
- Dose 1 coverage \geq Dose 2 coverage

Manual validation checks examples

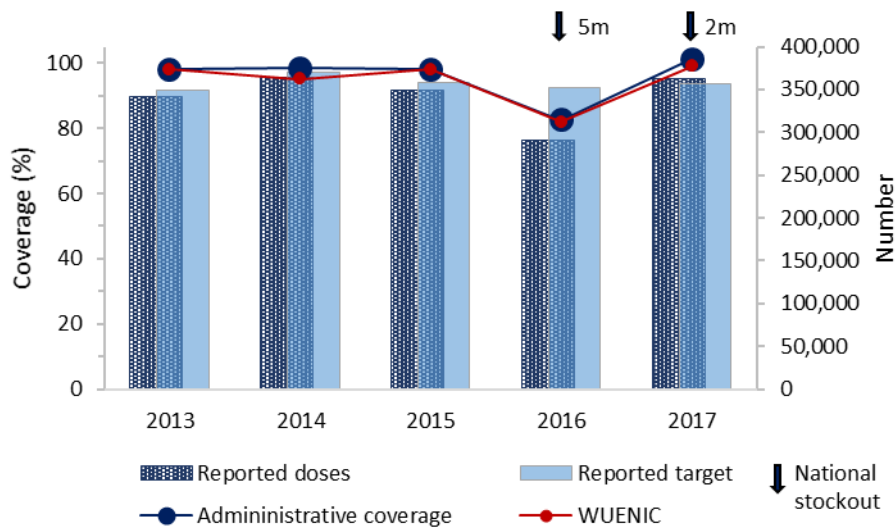
- Departure from expected on coverage trends over the previous 4 quarters
- Data extraction is for correct time period

Ad hoc analyses

- Triangulation of live births data with rotavirus and pre-natal pertussis coverage for denominator validation
- Triangulation of coverage in individual birth cohorts with age specific incidence

Shifting from periodic data quality assessments to routine monitoring of data quality would be a step in the right direction in terms of creating a cycle of data quality improvement, as discussed below and in Section 2.3.2. The approach would vary by level, but would entail an assessment of data quality alongside coverage. Currently at the global level, a graph of a single analysis relevant to data quality is published on the [WHO Monitoring Website](#) — comparing annual WUENIC estimates with reported administrative DTP3 coverage and reported number of doses by country over time (220). The addition of reported denominators and stock-outs would also be helpful in interpreting annual fluctuations in coverage and numerators (Fig. 6.1). Other unpublished analyses are performed as part of the annual WUENIC process. The routine publication of global desk reviews of immunization data quality should be considered, similar to joint MMWR and WER reviews that are conducted for polio, measles, rubella and routine immunization. At the regional and country level, incorporating data quality monitoring into feedback, monitoring bulletins, dashboards and other automated analyses would support the use of data and quality improvements (88).

Figure 6.1. Analysis of WUENIC estimates and reported administrative coverage with DPT-containing vaccine, vaccine doses administered, targets, and national vaccine stockouts for a country. (Source: WHO)



6.3 Building a data use culture: turning data into actionable intelligence at all levels

Strengthening routine health information systems involves building a data use culture that informs decisions at all levels of the health system (16, 221).⁵ In practice, this is challenging because it involves strengthening the entire health system (governance, tools, people, improvement processes) and changing aspects of a particular culture. To date, a lot of focus in this field has been devoted to interventions to assess and improve data quality. However, evidence from the IDEA review has highlighted the fact that interventions to improve the use of data may be a potential entry point for improving the quality of the data (88).

Two key ways of improving the use of data to inform programme planning and decision-making are: 1) making better use of existing data besides coverage data, including from other programmes; and 2) synthesizing different types of data through “triangulation”.

Making use of under-utilized data to supplement coverage data

The EPI programme has a lot of additional data that are under-utilized for programme planning and decision-making at all levels. For example, EPI programmes may not be making adequate use of VPD surveillance data because of a lack of coordination between the EPI and the surveillance unit, or because the surveillance data collected are not fit-for-use in managing EPI programmes. An example is aggregate reports that lack age stratification and laboratory data (see Chapter 2.2.2, Box 2.7, and Box 2.11). In these cases, either the coordination and sharing of data from different units needs to improve, or the decision to collect the relevant data from the beginning needs to be made, as part of a shift towards a comprehensive VPD surveillance strategy (see Box 2.4). In 2011, SAGE indicated that the impact of immunization on the incidence and severity of VPDs be included in assessments of country’s programme performance (4).

There is also an increasing interest in using vaccine supply data to better understand the performance of immunization programmes (e.g., by comparing data on vaccine shipments with

⁵ [Data use culture](#) is defined as the customs, dispositions, and behaviors of a particular group or organization to support and encourage the use of evidence, including facts, figures, and statistics, to inform their decision-making.

data on doses administered), but further research is needed to determine the usefulness of these comparisons at different levels (222).

Other examples of combining data from different sources to improve data quality as well as vaccination coverage include using rapid coverage monitoring data collected for different purposes, such as during supervisory visits, outbreaks, post-campaign evaluations, or data on vaccination status collected during surveillance (223-225). In Pakistan for example, children identified during polio vaccination campaigns who were incompletely immunized for other vaccines were followed up by the routine immunization programme, leading to improvements in coverage (Annex 22 and Box 6.5).

