

Monitoring COVID-19 vaccination

Considerations for the collection and use of vaccination data

INTERIM GUIDANCE
3 MARCH 2021



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WHO and UNICEF continue to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO and UNICEF will issue a further update. Otherwise, this interim guidance will expire 5 years after the date of publication.

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Abbreviations

AEFI	adverse events following immunization
AMC	COVAX Advance Market Commitment
BeSD	behavioural and social drivers
CEPI	Coalition for Epidemic Preparedness Innovations
CES	coverage evaluation surveys
COVAX	vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator
DHIS2	District Health Information System
DHS	Demographic and Health Surveys
EIR	electronic immunization registries
eJRF	electronic Joint Reporting Form
GIS	geographical information systems
HMIS	health management information system
HRMS	human resources management system
LMIC	low- and middle-income countries
LMIS	logistics management information system
MICS	Multiple Indicator Cluster Surveys
NHWA	National Health Workforce Accounts
NRA	national regulatory authority
PCCS	post-campaign coverage surveys
PPE	personal protective equipment
UNICEF	United Nations Children’s Fund
US CDC	United States Centers for Disease Control and Prevention
WHO	World Health Organization

1. Context

1.1 Background

Vaccines are being developed and rolled out at record speed in response to the COVID-19 pandemic. COVAX, a facility co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO, aims to accelerate the development and production of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

1.2 Assumptions

For most countries, large-scale vaccination efforts will start in the first half of 2021. Demand will outpace supply, and countries will need to prioritize who to target first for vaccination, based on risk and epidemiological considerations. Many of these efforts will be organized in “waves”, targeting different population groups in a staggered manner based on prioritization and as more vaccine doses become available. Current global guidelines¹ call for the prioritization of health workers, older people and people suffering from pre-existing conditions, which increase their risk of severe disease. Reaching these people will require novel vaccination strategies in most countries, leveraging the experience and capacity of existing programmes focused on childhood and maternal immunization as well as influenza vaccination.

Beyond 2021, vaccination strategies will depend on the vaccines’ effectiveness and duration of protection, vaccine demand, and the success of vaccination programmes to deliver the vaccines. At the time of writing, no definitive data are available to ascertain the duration of protection of the different vaccine products, their ability to protect against new or future variants of the virus, or the extent to which they will be able to stop transmission of the virus by vaccinated persons.² Unless circulation can be stopped altogether, there will be an ongoing need for vaccination, either in routine programmes targeting specific age cohorts or vulnerable people, or in an outbreak control context.

It is anticipated that most vaccines will require at least two doses for optimal immunogenicity, and it is currently recommended that the same product should be used for subsequent doses, although this may change as more data become available.

1.3 Purpose of this document

As COVID-19 vaccines are being introduced, national public health authorities will experience intense demand for data by national and subnational governments, the public, civil society organizations, media, and regional and global immunization partners. This document provides guidance about:

- minimum and optional data to collect as vaccines are being rolled out and delivered;

¹ Please refer to the WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply (<https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-roadmap-covid19-vaccines.pdf>, accessed 23 February 2021).

² WHO Interim position paper: considerations regarding proof of COVID-19 for international travellers (<https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers>, accessed 23 February 2021).

- key performance indicators and the anticipated use of these – to measure the performance of key components of the immunization system and to take corrective action when needed; and
- the use of information systems to collect, store, analyse and disseminate any relevant information.

1.4 Target audience

This guidance document is primarily directed at national authorities who are responsible for the management, implementation and monitoring of COVID-19 vaccine introduction and delivery in their countries. It may also be useful for any partners who provide the required support in countries, or organizations that develop and deploy information systems to support vaccination programmes.

1.5 Scope of this document

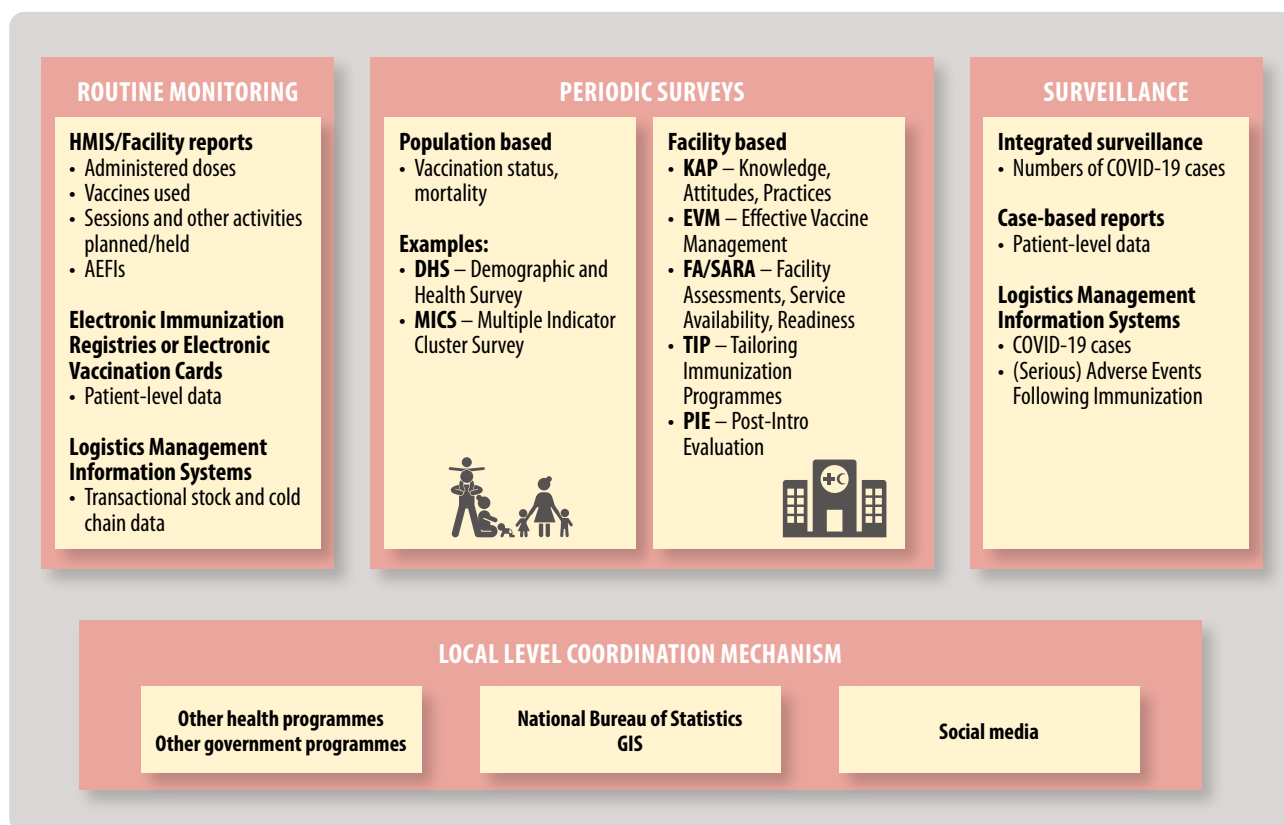
The guide focuses on the systems to monitor vaccination service delivery, including vaccine uptake and service availability, readiness and quality. Vaccine safety and effectiveness will be touched upon to the extent that documentation of vaccination will be required by surveillance systems. Since uncertainty still exists for longer term vaccination strategies and modalities, it will focus on the short-term needs in 2021 and 2022.

