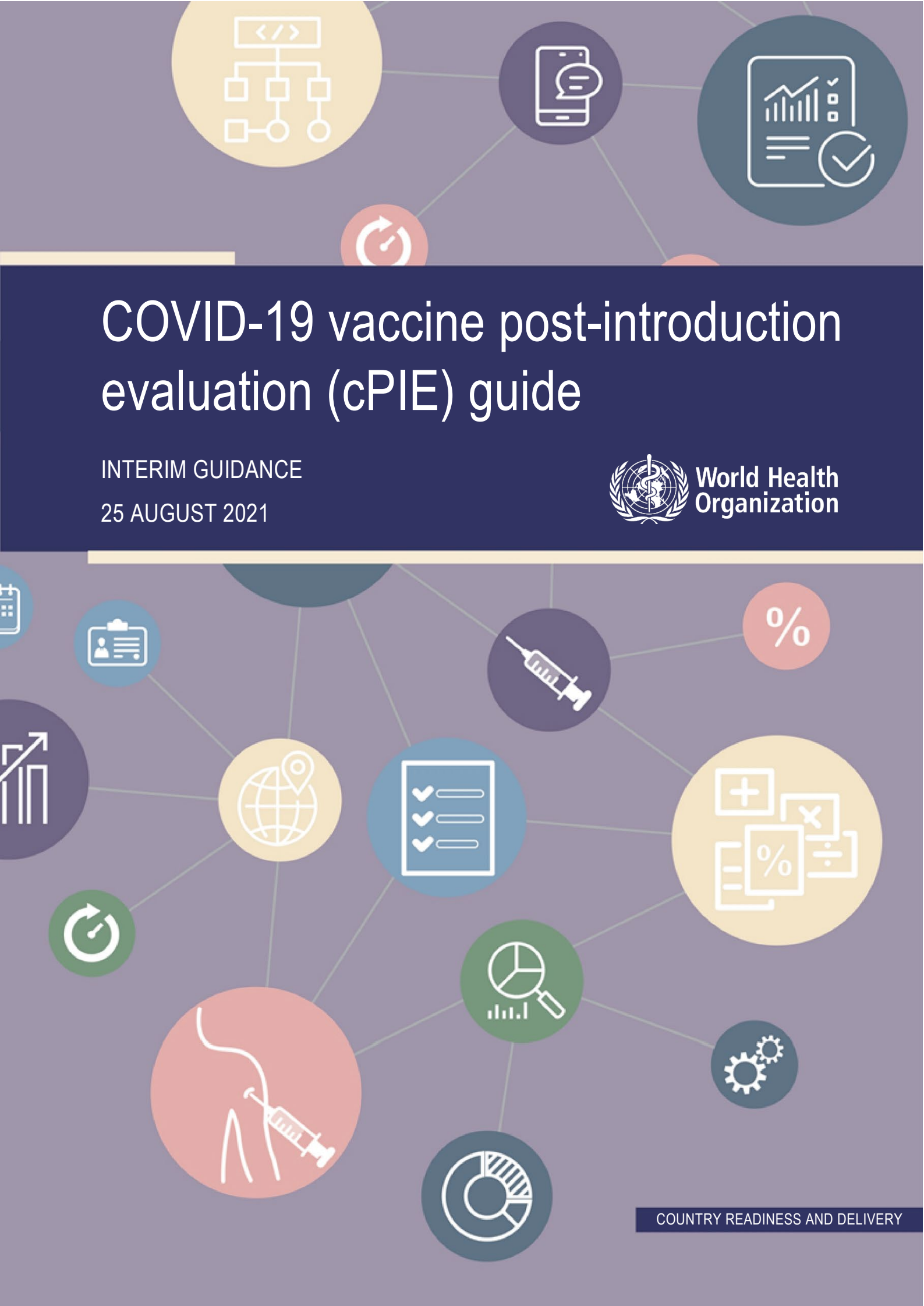
COVID-19 vaccine post-introduction evaluation (cPIE) guide

INTERIM GUIDANCE

25 AUGUST 2021

World Health Organization



COUNTRY READINESS AND DELIVERY

WHO reference number: WHO/2019-nCoV/cPIE/2021.1

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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Additional annexes can be found at the links below:

Web annex A. cPIE questionnaires
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Introduction

This COVID-19 vaccine post-introduction evaluation (cPIE) tool is designed to provide a systematic method for evaluating a COVID-19 vaccination programme, using structured interviews at the national, subnational, and health facility level, and with specific target groups, and is supplemented with systematic observations of vaccination sessions and vaccine storage sites. This tool was based on the publication, New Vaccine Post-Introduction Evaluation (PIE) Tool[1] and the Influenza Vaccine Post-Introduction Evaluation.[2]

The purpose of a cPIE is to:

- Highlight deployment activities that went well and should be maintained.
- Identify problems needing corrective action.
- Highlight lessons learned from the COVID-19 vaccine deployment to strengthen the overall national immunization system and services, specifically related to health workers, older adults, essential workers or persons with co-morbidities.
- Inform recommendations to improve roll-out of COVID-19 vaccines, especially in terms of vaccination of phased-in target groups and strategies for booster vaccination.
- Provide lessons learned for other countries for their own COVID-19 vaccine deployment and for future pandemic vaccine deployments.