Box 6.5 Use of polio campaign data to improve routine EPI coverage in Pakistan

The Expanded Programme of Immunization (EPI) and Polio Eradication Initiative (PEI) in Pakistan developed an initiative called “EPI/PEI Synergy” to use PEI data and staff to support the EPI and improve routine immunization coverage. During polio vaccination campaigns, vaccinators collect data on children who have not been vaccinated through routine immunization (“RI Zero dose status”). The polio teams also identify unvaccinated children during surveillance activities (“AFP Zero dose status”). Through the EPI/PEI Synergy Initiative, the two programmes have worked together at all levels to improve routine coverage through the following activities:

1. Sharing of “RI zero dose” data collected during polio vaccination campaigns and “AFP zero dose” data from surveillance for children aged 0-23 months with EPI management at the district level;
2. Joint planning and implementation of routine outreach sessions for “RI zero dose” children;
3. Joint monitoring and supervision of outreach sessions by EPI and PEI staff;
4. Reporting on the number & percentage of 0-23-month-old children vaccinated through joint efforts.

Punjab is one of the first provinces to establish the EPI/PEI Synergy initiative. The province demonstrated excellent collaboration between EPI and Polio Teams, with coverage of RI zero-dose children who were vaccinated within 14 days following a polio campaign ranging between 92%–98% from January 2017- September 2018 (Annex 22).

Performing “data triangulation”

Data triangulation involves the critical synthesis of two or more existing data sources to address relevant questions for programme planning and decision-making. The process identifies and aims to address limitations of any one data source and/or data collection methodology, and also encourages deeper insights by examining complementary data and putting them into the broader context. A framework document for Data Triangulation for Immunization and Surveillance Programs was developed in collaboration with the WG (Annex 2) (10). As part of this process, the U.S. CDC conducted a landscape analysis that identified five types of triangulation analyses that have been used by EPI programmes:

- 1) check of consistency across data sources (e.g., coverage monitoring);
- 2) estimation of coverage, target populations or disease burden;
- 3) diagnostic for targeting programme interventions (e.g., risk assessments, surveillance performance monitoring);
- 4) observational evaluation of the impact of interventions (e.g., vaccine introduction, campaigns); and
- 5) holistic assessment of programme adequacy (e.g., outbreak investigation, disease elimination verification).

To date, guidance on data triangulation for immunization (i.e., [DQR](#) and [JSI guide](#)) has focused exclusively on using this technique to assess data quality by, for example, checking the consistency of similar indicators across different data sources (e.g., administrative coverage vs.

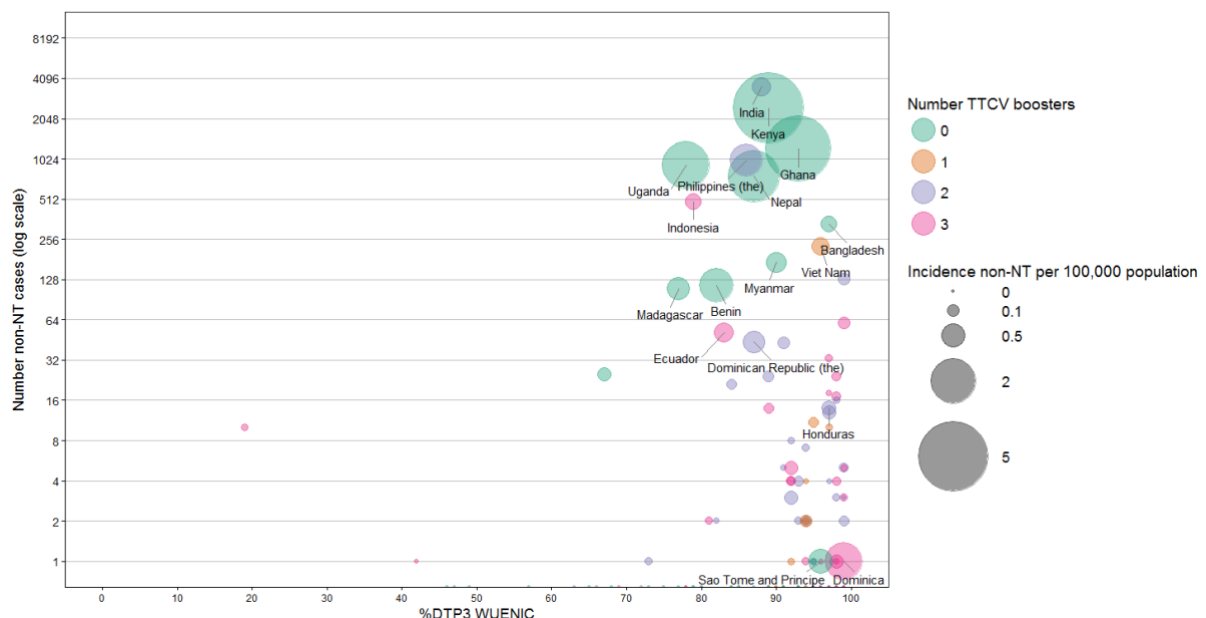
surveys). However, data triangulation can also be used to guide policy and strategies — from vaccine introduction to verification of disease elimination (Annex 2) (10). It has recently been suggested to the SAGE that data triangulation may be useful for identifying measles immunity gaps (226). It is also relevant for addressing issues of equity (199), improving population denominators (53), and addressing other key issues. The perspective of the WG is that triangulation should really be the default for public health analyses to make the best use of existing data, despite the limitations of individual data sources, and because it has the potential for deeper understanding and improved confidence in decision-making (Annex 2) (10). As a proof of concept, the WG commissioned a global data triangulation analysis described in Box 6.6 (Annex 5) (37).

Box 6.6 Example of global data triangulation of tetanus vaccine coverage and incidence

In order to evaluate the feasibility of using non-neonatal tetanus (non-NT) surveillance data to monitor the coverage of DTP-containing vaccines (DTPCVs), the U.S. CDC conducted an analysis that triangulated three types of data for 194 countries reported to WHO: 1) tetanus vaccine schedules, 2) vaccination coverage (using WUENIC estimates), and 3) tetanus (neonatal and non-neonatal) incidence. The review found a high tetanus burden in low- and middle-income countries in Africa and Asia. This is in contrast to the pattern of reporting observed for pertussis, which tended to be reported from high-income countries with greater capacity for laboratory confirmation (36). Higher non-NT incidence was observed in countries with low DTPCV3 coverage and/or ones without booster doses in their vaccination schedule (see figure). However, there was evidence of unreliable non-NT reporting, likely resulting in the burden being underestimated (Annex 5) (37).