Immunization programmes rely on three kinds of data sources (Fig. 1):

- **Routine monitoring** through administrative systems comprise any data generated by facilities or providers, for example through periodic reports, electronic immunization registries (EIR), logistics management information systems.
- **Periodic surveys** are either directed at households or facilities and providers, evaluating aspects of service delivery and immunization outcomes.
- **Surveillance systems** aim to monitor and manage cases of vaccine-preventable diseases or adverse events following immunization (AEFI).

This guide focuses foremost on routine monitoring needs, using administrative systems. Household surveys, facility assessments, disease and safety surveillance are not in the scope of this document, although any required linkages between the vaccination monitoring system and those systems and processes will be briefly discussed.

Fig. 1. An overview of potential sources for COVID-19 vaccination data



1.6 Methods and links with other publications

This guide was developed in consultation with COVAX facility partners and WHO regional office representatives and reflects the current understanding of how the best monitoring practices from childhood immunization and influenza programmes can be applied to the monitoring of COVID-19 vaccination. The guidance is interim and will be updated based on the learning from country experiences.

The considerations presented in this document build on initial guidance contained in the WHO *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* (see Further reading). Complementary regional guidance may be published to address specific challenges and operational translation based on each region’s context.

A previously published WHO Regional Office for Europe operational guide (see Further reading) includes a brief presentation of minimum data requirements, discusses the potential use of existing monitoring systems for influenza and childhood immunization, and provides more detailed information on the development of population estimates for priority groups. This current global level guide aims to complement the WHO Regional Office for Europe operational guide by further developing considerations for data collection and use along aligned minimum data requirements, while referring to the operational guide for detailed population estimates.

BOX 1. KEY MESSAGES

- As countries gear up to deploy COVID-19 vaccines, they will need to design and implement monitoring systems to measure the progress and effectiveness of these programmes.
- This involves measuring vaccine uptake and coverage among the overall population, as well as among the at-risk populations prioritized for vaccination. Specifically, the system should allow for disaggregated monitoring among health workers, older people (over 60), people living in at-risk settings such as long-term care facilities, and people with a pre-existing condition.
- Furthermore, it will be important to monitor equitable coverage, for example, among sexes or across regions of a country.
- Targets and population estimates will be needed for priority groups. These can be estimated top-down, based on census and survey data, or developed bottom-up, for example, by drafting beneficiary lists of health workers.
- Many countries will deploy multiple vaccines simultaneously. Differences in efficacy, safety and dose requirements will necessitate the monitoring of different vaccine products separately.
- Ahead of vaccine introduction, countries are urged to develop or adapt monitoring tools and systems, including home-based vaccination records, facility-based vaccination registers, tally sheets, and electronic database systems such as health management information systems (HMIS) and EIR.
- Countries will be requested to share vaccination, safety, surveillance and other programme data with the regional and global level partners in a more frequent and timely manner than for other vaccination programmes. The requirements for regional and global reporting will be kept at a minimum to facilitate high-quality reporting.

2. Uptake and coverage monitoring

2.1 Objectives

To meet the key anticipated information needs, country programmes should design a system to:

- monitor equitable uptake and coverage by dose and completed schedule, over time by geography, by population groups, and risk groups;
- monitor to what extent national policies to prioritize at-risk groups (based on age, nature of their work or pre-existing conditions) and at-risk settings (e.g. hospital and long-term care facilities) are effectively implemented;
- provide a reliable and trusted personal vaccination record/certificate for any health, occupational, educational and travel purposes (as per national policies);
- ensure that the necessary records and documentation are in place for use in surveys, safety monitoring, disease surveillance, and vaccine effectiveness studies; and
- ensure that individuals can be monitored for the full course, in the likely case that a multi-dose schedule is required, to track defaulters and reduce the incidence of dropouts.

2.2 Coverage and equity indicators

The following indicators measure progress with vaccination among a target population:

- **Vaccine uptake or vaccination rate:** the number of people vaccinated with a certain dose of the vaccine in a certain time period (e.g. during a month or year), which can be expressed as an absolute number or as the proportion of a target population.
- **Vaccination coverage:** the vaccinated proportion of a target population. Coverage can be estimated by accounting for vaccination in previous time periods (weeks, months, years).

The difference between these two concepts is that uptake expresses vaccination activity over time, while coverage expresses the resulting protection among a population. To illustrate this difference, consider a country with a total population of 1 million people that manages to vaccinate 400 000 people with two doses each year in 2021, 2022 and 2023. What is uptake and coverage in each of these years?

- In 2021, 400 000 people received a second dose, representing 40% of the population (uptake). This is also the best estimate for coverage in 2021.
- In 2022, again 400 000 people received a second dose, representing 40% of the population. But the resulting coverage is certainly higher than 40%. Coverage may be close to 80% (cumulative uptake), but to translate uptake numbers into coverage estimates, one would need to make sure that revaccinations (boosters) are not being reported as second doses. There is also a small effect of mortality among vaccinated people and new people becoming eligible for vaccination that would need to be taken into account.

- In 2023, it becomes clear that uptake numbers cannot be easily translated into coverage estimates, since cumulative uptake exceeds 100% of the population. Boosters might have been included as second doses. Also, the target population changed slightly as some people became eligible for vaccination (reached minimum age requirement) while some others died. In the long run, different methods (like surveys) will be required to estimate coverage more precisely.

As clarified in the example above, for the first year of introduction (2021), uptake and coverage can be used interchangeably, and since this interim guidance document focuses on the initial phases of vaccine introduction, it will not go into the potential complexities of using uptake data to estimate coverage.

Uptake and coverage should be tracked by dose and can be annotated as follows:

- **COV-1:** the number of people receiving a first dose of the vaccine, or the proportion of a target group that did so. For example, 50 000 doses of COV-1, corresponding to 5% of the total population.
- **COV-2, 3:** the number or proportion of people receiving a second or third dose of the vaccine, plus any booster doses if relevant for future recommended vaccination schedules.
- **Drop-out from COV-1 to COV-2:** the proportion of people who received at least one dose of a COVID-19 vaccine but did not receive a second dose yet. Calculated as:
 - $(\text{COV-1} - \text{COV-2})/\text{COV-1}$

Note: Where multiple vaccine products with different dose requirements are used in a country, there will be a need to compare coverage across products with the last protective dose for each vaccine.