The review concluded that the ability to use non-NT incidence data to monitor DTP3 coverage is likely to vary from country to country, based on the quality of surveillance data. It also highlighted several limitations with the global availability and quality of JRF-reported data (Box 2.7).

Reported non-NT cases and incidence, DTP3 coverage estimates (WHO/UNICEF), and number of TTCV doses by country,* 2016



*Note: 129 countries not depicted because reporting zero non-NT (82) cases or not reporting (47)

Encouraging the use of data triangulation methodologies, as has been done by HIV (227, 228), has the potential to promote a “data-use culture” by building capacity for critical thinking, data analysis and use within the context of an increasingly data-rich environment. The WHO, UNICEF

and U.S. CDC have proposed to develop guidance on data triangulation that: 1) adapts the data triangulation process used for HIV and expands the desk review process described in the DQR as best practices for data analysis across topics relevant for EPI programmes, 2) is driven by important questions relevant to immunization and surveillance programs (e.g., the identification of immunity gaps, and assessment of programme impact, 3) includes the use of disparate data sources (e.g., VPD surveillance, vaccine supply/use, programme management, serosurveys), and 4) attempts to reinforce critical thinking in processing data into information, including considering data limitations. The plan is to pilot-test draft guidance in two countries in 2019, and finalize the document in 2020 (Annex 2) (10).

6.4 Using an approach of continuous quality improvement and health systems strengthening

Continuous quality improvement (CQI) has been defined as the combined and continual efforts of everyone — healthcare professionals, patients and their families, researchers, payers, planners and educators — to make the changes that will lead to better patient outcomes (health), better system performance (care), and better professional development (229). CQI encourages stakeholders across the healthcare system — not only in the immunization programme — to continuously ask the questions: “How are we doing?” and “Can we do it better?” (230). It is a cyclical process of assessing performance, implementing improvement plans, and reassessing results to constantly strive to reach the best possible outcomes through data-driven decision-making (231) (Figure 6.2). Experiences in implementing a CQI approach for health system strengthening in LMICs have shown increases in ownership of the data and in the use of data for action (232). Ideally, this process occurs from the lowest (point of care) level all the way up to the highest level. Recent guidance has been developed on how to develop a continuous immunization supply chain improvement plan: [How to Develop a Continuous Improvement Plan \(cIP\)](#) (2018). It would be helpful for WHO/UNICEF to develop a plan for how these principles could be applied more broadly to EPI.

To date, assessments of immunization data quality in many settings has remained a top-down approach driven by the requirements of international agencies, rather than a country-led process focusing on improving healthcare delivery. As tools have been refined over time, including the latest DQR and *Handbook on the use, collection and improvement of immunization data*, increasing emphasis has been placed on performing a root-cause analysis of poor data quality to inform the development of a Data Improvement Plan (DIP) (15, 233) (see Chapter 2.3.2). The review findings can be used to identify barriers and propose tailored solutions that would be most effective. However, the reality shows that many DIPs are not evidence-based and do not include actionable recommendations and appropriate indicators to monitor progress on data quality. Preliminary findings from 34/40 (85%) DIPs systematically reviewed show that <45.5% included indicators, only 30% estimated the budget; 60% indicated the agency responsible for carrying out the activity and only 24% identified a responsible person (Davis L, King A. personal communication). The review is ongoing.

Figure 6.2. Schematic of possible Continuous Quality Improvement (CQI) cycle to strengthen data quality and use

Since 2000, Gavi has used vaccination coverage targets as part of its performance-based incentive schemes, in which countries become eligible for financial support for new vaccine introductions when national vaccination coverage levels meet or exceed a specified threshold (77). These pressures of crossing minimum thresholds to obtain additional financial support are often substantial and may encourage programmes to either game the system or falsify the data (234), potentially creating false reassurance about population protection against VPDs, as well as undermining data quality (see *Governance Chapter 3*).

To differentiate between a “measurement culture” and a “performance culture” (235), recent efforts have explored monitoring coverage of multiple vaccines doses (e.g., including BCG, DTP1, DTP3 and MCV1) rather than just one antigen (DTP3), as well as and monitoring relative immunization service delivery improvements (e.g. % improvement since previous period) alongside achievement of absolute vaccination coverage performance targets (89, 236) (*Annex 9*). Another benefit of assessing relative change is that some types of data quality issues, such as consistently inaccurate denominators, could be partially overcome (236). Aside from publications that have used such relative measures (89, 236), we are unaware of any research on the utility and effectiveness of relative measures of performance improvement compared to absolute targets as a way to improve immunization service delivery, while avoiding undesirable consequences such as data fabrication.

To maximize the impact of immunization strategies, CQI must focus not only on fixed targets but also on process evaluation, supervision and monitoring. Priority should be given to setting up mechanisms and processes that are institutionalized and sustainable to improve data quality and use at all levels of the health system. Examples of a long-standing institutionalized CQI programme from the U.S. immunization programme and a CQI intervention in the health system in Peru are described in Boxes 6.7 and 6.8, respectively (*Annex 23*). When trying to address improvements over different areas of the health system, the use of a “maturity grid” to assess country capacities may be helpful in prioritizing and coordinating technical support for improvement. The use of maturity grids for immunization programmes and VPD surveillance have recently been proposed for Africa (237). A draft WHO technical package to strengthen country health data for universal health coverage and the health-related SDGs called SCORE (Survey, Count, Optimize, Review, and Enable) also features a maturity grid. The WG advises

optimizing coordination of the global and regional EPI programs with such health systems approaches to create synergies and improve efficiency.

Box 6.7 AFIX Program in the U.S. for continual improvement of the immunization program

[AFIX](#) (Assessment, Feedback, Incentives, eXchange) is a strategy started in the U.S. during the 1980s focused on improving child and adolescent coverage at health clinics providing free vaccines to low income families by reducing missed opportunities to vaccinate and improving immunization delivery practices. The AFIX Program consists of four components:

- Assessment involves generating reports on vaccination coverage levels of selected health care providers and examining the effectiveness of providers' immunization delivery practices.
- Feedback provides an opportunity to share assessment results with each provider, discuss practice procedures and barriers, and collaborate to develop customized improvement strategies.
- Incentives recognize provider accomplishments and can be powerful motivation for providers to improve vaccination coverage rates.
- eXchange is the regular follow-up with providers to monitor their quality improvement progress and offer support through guidance and Incentives.

AFIX supports health care providers by identifying low immunization rates, determining opportunities for improving immunization delivery practices, and ensuring that providers are:

- Aware of their immunization rates and missed opportunities to vaccinate
- Motivated to incorporate changes into their current practices
- Ready to try new immunization service strategies
- Capable of sustaining improvements to their vaccination delivery services

Source: [AFIX website](#).

Box 6.8 Continuous quality improvement intervention in Peru

In Peru, with support from USAID, a continuous quality assurance programme was created covering child and maternal health services in half of the country, centered on an accreditation system of 90 major hospitals heading regional networks of health services. The accreditation was based on process indicators, rather than on fixed outcomes. Teams of healthcare staff engaged in a peer problem-solving methodology to develop a quality improvement plan in the areas of: data to make decisions, essential equipment and supplies, standardization of care, patient satisfaction and working with the health service network and with community health workers.

To monitor and catalyze the quality improvement system, indicators were established based on each quality areas described. A team was trained in independent assessment and made at least two visits to each hospital. Impressive improvements were observed across most indicators, reaching >80% of approval in all categories. All hospitals were able to be accredited, the main reward of which was a diploma signed by the MoH officials given to all members of the quality assurance team. Utilization of health services improved dramatically, as measured by the proportion of children and pregnant women covered by programs, and a significant drop in maternal mortality was observed only in the regions of Peru where the programme worked, documented by the country DHS surveys. Importantly, when several variables not used in the accreditation system were measured, important improvements in all of them also existed, including immunization practices and coverage ([Annex 22](#)).

6.5 Conclusion

There is a dynamic and cyclical relationship between data quality and data use. Although poor data quality has been reported as an important barrier to data use, the evidence to date suggests that greater availability of high-quality data, on its own, is insufficient to ensure that the data are actually used (8). On the contrary, limited evidence suggests that data quality improves through its use (88). Presumably, as decision-makers start using their data and identifying inconsistencies with the quality of the data, they will take corrective actions to improve data quality. Increasing and improving the use of data — and ultimately the performance of the immunization programme — can come about both by strengthening the data-related skills and knowledge of health workers (see *Workforce Chapter 4*) and by making better use of a diverse range of available, often-underused data, including by performing data triangulation. In addition, shifting from periodic assessments to the routine monitoring of data quality, as part of monitoring the performance of the immunization programme, will provide a stronger framework for accountability and confidence in the data. It is also critical that efforts to improve immunization data quality and use be part of broader efforts to improve the overall performance of the immunization programme and larger health system.

7. Evidence

7.1 Gaps in evidence

The WG's scope of this work included vaccine coverage, immunization programme process indicators (e.g., vaccination sessions), vaccine supply, and VPD surveillance data. We did not assess evidence or make recommendations outside these areas.

In relation to “data quality”, an important challenge encountered by the WG included the lack of a consensus definition on the term and a lack of an agreed approach to monitoring data quality. To address these fundamental gaps, the WG proposed a working definition and outlined attributes of data quality and associated indicators, as well as uses of data by level in order to advance the discussion. Further field-testing and feedback from users are needed before key indicators can be adopted as part of any global monitoring framework, e.g., for the next Global Immunization Strategy. Of note, relevant data quality indicators are likely to differ by context and level.

Another fundamental challenge is sparse evidence on how better data quality and use leads to better decision-making and better immunization programme performance. While these relationships have been demonstrated in the field of healthcare quality improvement, further work to examine the relationship between data quality, data use, and immunization programme improvement would be useful. The IDEA project created an evidence gap map that highlights that more evidence exists on the impact of interventions on improved data quality and availability, but less evidence on what works to support decision-making informed by data, particularly at the facility level (Gap Map, [IDEA Report](#) *Precis Annex in Yellow Book*) (88). Nevertheless, and reassuringly, “data-driven” impact has been demonstrated in other sectors from leadership guiding their managerial decisions using data (238, 239).

This report highlights that ultimately data quality at all levels is underpinned by the quality of data collection and processing at the local level (facility or community), but also affected by errors that may occur during data entry and aggregation as data is reported up. Comprehensive evidence on the relative contribution of different types of data errors, at different levels, and the relative impact of different types of interventions to increase data quality is lacking. More evidence is needed around what the motivating and demotivating factors are for using data and producing data of high quality.

The WG noted that much of the evidence reviewed regarding interventions designed to increase data quality and use were generally lacking robust evaluations. There is very limited evidence on the effectiveness, cost-effectiveness and sustainability of interventions which aim to improve data

quality and use. For example, despite the many pilots of novel ICT approaches to data collection, processing and reporting, few documented examples exist of evidence-based decisions on when and how to scale interventions.

The issue of denominator deserves a special mention. Better evidence around how to improve immunization targets (denominators), especially at local levels and in the context of mobile populations, was also identified as a fundamental gap. This issue was repeatedly highlighted as a key issue in most informant interviews, and also highlighted in the reviews; more guidance is desired. Denominator challenges include both technical and political dimensions, and each needs their own solutions. To address the gaps in this area, conducting further research, collaborating with other health programmes facing similar denominator issues, and considering how to move innovations from the research phase into programmatic use would be worthwhile.