- **COV-c:** represents the number of people who received a last recommended dose of any vaccine. The “c” denotes the dose that completes the schedule, which might be a first, second or third dose depending on the product that was used. In this case, the drop-out should be calculated from COV-1 to COV-c.
- Since no data are available on the interchangeability of doses of different COVID-19 vaccines, it is currently recommended¹ that the same product should be used for subsequent doses. This implies that if an individual received a second dose with a different product, that dose needs to be counted as the first dose of that new product. These recommendations may be updated as further information becomes available on interchangeability, and monitoring practices should align with the national policy in this regard.

2.3 Disaggregated monitoring

Vaccine uptake can be evaluated by dose for the entire population of a country to show headline progress, but more granular data will be needed to measure vaccination by product and targeted population group. Disaggregated monitoring by vaccine product is required where several vaccine products are used, especially if different numbers of doses are required. Furthermore, to measure whether prioritization policies are effectively implemented, and vaccines are equitably distributed, additional dimensions of disaggregation are needed.

Table 1 summarizes minimum (recommended for all countries) and optional requirements for disaggregation. Note that countries benefiting from COVID-19 vaccines through the COVAX Advance

¹ As per SAGE interim recommendations for the use of different vaccine products that have become available to date. For example, WHO *Interim recommendations for use of the AZD1222 (ChAdOx1-S recombinant) vaccine against COVID-19 developed by Oxford University and AstraZeneca* (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1/), accessed 23 February 2021).

Market Commitment (AMC) mechanism may be required to report more detailed data. Different WHO regions may also propose different minimum reporting requirements.

Table 1. Dimensions for disaggregating vaccine uptake and coverage

Dimension	Recommended	Optional	Use and comments
Vaccine	By product and dose		<ul style="list-style-type: none"> Calculate uptake and coverage with a last recommended dose of different vaccines used in the country
Geography	By district or other subdivision		<ul style="list-style-type: none"> Monitor equitable distribution across regions in a country
Sex	Sex-disaggregated monitoring is recommended for all countries		<ul style="list-style-type: none"> Monitor gender equity COVAX may require AMC countries to record and report doses in a sex-disaggregated manner
Age group	Among older people (defined as 60 years or older)	<ul style="list-style-type: none"> More refined brackets across all ages may be considered if feasible, according to country system and needs 	<ul style="list-style-type: none"> Monitor uptake among older people, who have an increased risk for severe COVID-19 A common cut-off at 60 years old is proposed, but countries may use their own definition of older people, based on local context and prioritization Countries may add more age brackets if deemed necessary and feasible
Occupation	Among health workers, including care workers and support staffs in long-term care facilities	<ul style="list-style-type: none"> Other frontline and essential occupations according to country priorities 	<ul style="list-style-type: none"> Monitor uptake among health workers and other prioritized groups
Pre-existing conditions	Among people with at least one pre-existing condition	<ul style="list-style-type: none"> For specific, defined, conditions Among pregnant women 	<ul style="list-style-type: none"> Monitor uptake among people at risk Note: may not be feasible in all countries; challenges disaggregating doses as well as establishing targets
At-risk settings	Among residents of long-term care facilities (if exist in the country)	<ul style="list-style-type: none"> Prisons Schools High-density slums Refugee/internally displaced people settings, etc. 	<ul style="list-style-type: none"> Evaluate whether prioritization policies focused on at-risk settings are implemented
Other equity dimensions		<ul style="list-style-type: none"> Socioeconomic, ethnic, linguistic, religious, other disadvantaged 	<ul style="list-style-type: none"> Monitor equitable distribution across different populations in a country Note: only surveys may be able to measure this adequately

Disaggregated coverage or uptake monitoring requires separate recording and reporting of vaccinations administered to specific populations. Section 4 describes how this can be best organized.

Country programmes should determine whether it is useful and feasible to evaluate coverage in the mentioned subgroups. Each additional dimension of disaggregation adds complexity to the monitoring system, and the potential benefits of obtaining more detailed data should be weighed against higher workload and potential data quality problems. Disaggregated reporting is only useful if corresponding targets estimates for the relevant population can be found (see below).

2.4 Target setting and population estimates

Many low- and middle-income countries (LMIC) have limited experience with the roll-out of public health programmes that target the populations that are now prioritized for COVID-19 vaccination (health workers, older people, people with an existing condition). This means that immunization programmes need to develop strategies to mobilize and vaccinate people in each group, and it involves quantifying these

target populations. Target population estimates are needed to help with planning and micro-planning, and also for progress monitoring, and for immunization coverage estimation.

Target estimates can be established or obtained in different ways, using different in-country sources:

- **Census-based population estimates** are available from the national statistics office or similar, and exist for the total population of a country, as well as its geographic regions. These estimates should also be available by age group and sex. High-level estimates may exist for occupational categories.
- **Enumerations (counts)** could be organized for very specific beneficiaries of vaccination, such as health workers, or people in specific at-risk settings such as long-term care facilities. The HMIS may be useful to organize these enumerations from the bottom-up, for example by requesting district administrations to count and report on health workers in their jurisdiction. In that case, it is very important to be clear about the exact definition in each group. For example, the WHO definition¹ of health workers includes “all people engaged in work actions whose primary intent is to improve health”. This includes health service providers, such as doctors, nurses, midwives, public health professionals, laboratory, health and medical and non-medical technicians, personal care workers, community health workers, healers and practitioners of traditional medicine.
- **Registers and databases** may already exist for some of these priority populations, for example health workers registers, or health insurance databases.
- **Service data** for existing programmes such as influenza vaccination may provide additional estimates for people at risk.
- **Surveys**, such as Demographic and Health Surveys (DHS), may also be useful to estimate the number of people in certain categories such as people with at least one pre-existing condition, or essential occupational categories.

Ideally, denominators are based on country-level data, but in-country sources can be triangulated with and compared with publicly available data at global and regional level. The WHO Regional Office for Europe *Operational guidance: COVID-19 vaccination data and information management, including monitoring vaccine effectiveness* highlights the following sources:

- The World Population Prospects 2019,² published by the United Nations Department of Economic and Social Affairs/Population Dynamics, contains overall population estimates by country, including sex and age specific estimates.
- The National Health Workforce Accounts (NHWA)³ contain estimated numbers of health workers in WHO Member States.
- The Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) 2017 was used in a study by Clark et al., published in the *Lancet*,⁴ to model population estimates. An Excel file with these modelled estimates by country was also published,⁵ and countries can take advantage of that tool to compare

¹ For a full definition, please refer to *The world health report 2006* (https://www.who.int/whr/2006/06_chap1_en.pdf, accessed 23 February 2021).

² United Nations World Population Prospects 2019 (<https://population.un.org/wpp/Download/Standard/Population/>, accessed 23 February 2021).

³ WHO National Health Workforce Accounts Data Portal (<https://apps.who.int/nhwportal/>, accessed 23 February 2021).

⁴ Clark A, Jit M, Warren-Gash C, Guthrie B, Wang HHX, Mercer SW. Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: a modelling study. *Lancet*. 2020;8(8):E1003–E1017 ([https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(20\)30264-3/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30264-3/fulltext), accessed 23 February 2021).