GVAP adopted equity targets, but related monitoring has been hindered by the insufficient quality of subnational immunization data. Methods like data triangulation and geospatial modeling of subnational immunization coverage are some of the promising approaches for addressing geography-related issues. As with denominator data, collaborating with stakeholders in other programmes that also monitor equity (HIV, malaria, maternal health) may be beneficial to outline a common research agenda around measuring inequalities and developing strategies to improving equitable immunization coverage.

Serosurveys aim at measuring population immunity. However, serosurveillance was another area where gaps exist, though they have been conducted in high-income countries for years and are being increasingly conducted in middle and low-income countries. These surveys may also contribute to improving immunization data quality through triangulation with vaccination coverage data. WHO has produced guidelines for conducting serosurveys for hepatitis, measles and rubella, dengue, and tetanus. Yet, more needs to be done to summarize the evidence regarding the utility of serosurveys by disease and different epidemiologic/county contexts and comment on the role of serosurveys as part of immunization programme monitoring (e.g., relative to other programme priorities).

Finally, the WG is proposing greater emphasis on continuous quality improvement approaches. Closer evaluation of existing approaches from other health fields would be useful, as well as conducting immunization programme research in different contexts. One specific question is whether moving targets, or relative increases in performance over baseline, in combination with a focus on targeted strategies to reach unvaccinated persons might generate greater success than focusing on absolute performance targets.

7.2 Research Agenda

The section below summarises specific research topics based on the identified gaps in the evidence. It should be noted that based on the objectives and situation of data quality and use in each country, local evidence should be considered, and a research agenda developed.

Data quality and use

- Documenting which data are most useful at different levels in different contexts
- Testing the feasibility and usefulness of implementing data quality and use indicators suggested in this report
- Evaluating the impact data quality and use interventions in terms of impact on indicators, cost effectiveness and time efficiency.
- Documenting examples of countries that succeeded or failed to improve data quality and use in a systematic and/or sustainable manner through case studies
- Identifying and characterizing the technical and non-technical barriers to denominator estimation and numerators and how can they be overcome
- Defining data quality and use assessment/validation approaches for VPD surveillance data

Workforce

- Evaluating the effectiveness, cost effectiveness and sustainability of interventions aimed at strengthening data-related workforce capacities, including evaluating the immunization competency assessment and training
- Identifying factors that motivate/demotivate health workers collect and use data to improve vaccination delivery
- Documenting best practices on training for immunization and surveillance data

Information systems and tools

- Qualitative research to better understand what is needed for integrated systems to meet needs of immunization and VPD surveillance programs, and what are the advantages and efficiencies created
- Evaluating effectiveness and cost-effectiveness of novel technologies to improve data quality and use in different contexts
- Documenting processes and outcomes of scaling of novel technologies, including the replacement of conventional data tools

Data triangulation, including modeling

- Field testing of data triangulation guidance (currently in draft state), in particular triangulating coverage with VPD surveillance and vaccine supply data) and documenting instances of the use of data triangulation in service delivery and its impact on data quality and use and programmatic decision-making
- Validating modeled subnational coverage data, and evaluation of usefulness in overcoming data quality issues with reported subnational administrative coverage
- Exploring modelling approaches and incorporation of other inputs, such as vaccine supply data, as part of WUENIC

Monitoring and accountability- or CQI

- Determining what incentives lead to both improved data quality and programme performance
- Evaluating the potential impact of CQI interventions on improving data quality and use
- Evaluating the impact of relative vs. absolute targets on programme performance. Thus, avoiding perverse incentives that may lead to inflated reported coverage
- Document examples of how “health system approaches” have improved immunisation and surveillance data quality and use in a systematic review of the evidence.

Other topics (denominator, equity, life-course, surveys)

- Developing a research agenda around denominators to better understand technical and non-technical barriers to denominator estimation and how can they be overcome
- Determining the effectiveness and cost of GIS and other methods for improving population denominators
- Exploring how to enumerate special populations such as migrants, asylum seekers and age groups beyond infancy, etc. (lessons learned from NGOs, polio) and then monitor vaccination in these groups
- For coverage equity, developing standardized equity monitoring indicators and approaches
- For coverage surveys, implementing the research that has been identified (13), notably around:
 1. Validity of respondent recall,
 2. Utility of facility traceback to improve documentation of vaccination vis-à-vis costs,
 3. Feasibility of different household sampling methods (e.g., GIS grids),
 4. Analytic approaches to dealing with missing information, and
 5. Easier proxies to wealth questions and computation

- Serosurveys
 1. Research on the feasibility of integrating immunization coverage and VPD serosurveys with other large surveys/serosurveys (HIV, malaria),
 2. Triangulation of seroprevalence, coverage estimates and other data
 3. Implementation research on the usefulness of new laboratory technologies with improved performance characteristics (point-of-care, multiplex, capture ELISAs with improved sensitivity and specificity)

8. Moving Forward

There is no shortage of immunization and VPD surveillance data, at all levels — local, national, regional, and global. The global strategic drive towards better quality data is based on the assumption that use of quality data is a catalyst for improving programme performance and efficiency. Yet despite tremendous progress, coverage has plateaued, and the EPI programme still has the potential to reach more and more people with lifesaving vaccines. A number of possibilities therefore exist:

- Quality data, i.e., fit for purpose, exists but is not sufficiently accessible where needed to inform public health action;
- Data is not of sufficient quality for use; or
- Data is available, but not used.

This report highlights that the current situation is a likely result of a combination of these three factors. Though evidence that high data quality improves data use is lacking, use seems to improve quality. Using better data will ultimately contribute to better identifying and targeting those who are eligible for vaccination.

A barrier to evaluating the importance of data quality in improving programme performance may be a lack of common operational definition and monitoring framework for assessing data quality. This report suggests a definition for data quality as well as a list of attributes contributing to quality data. This report takes a pragmatic approach and suggests a definition of data quality as “good enough for the intended purpose,” such as monitoring performance, supporting efficient programme management, or providing evidence for decision-making. We recommend that SAGE endorses this definition and that WHO agrees on data quality attributes using those suggested in the report as a starting point to including data quality as part of a comprehensive immunization monitoring framework in the near future.

Historically, the data quality debate has been too focused on vaccine coverage accuracy at the global level and the monitoring needs of global stakeholders, rather than producing data of sufficient quality to accomplish to goals (e.g., finding un or under vaccinated persons and preventing disease). This report recognizes that data quality at all levels ultimately depends on the quality of data collection at the point of vaccination. Thus, *data quality interventions must target the local level where data collection occurs*. In addition, the use of data at the national level downwards, down to the level where individuals are vaccinated, is modest at best. In order to achieve impact, we need to refocus the data quality debate on underlying causes of insufficient data quality and use at national and subnational level, and in particular at the facility level.

Even where the local level collects and reports quality data, more often than not there is no feedback of analyzed data from the higher levels to enable facilities to use these data to address gaps in the immunization programme. Creating a strong “data use culture” where data is collected, reported, analysed and fed-back as intelligence relevant to improving the delivery of an immunization programme would go a long way in driving data quality upwards. Such a data use culture emphasizes moving beyond sporadic data quality reviews and assessments (often perceived as “tick box” requirements) that treat quality data as an outcome, to supportive continuous quality improvement interventions that demonstrate the public health impact of better data to those who use it.

This report suggests consideration of several complementary approaches to optimize the use of existing data in order to move beyond the exclusive use of vaccine coverage data as the hallmark of immunization programme performance and immunization data quality: (i) Triangulation, or synthesizing existing data from two or more sources (e.g., coverage and surveillance data), is a pragmatic approach that is commonly (but not systematically) used in the public health field. This report suggests triangulation should become the default approach for EPI data analysis and use; (ii) giving prominence to other data sources such as surveillance data; (iii) moving away from evaluating programme performance exclusively against absolute performance targets. While achieving targets can be important in an eradication, elimination or disease control context, it can create perverse incentives, in particular when reaching these targets have financial implications. This report proposes that data quality be monitored alongside data used to monitor performance (e.g. mainly vaccine coverage) using a panel of indicators, and that gradual improvement of performance and data quality are rewarded alongside reaching coverage targets.

Optimal data quality and use ultimately requires a skilled workforce. Currently, capacity, capabilities and, in many cases, structural factors are limiting factors. It is crucial to understand that data are collected by individuals at the local level who often have to balance clinical duties with data related activities. It is assumed that at the local level healthcare workers will collect, input, report and sometimes analyse the data on top of their clinical activities. In practice, data related activities compete with clinical duties for staff time, and data is often an afterthought. To improve data quality and use, data related activities need dedicated time, and staff need to be equipped and motivated to perform the data-related activities expected of them. Creating capacity and capability requires including dedicated data-related time in workforce planning at all levels, and a multi-pronged training approach that includes both pre-service and in-service components, with regular reinforcement through supervision and feedback. This report attempts to define what the data-related expectations are at each level, which can help inform staff time and training requirements. In addition to the often overlooked workforce, this report also highlighted important issues related to governance, such as having enough financing for data collection and analysis, government leadership, coordination with partners to prevent fragmented data systems, setting data and information system standards, and data sharing agreements.

Technology and innovation are often used to non-specifically to compensate for the root causes of insufficient data quality highlighted above. The plethora of pilot projects that fail, are never scaled up or never evaluated is testament to the fact that while technology can solve technological problems, it is not a magic bullet that solves all data quality and use issues. Certain applications of technology such as the combination of global information systems (GIS) and predictive analytics to generate population estimates i.e., denominators, could prove to be genuine advances in our ability to better monitor vaccine programmes. Not all innovations will prove to add public health value and the limited data available regarding the effectiveness and costs of digital health solutions is telling of how much more we need to learn before we can properly make evidence-based decisions regarding the use of new technologies. Innovation such as health information systems, in the right context, can improve the quality of immunization and surveillance data quality, and decision-making tools such as dashboards have the potential to drive data use, and as such, the WG is supportive of the development of WIISE.

Despite most countries gradually transitioning to electronic HIS, the tension between standalone and integrated systems remains unresolved. In theory, integrated approaches are generally more efficient, both from the country perspective and from the perspective of the frontline healthcare worker doing all the data collection for various programme areas. But, in practice this requires coordination across programme areas and developing and integrating EPI programme standards into a whole-systems approaches to data management. In some cases, standalone tools continue to exist because integrated systems do not adequately address the needs of the EPI program. The utilization of well-planned and coordinated integrated information systems, training, and assessment approaches has the potential to create greater synergy on health system strengthening that can be cost-saving and time efficient. Regardless of the approach, the successful use of digital health interventions still requires the right contextual factors to be in place – infrastructure, resources, connectivity, governance, clear processes and a skilled and motivated workforce – to use well-designed user-centered tools.

Improving data quality in itself is necessary but not sufficient to improve vaccine programmes. Users must be able to find the data they need and guidance on how to use it in an optimal way. This report highlights the plethora of available data and related guidance on various aspects of data use, collection, monitoring, and quality assessment. However, these data and guidance are not necessarily easily discoverable or accessible. WHO, UNICEF and global must ensure that global data collection continues and is strengthened so that those who need data at the global level can find it and those who manage and use data to deliver the immunization programme can easily find relevant guidance. The latter can be done by making guidance easily discoverable on relevant communication channels such as websites and apps, and by analyzing carefully where guidance is needed in order to prevent duplication. In addition, immunization and surveillance data must be shared in way that is proportionate to public health needs and in a manner that ensures the benefits of the data are shared equitably.