⁵ Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: a modelling study (https://cmmid.github.io/topics/covid19/Global_risk_factors.html, accessed 23 February 2021).

and validate national estimates. More information on noncommunicable diseases by country can be found in the WHO Noncommunicable diseases country profiles 2018.¹

Please refer to the WHO Regional Office for Europe operational guidance in Further reading.

2.5 Use of uptake, coverage and equity indicators

Uptake, coverage and equity indicators can be used to evaluate:

- **Progress over time:** monitor vaccine uptake by total population, by geographic area, and by any population group for which disaggregated data exist. Vaccination uptake may be evaluated against targets (for example, 80% coverage among the general population), or milestones (vaccinate 50% of all people over 60 by June).
- **Prioritization:** monitor justified differences in immunization outcomes, for example, to assess to what extent older people or health workers are vaccinated ahead of the general population.
- **Inequities:** monitor unjustified differences in immunization outcomes, for example, differences between males and females, between regions of a country, or between ethnic groups.

BOX 2. COVERAGE AND EQUITY MONITORING ILLUSTRATED

Monitoring coverage by the suggested dimensions will allow public health officials to report that, for example:

- 50 000 people received a final dose of any COVID-19 vaccine by May 2021, corresponding to 5% of the total population of 1 000 000 (COV-c = 5%).
- 30 000 people received a single dose of product A, which requires one dose, and 20 000 a second dose of product B, which requires two doses.
- This total includes 15 000 health workers, out of 20 000. Coverage among health workers is thus estimated at 75%.
- 30 000 (60%) of those vaccinated were over 60 years old – corresponding to 20% coverage in this age group (30 000 out of an estimated total of 150 000).
- 40% of vaccinations were provided to males, versus 60% to females, which may indicate an equity issue, or it may indicate biases in early targeted populations (the health worker population may be more female, for example).

Note that coverage should always be expressed as a percentage of a population target, i.e. the total population in a certain country, district or priority group, rather than as a percentage of an operational target. That is, a country that plans to vaccinate 10% of its population may consider it has a 100% implementation rate if it reaches that target, but population coverage is still only 10%

¹ WHO Noncommunicable disease country profiles 2018 (<https://www.who.int/nmh/publications/ncd-profiles-2018/en/>, accessed 23 February 2021).

3. Monitoring other aspects of vaccine delivery

3.1 Objectives

Programmes will need to measure and manage service availability and readiness aspects of COVID-19 vaccine delivery, for example their human resource capacity, the availability of vaccines and supplies, the availability of personal protective equipment (PPE), or cold chain capacity. Data about these critical capacities can be reported through a monthly facility reporting system, captured in a dedicated system such as a human resources management system (HRMS) or logistics management information system (LMIS), or assessed through facility surveys.

3.2 Health service capacity assessments

Against a rapidly evolving situation, many countries may face challenges in the availability of accurate and up-to-date data on the capacities of their health services to deliver the COVID-19 vaccine(s) while simultaneously assuring continuity of routine vaccination programmes and other essential health services. In such contexts, countries may consider implementing high-frequency health facility assessments to track and monitor health service capacities and bottlenecks.

The WHO *Harmonized health service capacity assessments in the context of the COVID-19 pandemic*¹ provides tools to support rapid and accurate assessments of the current and surge capacities of health facilities throughout the different phases of the pandemic. The tools include a set of modules used to inform the prioritization of actions and decision-making at health facility, subnational and national levels. Countries may select different combinations of modules according to country context and the need for one-time or recurrent use throughout the pandemic.

3.3 Vaccines and supplies

Countries can in many cases use existing LMIS to track the distribution of vaccines and ancillary supplies such as syringes, safety boxes, vaccination cards and PPE, to the service delivery points. There are a few areas in which the use of supply data will differ between traditional vaccination programmes (such as childhood programmes) and COVID-19 vaccination.

- **Vaccine availability:** traditionally, programmes aim to achieve full availability of vaccines and supply to ensure that no vaccination opportunities are missed. In the context of limited supply, stock-outs are expected and do not provide a good performance indicator for the supply system.
- **Wastage:** traditionally, some wastage is expected and accepted as a price to pay for achieving high coverage, especially for vaccines that are presented in multi-dose vials. In the context of limited supply however, every wasted dose represents a missed opportunity for vaccination, and the target for wastage should be close to zero.

¹ *Harmonized health service capacity assessments in the context of the COVID-19 pandemic* (<https://www.who.int/teams/integrated-health-services/monitoring-health-services>, accessed 23 February 2021).

Additional indicators that may be useful for COVID-19 vaccines are:

- Vaccines allocated:** the number doses of vaccines allocated to a certain region or district as a percentage of the total population, or the percentage of people eligible at a certain phase in the vaccine roll-out, divided by the number of doses in the schedule. This provides a sense of the vaccine sufficiency and fair distribution of vaccines in a country.
- Vaccines delivered:** the number of doses distributed during a time period, as a percentage of the number of allocated doses for the same period.
- Administered vaccines:** this number can also be compared with delivered vaccines to assess the efficiency of the vaccination process by facility or district.

3.4 Human resources

The roll-out of COVID-19 vaccine in countries will be impacted by the availability and capacity of health workers, including vaccinators, community mobilizers and supervisors. Country programmes should maintain a system to monitor and track health workers and community mobilizers who can be deployed for the vaccine roll-out. The system can be either paper based or electronic, and can collect either aggregate data about the numbers of health workers involved with COVID-19 vaccination, and in post by week or month, or keep track of individual health worker data, including:

- worker personal profile information (name, job title)
- work location, including district, subdistrict
- length of service (hire date)
- local languages spoken
- trained in vaccination administration and related duties
- trained in communication
- trained for COVID-19 vaccination
- tested for COVID-19
- vaccinated for COVID-19.

Data from the monitoring system will assist programmes with characterizing the workforce at the subnational level and developing strategies for addressing human resources gaps.

3.5 Vaccine safety

As with any vaccine roll-out, it is very important to monitor vaccine safety. This involves recording, investigating, and reporting any AEFI. Typically, case investigation reports are made for serious cases, while a full line list of all detected cases is used by district, intermediary, and national levels, and shared with the national regulatory authority (NRA). Sometimes, aggregate numbers of serious and non-serious AEFI are also reported through the administrative reporting system. Monitoring these numbers can provide early warnings about safety concerns with a certain vaccine or vaccine batch, or about unsafe administration practices. Comprehensive guidance for safety surveillance and AEFI monitoring is provided in a WHO *Covid-19 vaccines: safety surveillance manual*.¹

3.6 Vaccine demand

Please refer to the interim guidance – *Acceptance and demand for COVID-19 vaccines* (see Further reading).

¹ *Covid-19 vaccines: safety surveillance manual*. Geneva: World Health Organization; 2020 (<https://www.who.int/publications/i/item/10665338400>, accessed 23 February 2021).