As the global EPI matures and coverage improves, the growing number of immunized individuals increasingly requires enhanced use of better quality data. As vaccine coverage has increased dramatically in most settings since the beginning of the 21st century, closing the immunization gap will require to use data to answer questions such as: How equitable is immunization service delivery? Are we reaching underserved populations such as migrant populations or those living in slums? What about those who use private healthcare facilities? How are vaccines targeting groups outside infancy reaching their goals and what is their impact in those populations? Alongside strengthening the quality and use of what is considered routine data, it is time to consider what data is needed to answer these questions at the different levels, how to collect it in a cost-effective manner, and more importantly how to ensure that it achieves the objective of improving the delivery of the immunization programme in terms of effectiveness and efficiency. This report suggests answering these questions should be prioritized as part of the research agenda.

Finally, while this report focuses on immunization data, this report recognizes that data quality and use issues encountered in the EPI are not unique. It also acknowledges that in many cases, and in particular at the most local level, individuals responsible for immunization data will also manage data from other public health programmes, who will commission similar reviews on data quality and use. While the structure of public health programmes precludes an exclusively whole health systems approach, there is value in the global immunization programme working through a whole health systems approach, collaborating more closely with other programmes on data quality and use issues, as well as data initiatives that are not programme specific, within WHO or outside.

9. Recommendations

Achieving equitable immunization coverage and timely detection of VPDs requires high-quality programme data. Concerns about the quality and use of immunization and VPD surveillance data have been highlighted on the global agenda for more than two decades. As countries strive to meet the ambitious goals of GVAP and future goals Post-2020, improved information systems and more precise and finer types of measurements will be required to achieve improvements in equity of service delivery across the life-course and reductions in disease burden for an expanded set of VPDs.

The WG defined “data quality” as the degree to which data are fit for the intended purpose (i.e., accurate, precise, relevant, complete, and timely enough for use). Following a 1.5-year review, the SAGE WG on the Quality and Use of Global Immunization and Surveillance Data recommended the following actions at various levels to be considered by SAGE.

1. Embed monitoring of data quality and use into global, regional and country monitoring of immunization and VPD surveillance.⁶

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) WHO to develop a common definition, attributes and indicators of data quality attributes (i.e., small panel of indicators corresponding to the different data quality attributes), using those identified in this report as a starting point	G	1, 2, 6
b) Integrate ongoing monitoring of data quality indicators alongside other routine programme performance (e.g., coverage) and outcome indicators (e.g., disease incidence)	G R N	2,6
c) Develop and utilize data quality assessment approaches for immunization programme data other than coverage (i.e., VPD surveillance, stock data, etc.)	G R N	2,6
d) Evaluate the impact, cost, and sustainability of interventions which aim to improve data quality, management, and use to inform decisions on scale-up	G R N	3,5,7

2. Increase workforce capacity and capability for data quality and use, starting at the lowest level where data collection occurs.⁷

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) Develop and disseminate data-related competencies guidance and capacity building tools to implement assessment of workforce at country-level	G R N	2,4
b) Ensure data functions (collection, analysis, and use) are accounted for and resourced in workforce management plans, e.g., devoting adequate person-time equivalents, staff recruitment, retention	N	4
c) Build data capabilities with training across various levels and career stages (pre-service, refresher, supportive supervision, etc.), considering new approaches (e.g., e-Learning) potential efficiencies created by coordination across programs	G R N	4

⁶ The recommendation builds on a SAGE recommendation to “continuously review the Progress on GVAP and the need for reformulation of the indicators or mechanisms for collection and reporting of data” (Nov. 2012).

⁷ This recommendation builds on a SAGE recommendation to “create tools to assist countries in different aspects of immunization human resources management including: staff turnover and rotation policies, performance evaluations, and design of training” (April 2017).

3. Take actions to improve the accuracy of immunization programme targets (denominators).

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) WHO and UNICEF to revise and finalize the draft guidance on <i>Assessing and Improving the Accuracy of Target Population Estimates for Immunization Coverage</i> (2015), including proposing practical and evidence-based solutions	G	2
b) Increase immunization programme coordination with national statistics office, birth/civil registration offices, and other relevant programmes/organizations for improving the quality of denominators	N	3
c) Identify and attempt to address the technical (e.g., resident vs non-resident) and non-technical barriers (e.g., political) to accurate denominators in countries, including the use of operational denominators	G R N	2,3,5,6
d) Document best practices and country experiences about using different sources of denominators (birth cohorts, vital registries and census estimates) or methods for improving denominators.	G R N	2,3,5,6

4. Enhance the use of existing data at all levels for tailored action, including immunization programme planning, management, and policy-change.

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) At all levels, increase the use of data sources beyond administrative coverage for monitoring, planning and decision-making (e.g., numerators, denominators, surveys, surveillance, vaccine supply, service delivery, serosurveys)	G R N	6
b) Develop and incorporate guidance and training on data triangulation for immunization and surveillance programmes at the national and subnational levels	G R N	2,6
c) Support the development and use of decision-support tools (e.g., monitoring charts, dashboards), as needed, for better planning and programme management	G R N	5,6
d) Further work on defining the role of serosurveys for immunization programme management at different levels, across different diseases and different epidemiological contexts ⁸	G	7

⁸ This would strengthen previous SAGE recommendations “that WHO identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage...as well as support new research for biological specimen collection including rapid on-site diagnostics that could improve coverage and susceptibility estimates” (November 2011) and “Where feasible, the use of (tetanus) serosurveys to validate assessment of risk identified from other data sources should be considered to guide vaccination strategies, especially in high-risk districts. Close attention should be paid to sampling strategies and laboratory methods to ensure that results are valid and interpretable. WHO should provide guidance on: sampling methods; sample collection and testing; and analysis, interpretation and use of serosurvey data for monitoring. WHO should consider establishing reference laboratories and reference serum panels to support standardization and quality assurance of the laboratory methods used in serosurveys” (October 2016).

5. Adopt a data-driven continuous quality improvement (CQI) approach as part of health system strengthening at all levels.

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) Shift from identifying data quality issues to root cause analysis and improvement planning, as outlined in the draft <i>Handbook on the Use, Collection and Improvement of Immunization Data</i>	GRN	6
b) Monitor the implementation and impact of previous recommendations to improve accountability and inform new recommendations (e.g. create data-driven improvement cycles)	GRN	6
c) Strengthen data collection and use by implementing multi-component strategies, which may include capacity-building activities, tools, supportive supervision, actionable feedback, staff recognition (e.g. certificates, awards) and accountability mechanisms	GRN	3,4,5,6
d) Recognize that perverse incentives may have led to overestimation in reported coverage, and ensure that data quality improvements leading to lower coverage are not penalized (i.e., promote accurate reporting)	GRN	3,6
e) Develop a vision for a CQI approach for EPI, including measuring relative changes, in addition to achieving absolute indicator targets	GRN	6

6. Strengthen governance around piloting and implementation of new information, communication, and technology (ICT) tools for immunization and surveillance data collection and use.

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) Design systems and tools based on needs, user requirements, and local context ⁹	GRN	3,5
b) Review existing evidence on cost, impact and effectiveness when considering pilot or scale-up new tools for data collection/ management	GRN	5,7
c) Plan for and ensure integration and interoperability of any newly introduced tools within the existing information system	GRN	3,5
d) Ensure any new information system includes historical data, supports all data management functions (archiving, security and linkage of relevant data), and are accompanied by guidance, standards and specification	GRN	2,3,5

7. Improve data sharing and knowledge management across areas and organizations (e.g., private sector) for improved transparency and efficiency.

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) Include best practices on data management (archiving, migration, sharing, and security) in immunization monitoring and surveillance guidance and training	GRN	3
b) Make data, guidelines, documentation, and reports readily available and accessible to relevant users by building and maintaining user-friendly websites, mobile apps and other communication tools	GRN	2
c) Improve routine coordination between stakeholders (epidemiologic surveillance, laboratory, and immunization units; private providers, CSOs and partners) with regards to reporting/sharing of relevant data and information	GRN	3,6

⁹ [PAHO Electronic Immunization Registries \(eIR\) Guide \(2018\)](#)
[Planning and Information Systems Project \(2013\)](#)

8. WHO and UNICEF to strengthen global reporting and monitoring of immunization and surveillance data through a periodic needs assessment and revision process.

	<u>Relevant levels</u>	<u>Chapters providing evidence</u>
a) Continue development and implementation of global (WIISE) and regional information systems and electronic JRF for coverage and surveillance data	GR	2
b) Collect and monitor disaggregated coverage (e.g., subnational) and surveillance data (e.g., by age group, vaccination status, lab confirmation) ¹⁰	GR	2,6
c) Develop approaches for data collection and monitoring of emerging immunization issues, e.g., coverage equity, vaccination across the life-course, vaccination coverage and disease incidence among migrants /mobile populations, management and use of qualitative data (e.g., reasons for non-vaccination, recommendations from assessments)	G	2,3,4, 5, 6
d) Collaborate to convene new research and validate existing research for improving denominators and national/ subnational coverage (e.g., spatial modeling), including use of data sources beyond coverage (e.g., stock) to inform guidance for programme use.	G	2, 6

9. WHO SAGE should periodically review the implementation status of the WG recommendations, lessons learned and gaps to be addressed.

¹⁰ This recommendation reinforces earlier SAGE recommendation “that additional disaggregation was needed in the analysis of the progress achieved on the ground, and in identifying bottlenecks for progress, and recommended that reports display disparities observed at subnational levels” (April 2015) and “that the accumulation of susceptible persons at both the national and subnational level should continue to be monitored to identify and address immunity gaps” (October 2016).

10. Table of Annexes

Annex in Yellow Book

Precis from IDEA realist review report ([full report¹¹](#)) (TOR 4b)

Online Annexes

1. Global Framework to Strengthen Immunization and Surveillance Data for Decision-making
2. Framework for Triangulation for Immunization and Surveillance Data (TOR3)
3. Table of data quality attributes (TOR3)
4. Summary of key informant interviews on EPI data availability (TOR1)
5. Triangulation analysis of tetanus vaccination and surveillance data (TOR3)
6. *Case study*: Electronic immunization registry, Chile
7. Literature review: Barriers limiting quality of VPD surveillance data (TOR 4a)
8. Summary table of global EPI guidance (TOR2)
9. Summary table from review of data quality indicators (TOR3)
10. *Case study*: Improving vaccination coverage data quality, China
11. *Case study*: Utilization of data for evidence-based decision-making, India
12. *Case study*: Efforts to improve data quality and use, Nigeria
13. Literature review: Novel methods for polio surveillance (TOR5)
14. Scoping review: Factors limiting immunization data quality in LMIC (TOR 4a)
15. Scoping review: Pre- and in-service training on immunization data in LMIC
16. Summary table of innovations for immunization and surveillance data (TOR5)
17. Literature review: Novel approaches for immunization data (TOR5)
18. *Case study*: Integration of VPDs into communicable disease surveillance, Vietnam
19. *Case study*: Polio map-athon — using georeferenced data to strengthen microplans
20. Proposal to SAGE on role of serosurveillance for immunization monitoring
21. *Case study*: Improving the quality and use of vaccine coverage data, England
22. *Case study*: Using polio campaign data to improve EPI Coverage, Pakistan
23. *Case study*: Continuous quality assurance processes, Peru
24. References for this report

¹¹ <https://findyourfinding.org/>

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