4. Monitoring systems

4.1 Overview

Vaccine uptake and other aspects of vaccine delivery can be monitored through an “administrative system” or evaluated through surveys. These two sources are complementary:

- **Administrative reporting systems** can provide data about vaccinations, AEFI, vaccine usage, cases of vaccine-preventable diseases and other service-level data in a frequent and timely manner. They are limited in the number of ways data can be disaggregated and depend on reliable population estimates and accurate reporting.
- **Household surveys** can provide reliable coverage estimates based on representative sampling and offer more possibilities for disaggregate coverage evaluation than administrative systems can, they can also provide insights into aspects of demand, and the public’s perception of the quality of services. They are, however, more expensive, and their quality depends on the availability of reliable vaccination records. They are available in a less timely and less frequent manner.

BOX 3. THE ROLE OF COVERAGE EVALUATION SURVEYS IN COVID-19 VACCINATION EFFORTS

Household surveys such as Demographic and Health Surveys (DHS), Multiple Indicator Cluster Surveys (MICS), and vaccination coverage surveys, also known as coverage evaluation surveys (CES), are often used in LMIC to complement administrative coverage estimates, and to collect additional data for public health programmes such as childhood immunization. A similar sample-based approach could be used to provide snapshots of progress with COVID-19 vaccine introduction. However, in an early stage, surveys will likely be inefficient because a very large number of household interviews need to be conducted to find a relatively low number of vaccinated individuals. COVID-19 containment measures may make household surveys even more logistically challenging. Telephone-based approaches may be easier to implement and provide some information, but these may be subject to biases.

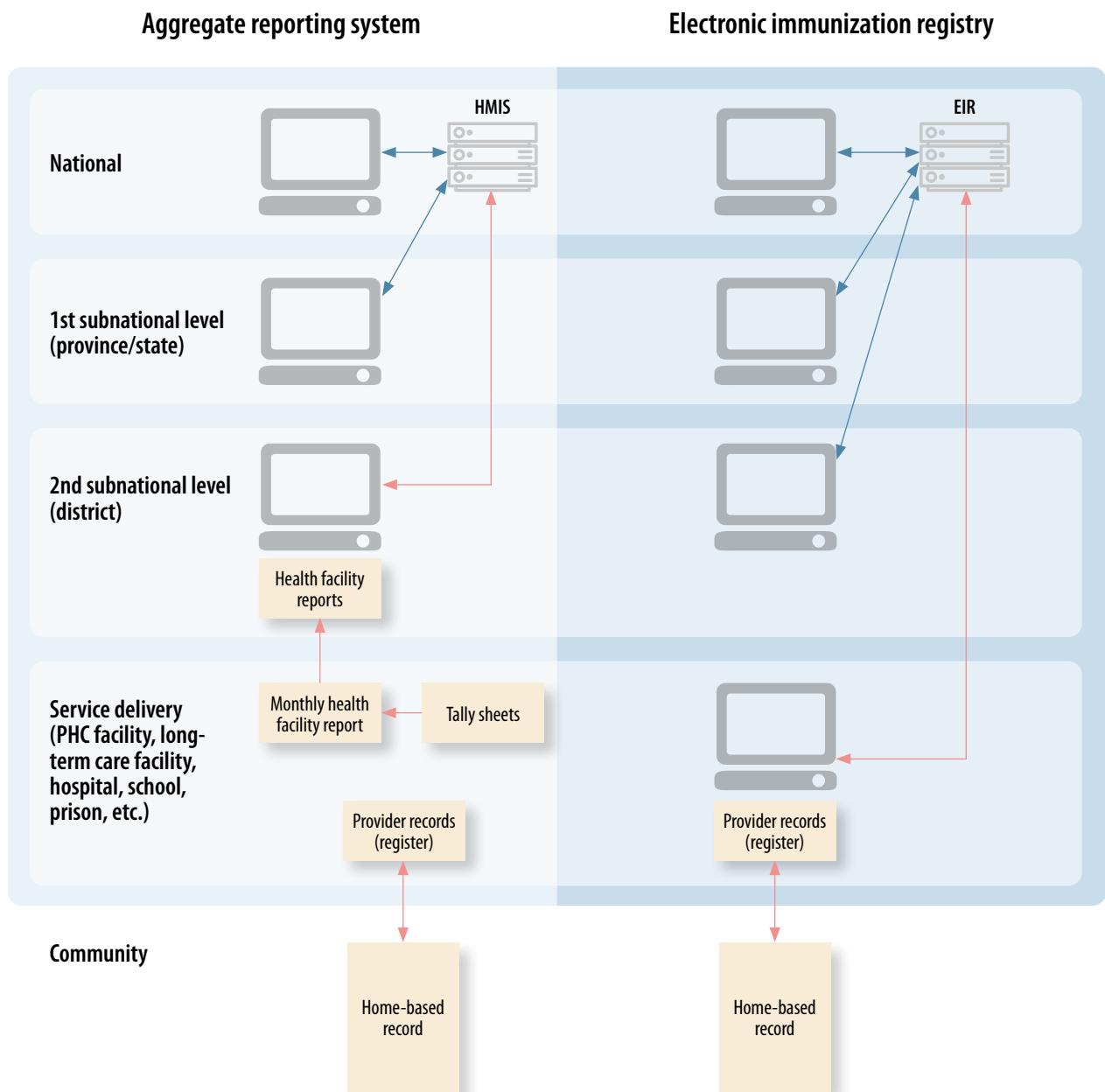
(Informal) community surveys can help understand attitudes towards vaccination, including reasons for non-vaccination. A WHO working group on measuring behavioural and social drivers (BeSD) of COVID-19 vaccination developed guidance for surveys that can help aspects of vaccine demand (see Further reading).

Post-campaign coverage surveys (PCCS) may become a good tool to evaluate the effectiveness and reach of mass campaigns, once the vaccination effort had reached the point where a campaign-like approach is used.

The remainder of this document will focus on administrative systems. In general, countries use one of two systems to monitor their immunization programme as shown in Fig. 2:

- **Aggregate reporting systems**, in which administered doses are recorded, tallied along key dimensions, and reported up the health system, often using a mix of digital and paper tools; and
- **Electronic immunization registries (EIR)**, in which vaccination encounters are recorded digitally, and access to these records and aggregate data about numbers of vaccinations are shared (possibly anonymized) between providers and public health authorities.

Fig. 2. Aggregate versus individual monitoring



The next sections will describe the tools that are needed in a HMIS, then discuss different kinds of digital systems to collect, report and analyse immunization data.

4.2 Recording and reporting tools

4.2.1 Home-based records (vaccination cards)

Physical, paper-based personal records (personal vaccination records, vaccination cards or certificates) are needed both in aggregate and individual systems. They are a tool to facilitate continuity of care, provide vital information for coverage evaluation, safety and vaccine effectiveness monitoring, and as proof of vaccination. Such cards:



- remind the vaccinated person when the next dose is due;
- allow a health worker to establish if a next dose is due;
- help to establish an individual's vaccination status in coverage surveys;
- provide vaccination information in case of an AEFI;
- provide vaccination information in case of a positive COVID-19 test;
- provide a proof of vaccination for individuals' travel, educational or occupational purposes; and
- provide a useful vaccination card for adults and older adults to which COVID-19 vaccines and other recommended vaccines can be added.

Fig. 3. Example of a Covid-19 vaccination card (US CDC model)

COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Cxxx

Last Name

Adam

First Name

MI

1/19/19XX

Date of birth

Patient number (medical record or IIS record number)

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1 st Dose COVID-19	Pfizer COVID EJ1685	12/19/20 <small>mm dd yy</small>	North lake
2 nd Dose COVID-19		<small>mm dd yy</small>	
Other		<small>mm dd yy</small>	
Other		<small>mm dd yy</small>	

For all these use cases, the vaccination card requires fields for the following information:

- Personal information (names, identity number, birth date, address, sex, as relevant).
- Different lines for each anticipated dose and booster. Yearly COVID-19 vaccinations, or the use of the same card for influenza vaccination, for example, would require plenty of extra lines.
- Per line: the date of vaccination, vaccine product and manufacturer, the dose number, the batch or lot number, the name of the provider (vaccinator or institution), and space for a stamp or signature by the provider.
- A reminder date for the next dose; this can either be added as an additional column or field for each line, or as an erasable field in the card's header, footer or front page.

Consideration may be given to the use of the same card to include COVID-19 test results. However, that may compromise its use as a certificate; individuals may be willing to share their immunization status with others, but not necessarily test results. Furthermore, such a record could be interpreted as an "immunity passport". At this point, WHO does not recommend the use of such passports, as not enough data are available to show that either a previous infection or vaccination stops transmission of COVID-19.

Given the potential importance of vaccination to individuals for travel, work, participation at events, etc., falsification of certificates may become a problem. Some mitigation strategies include:

- Printing cards on paper or material that is harder to copy or obtain by fraudsters may discourage some falsification. However, when cards cannot be reproduced by service providers or districts, it is even more important to guarantee adequate supply of cards by the central level.
- Requiring a signature by the health care professional on the card is another deterrent as falsifying a signature is often a criminal offence.
- Using a unique identifier (serial number, barcode) for each card (either pre-printed or to be filled in by the service provider, and copying that unique number to a facility based register would make it possible to trace falsifications to some extent.
- Using digital certificates or vaccination cards can provide ways to check the integrity of digital and physical records, for example, using barcodes. Digital certificates can, for example, be sent by e-mail or text message and stored in the digital wallet of a phone. Please refer to Section 4.3.3 more information.

4.2.2 Facility-based records (immunization registers)

Facility-based records refer to physical register books (provider records, vaccination registers, consultation registers) or digital record systems (EIR, medical record systems). They are kept in or are accessed by the facility, hospital, long-term care facility, prison or doctor's office. These registers or provider records serve broadly the same purposes as personal vaccination records, but also enable providers to:

- track the immunization status of the people in the care of each facility, and track defaulters;
- send reminders for next doses to vaccinated people;

- report data to public health authorities, e.g. in case a safety concern arises with any vaccine product or batch;
- link vaccination data with other medical information, such as pre-existing conditions, COVID-19 test results or AEFI.

Facility-based records may contain fields for the following information:

- information about the vaccinated person: names, identity number, contact information, address, birth date, sex, occupational group, risk profile, as relevant;
- for each anticipated dose and booster: the date of vaccination, vaccine product, the batch or lot number;
- COVID-19 laboratory test results; and
- any AEFI and known allergies.

BOX 4. DOCUMENTATION REQUIREMENTS IN THE CONTEXT OF THE COVAX NO-FAULT COMPENSATION PROGRAMME FOR AMC ELIGIBLE ECONOMIES

AMC eligible countries can access a scheme aimed at compensating individuals who suffer a severe AEFI. One of the requirements of this scheme is that registered health care professionals keep records of the following information about each COVAX-distributed vaccine and its diluent:

- name of vaccine and name of its diluent (if any)
- dose
- batch or lot number
- expiry date
- date of administration to the individual.

4.2.3 Tally sheets

Tally sheets are used in the context of an aggregation-based system to count the number of vaccinations administered during a day, week, month, immunization session or campaign day. They should allow for the tallying of COVID-19 vaccinations by dimension of disaggregation mentioned above.

Keeping separate sheets for each strategy and group (such as health workers) may simplify their design and use. Specific recommendations for the design of tally sheets include:

- The header should contain information about the location, the targeted group, the vaccinator, the COVID-19 vaccine product used, the applicable date or date range.
- Separate spaces (boxes) should be available for the different COVID-19 vaccine doses, and for any required dimension of disaggregation like sex and age range.

There are two ways to organize the collection of disaggregate data:

1. Define “mutually exclusive categories” that reflect the primary reason for which an individual was prioritized for vaccination. For example: health care workers; residents of long-term care facilities; people older than 60; people under 60 with a pre-existing condition; and everybody else. This kind of system might be somewhat ambiguous as someone might be member of more than one of these groups. Doing it this way, some information about the characteristics of the vaccinated people are lost. For example: with the above system we don’t know how many vaccinated people had a pre-existing condition, since many would be in the 60+ category.
2. Categorize every vaccinated individual according the dimensions of interest (age, sex, existing condition or not). Annex 1: Example tally sheet template illustrates that approach, in which more granular information is retained, but which may be harder to interpret.

Either way, tally sheets become increasingly complex to use as more dimensions are introduced, which is one reason why the number of dimensions to be included needs to be considered carefully.

4.2.4 Periodic reports

Periodic reports are often prepared as a paper report at the service delivery level and entered as a digital report by a district administration into the national HMIS. Many countries already have such systems. If not, applying alternative systems like an influenza uptake system to COVID-19 vaccine introduction can be considered. The frequency of reporting and target reporting dates (deadlines) for COVID-19 vaccines should be established and well communicated.

Periodic reports are used to summarize the vaccinations administered along the same dimensions as the tally sheets, together with vaccines used and other relevant information. Health facilities normally consolidate several tally sheets in one report. However, in a first phase when the volume of vaccinations is high and frequent reporting is required, it may be a good option to skip the consolidation step and enter tally sheets or session reports directly into the HMIS.

4.2.5 Dashboard

A COVID-19 vaccination dashboard could be developed to provide insights into a variety of programmatic aspects in addition to vaccination data, and to serve as a useful communication tool. For example, the dashboard could show key performance indicators, bringing together data on:

- service availability and readiness (human resource capacity, cold chain and supply)
- vaccine uptake and coverage
- AEFI.

The vaccination component could also be part of a broader COVID-19 dashboard, that would include surveillance (cases and deaths). Designing a dashboard and considering what information to include in it is also a useful exercise to help determine what data need to be collected.

4.3 Digital systems

Just as digital systems have extensively been used in the COVID-19 response so far,¹ for example, to organize tracking and tracing of infections, they will also play a vital role in vaccine implementation.

4.3.1 Health management information systems (HMIS)

Many countries already use a digital HMIS to collect aggregate and case-based service level data, including for vaccination, vaccine availability, AEFI and cases of disease-preventable diseases.

The District Health Information System (DHIS2)² is a widely implemented HMIS which already has pre-configured modules to facilitate reporting of all these. Countries that use different systems can use this guide to add the required data elements, indicators, dashboards and reports. Please refer to the DHIS2 website³ for more information.

4.3.2 Electronic immunization registries (EIR)

Many high-income countries, and some LMIC do not rely on aggregate reporting systems, but on EIRs that can be used to register individuals and their vaccinations, send reminders, track people who fail to return for a next required dose, and monitor uptake at the population level. Some of these systems also include modules for the reporting and management of AEFI, management of vaccines and supplies, and/or cold chain management.

These EIR have many potential advantages, as they allow for much more granular and rich information. They can also make information available in a more timely manner, as there is no specific aggregation and reporting step needed. Most importantly, in the context of COVID-19, it would help in rapidly monitoring vaccine coverage and making timely programmatic decisions and appropriate adjustments to improve vaccine uptake and coverage and address issues of inequity, mistargeting of priority populations, off-target population vaccination, etc.

In its digital health guidelines⁴ WHO recommends “the use of the use of digital tracking of clients’ health status and services combined with decision support in settings where the health system can support the implementation of these intervention components in an integrated manner...”. In the absence of existing EIRs, it would be challenging for many countries to develop and operationalize effective systems for COVID-19 vaccines in a timely manner, but it may be possible to use existing systems to register COVID-19 vaccinations. The target population and user base of existing EIRs may be quite different, however. For example, an EIR that is currently used by public health facilities or childhood clinics may not be easily extendable to hospitals, long-term care homes and private practitioners. Furthermore, existing systems may not include functionality to facilitate eligibility screening, prioritization, appointment management, informed consent registration, etc.

¹ See, for example, Johns Hopkins University *Assessment of digital solutions for COVID-19 response in low- and middle-income countries* (<https://www.jhsph.edu/departments/international-health/news/johns-hopkins-researchers-publish-assessment-of-digital-solutions-for-covid-19-response-in-low-and-middle-income-countries.html>, accessed 24 February 2021).

² DHIS2 (<https://www.dhis2.org/>).

³ DHIS2 COVID-19 Vaccine Delivery Toolkit (<https://dhis2.org/covid-vaccine-delivery/>).

⁴ WHO *Guideline: recommendations on digital interventions for health systems strengthening* (recommendation 8, page 67) (<https://www.who.int/reproductivehealth/publications/digital-interventions-health-system-strengthening/en/>, accessed 24 February 2021).

Examples of EIRs that are targeted to LMIC include: OpenSRP;¹ Shifo;² VaxTrac;³ and the relevant module in DHIS2. CommCare⁴ is a mobile phone-based platform that was leveraged to support a range of COVID-19 related processes, including vaccination. Countries that do not have existing EIRs should carefully consider the challenges associated with the implementation and maintenance of such systems; and the urgency of COVID-19 vaccine introduction is such that most countries will have to rely on the reporting systems that are already in place.

4.3.3 Digital vaccination cards and certificates

Digital vaccination cards or certificates, refer to digital immunization records that are accessible by the vaccinated person, and serve the same purposes as traditional home-based records: provide a tool to ensure continuity of care and proof of vaccination.

They can be purely digital, for example, stored on a smartphone app or cloud-based server, or complementary digital “twins” of traditional paper home-based records. In this case, the link between the paper record and the digital record could be facilitated by a barcode that is printed on the paper vaccination card to allow for easy retrieval and validation of information.

Electronic certificates not only provide a way to mitigate the falsification of paper-based vaccination certificates, but they can also support and enhance the key functionality that home-based records provide. For example, electronic vaccination certificates can provide automated reminders to the vaccinated person of when the next dose is due. They can also allow for pre-population of specific data fields in AEFI reporting forms and a person’s electronic medical records, in the case where there is an adverse event, ensuring that the integrity of data across multiple information systems is maintained. Furthermore, electronic vaccination certificates allow for technological mechanisms to verify and validate an individual’s proof of vaccination in a reliable and trusted manner, for any health, occupational, educational and travel purposes (as per national and international policies).

At the time of publication of this document, and at the request of the International Health Regulations (2005) Emergency Committee,¹ a WHO expert group was established to develop a position on the use of digital vaccination certificates, considering the ethical and policy considerations, and to create the necessary interoperability standards and implementation guidance for countries.

4.3.4 Logistics management information systems (LMIS)

In addition to vaccination monitoring, it will be important to monitor and manage the vaccine supply chain. Many countries already have the main components of such a system in place. Paper tools that are used in vaccine stores include vaccine ledgers, order forms, and temperature monitoring charts. Data about vaccines and cold chain are also electronically collected and managed, either by including them in facility reports, or through a transactional supply chain management system that aims to keep track of all orders, stock movements, and balances, often not just by product, but also by vaccine lot.

COVID-19 vaccines may be labelled with barcodes on secondary packages, with machine readable information about the vaccine product, lot number and expiry date, as well as a serial number for each box

¹ Open SRP (<https://smartregister.org/>).

² Shifo (<https://shifo.org/en/solution/>).

³ VaxTrac (<https://www.ehealthafrica.org/vaxtrac>).

⁴ CommCare (<https://www.dimagi.com/commcare/>) and (<https://www.dimagi.com/blog/covid-19-equitable-vaccine-delivery/>).

¹ Statement on the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic, 15 January 2021 ([https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)).

(secondary package). These barcodes can be useful to achieve lot and item level traceability, depending on the system and infrastructure available in each country.

4.3.5 Geographical information systems (GIS)

Geographical information systems can be useful to help with micro-planning. Please refer to the UNICEF guide on the use of geospatial data and technologies in immunization programmes¹ for more information.

¹ *Guidance on the use of geospatial data and technologies in immunization programs*. New York: United Nations Children's Fund, 2018 (<https://www.unicef.org/media/58181/file>, accessed 24 February 2021).

5. Global and regional reporting requirements and monitoring objectives

COVAX partners are committed to ensure equitable access to COVID-19 vaccines, and in that context will require country-level data about aspects of vaccine introduction, policies, uptake, safety and effectiveness.

In order to reduce the reporting burden on national authorities, WHO and UNICEF, with partner agencies, defined a core set of indicators needed from all countries, as well as an extended set required from Advance Market Commitment (AMC) participants, and established a single reporting mechanism to serve a need across key partners and the global community. The primary means for global and regional monitoring will be official Member State reporting through a COVID-19 module of the WHO-UNICEF Joint Reporting Form (JRF).

As of 2021, reporting on the JRF will be electronic. The COVID-19 vaccination module in the eJRF contains both programmatic questions and core indicators, such as numbers vaccinated across different target population groups, in accordance with the guidance provided in this document. It is intended to facilitate consistent COVID-19 programmatic monitoring across all Member States towards meeting COVAX goals of ending the acute phase of the pandemic and ensuring equitable and fair access to COVID-19 vaccines. Refer to Annex 2 for the questions related to uptake monitoring.

The COVID-19 module is adaptable and dynamic in nature. For example, for some questions, countries can see previously reported responses and can opt to update only if they have new information to share. The module is also adapted to different groups of countries (such as COVAX AMC countries).

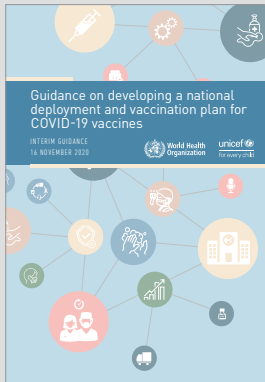
For 2021, countries will be requested to report at least on a monthly basis with possibility of more frequent reporting for vaccination uptake during the early stage of vaccination roll-out through the eJRF (with frequency of reporting to be revisited as COVID-19 vaccine programmes become increasingly integrated within routine immunization programmes).

Data will be used to monitor global uptake of vaccination, and adherence with WHO policy recommendations for prioritizing use of COVID-19 vaccines in the context of limited supply. For AMC eligible economies data will inform prioritization of allocation delivery order in case of limited supply.

As with other Expanded Programme on Immunization programmes, eJRF data will be complemented through a variety of other monitoring, learning and evaluation related exercises. These include, for example, programmatic evaluations, vaccine effectiveness studies, case studies and other informal/formal learning exchanges. WHO and COVAX partners will try to coordinate such efforts as much as possible.

Further reading

VACCINE DEPLOYMENT PLANNING

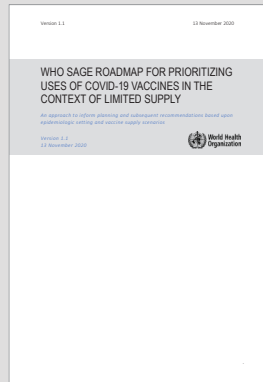


Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines

WHO 2020

https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1 (🌐)

POLICY, PRIORITIZATION

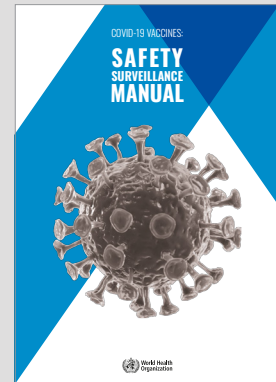


WHO SAGE Roadmap for prioritizing uses COVID-19 vaccines in the context of limited supply. Version 1.1, 13 November 2020

WHO 2020

<https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-roadmap-covid19-vaccines.pdf> (🌐)

SAFETY SURVEILLANCE

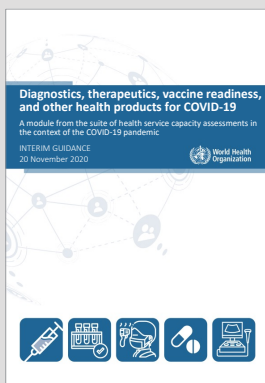


COVID-19 vaccines: safety surveillance manual

WHO 2020

<https://www.who.int/publications/i/item/10665338400> (🌐)

HEALTH FACILITY ASSESSMENTS

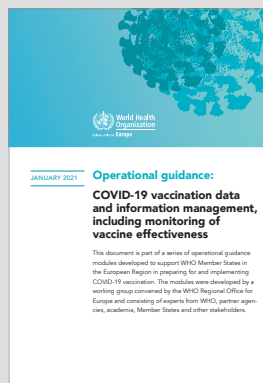


Suite of health service capacity assessments in the context of the COVID-19 pandemic

WHO 2021

<https://www.who.int/teams/integrated-health-services/monitoring-health-services> (🌐)

REGIONAL GUIDANCE

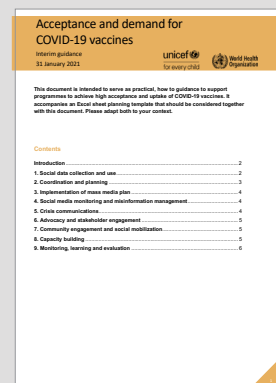


Operational guidance: COVID-19 vaccination data and information management, including monitoring of vaccine effectiveness. January 2021

Copenhagen: WHO Regional Office for Europe 2021

<https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/publications-and-technical-guidance/2021/operational-guidance-covid-19-vaccination-data-and-information-management,-including-monitoring-of-vaccine-effectiveness,-january-2021-produced-by-who-europe> (🌐)

ACCEPTANCE AND DEMAND FOR COVID-19 VACCINES



Acceptance and demand for COVID-19 vaccines: interim guidance. 31 January 2021

WHO 2021

<https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/acceptance-and-demand> (🌐)

Annex 1: Example tally sheet template

Model template allowing for: disaggregation by dose; two age groups; existence of condition; and sex. Priority populations (health workers, residents in long-term care facilities etc.) can be indicated in the header. In that case, different tally sheets are to be used for these specific target populations.

Facility/provider:	District:	Province:	Date or period:
Check the targeted population: <input type="radio"/> General population <input type="radio"/> Health workers <input type="radio"/> Other essential workers <input type="radio"/> Long-term care facility <input type="radio"/> Other:			

		60 or older				Younger than 60			
		At least one existing condition		No existing condition		At least one existing condition		No existing condition	
		Male	Female	Male	Female	Male	Female	Male	Female
1st dose		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
	Total:	Total:	Total:	Total:	Total:	Total:	Total:	Total:	Total:
2nd dose		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
	Total:	Total:	Total:	Total:	Total:	Total:	Total:	Total:	Total:
Booster doses		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
		00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
	Total:	Total:	Total:	Total:	Total:	Total:	Total:	Total:	Total:

Vaccine	Product:	How to use this form:
	Lot/batch numbers:	
	Opening balance:	
	Doses received:	
	Doses used:	
	Vaccinations:	
	Wastage:	
	Closing balance:	

Annex 2: Global and regional reporting form – eJRF

Starting in March 2021, COVID-19 vaccination data will be collected on a monthly basis through the electronic Joint Report Form (eJRF) by WHO and UNICEF. Data will be collected about several areas, including vaccination uptake, for which the current draft table is shown below. Countries will be asked to provide the **cumulative** number since the start of vaccination. Some data, such as the “target population”, will be pre-populated with the data that a country reported the previous time. The dimensions of disaggregation shown here are not mutually exclusive.

C13	Number in target group	Number vaccinated with at least 1 dose (COV-1)	Number vaccinated with last recommended dose (COV-c) In case of a vaccine with a 2-dose schedule enter second dose	Comment
All vaccinations	<enter total population>			
By vaccine type <select from the list>	Not applicable			
Dimension of disaggregation (if available)				
Among males				
Among females				
Among health workers				
Among older people (aged 60 years or over) If different age breakdown used for older adults, please specify under Comment More granularity for age groups may be required by certain regions				
Among people with co-morbidity				
Among residents living in long-term care facilities				
In other groups (please specify)				



World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland
www.who.int