The implementation of COVID-19 vaccination differs in several key aspects from prior new vaccine introductions into the national immunization programme. The cPIE strategy is adapted to COVID-19 vaccination approaches considering that multiple vaccine products may be in use in a country. Certain vaccine products may be targeted to different priority populations (e.g. health workers, persons 65 years and older, persons with co-morbidities, other essential workers, etc.) or in certain geographies. Certain COVID-19 vaccines require special considerations for ultra-cold-chain capacity and management, which has never been required for prior vaccines used within the Expanded Programme for Immunization (EPI). In addition, countries may undertake phased introduction by priority population, depending on available vaccine supply. The cPIE tools address all of these issues pertaining specifically to COVID-19 vaccines.

[1] New Vaccine Post-Introduction Evaluation (PIE) Tool, World Health Organization. http://apps.who.int/iris/bitstream/handle/10665/70436/WHO_IVB_10.03_eng.pdf

[2] Influenza Vaccine Post-Introduction Evaluation, World Health Organization. https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/seasonal-influenza/influenza-vaccine-post-introduction-evaluation-(ipie).

When and where should a cPIE be done?

A cPIE is recommended to be conducted 6–18 months after initial COVID-19 vaccine introduction. More than one cPIE may need to be conducted during this period. In the early post-introduction period (within 2–6 months of introduction), prior to conducting the cPIE, countries are recommended to conduct a lighter, more flexible review known as the mini-cPIE, which uses the WHO intra-action review (IAR) platform.[3] The mini-cPIE covers the same programme areas that are addressed in the full cPIE but does not require facility/site visits and direct observations.

The full cPIE should be performed at all levels of the health system. The minimum and maximum number of site visits at each level of the health service that are required to obtain a comprehensive overview of the system are outlined in Table 1. The maximum number of sites to be visited will depend on the size of the country, the heterogeneity of its health and vaccination services and the human and financial resources available to conduct the evaluation.

Table 1. Minimum number of interviews by health administration level

Health administration level	Minimum number of interviews
Central level	1
Regional/provincial level	3 – 6
District level	6 – 12
Health facility level	18 – 36

*Some countries may only have three administrative levels, and some may have more; the table can be adapted as appropriate.

The decision regarding which regions/provinces, districts and health facilities or vaccination sites to select for evaluation will vary based on country context but should be identified early to allow for site planning. Sites are selected based on a purposive sampling strategy that aims to provide a complete picture of immunization service delivery. This strategy is in keeping with recommendations for past PIEs and is not designed as a statistically representative survey, such that it can be conducted quickly without a need for statistical support for planning and analysis. Using the purposive sampling strategy, a variety of health facilities or other vaccination sites should be selected with consideration for the following criteria:

- Types of sites providing vaccination to priority groups, be they fixed or mobile;
- Priority population(s) served including sociodemographic groups particularly at risk and diversity in ethnic minorities, where appropriate;
- Predicted or estimated performance based on prior immunization coverage rates or other appropriate metrics;
- Estimated COVID-19 disease burden;
- Size range of the catchment population;
- Urban, peri-urban or rural location.

[3] Guidance and tools for conducting an Intra-action Review, World Health Organization. https://www.who.int/publications/i/item/WHO-2019-nCoV-Country_IAR-2020.1.

The sampling frame from which to select sites to be visited would include vaccination services in hospitals, health centres, health facilities, but also in places of work, long-term care facilities for elderly or handicapped persons, educational institutions, military or police barracks, prisons, or private sector facilities/sites, as appropriate to the local situation.

Conducting the cPIE

Desk review and adaptation of the tools

Pre-planning is crucial for a successful cPIE. A timeline of pre-cPIE activities is provided in Annex 1. A desk review is an important part of the evaluation and should be conducted prior to the field work. Table 2 outlines some of the data and documents that should be sent to participants, if possible, in advance, and reviewed as part of the desk review. These will provide essential background information and orientation on the country context for the cPIE.

Table 2. Example of data and documents for cPIE desk review

Data/documents	Examples
Documents relating to COVID-19 vaccine deployment	▪ National Deployment and Vaccination Plan ▪ COVID-19 vaccination guidelines or policy documents for each vaccine product used ▪ Sample microplan used at sub-national level
Materials relating to COVID-19 vaccine deployment	▪ Samples of media campaign/social mobilization/education materials, e.g. brochures, posters, leaflets
Data relating to the current immunization system	▪ COVID-19 vaccination report, including vaccine usage, drop-out, wastage ▪ COVID-19 vaccine National Adverse Event Following immunization (AEFI) management guidelines ▪ COVID-19 vaccine AEFI reporting form ▪ COVID-19 surveillance report(s) or website

Conducting the fieldwork

With advance planning and adequate resources, the PIE can be completed within 10 days. An overview of a typical 10-day evaluation timeline is outlined in Annex 1. Staff should plan to spend a half day at each site. Each questionnaire takes approximately one hour to complete, and completion of the observation checklist approximately 30 minutes. A summary of fieldwork is outlined in Table 3.

Table 3. Summary of fieldwork by health administrative level				
Health administrative level	**Questionnaire**	**Number of sites to visit**	**Type of people to interview**	**Observations required**
Central	**Annex A.1** National level questionnaire	1	Responsible individual(s) within the COVID-19 vaccination taskforce, MoH, key partner organizations, etc.	Vaccine stock records, immunization data records
	Annex A.4 Vaccine storage observation	1	Central cold store manager	Central cold store or other private cold storage facilities, dry storage area
Provinces	**Annex A.2** Subnational level questionnaire	3-6	Person responsible for COVID-19 vaccination programme	Vaccine stock records, immunization data records
	Annex A.4 Vaccine storage observation	3-6	Provincial cold store manager	Vaccine stock records, immunization data records
Districts	**Annex A.2** Subnational level questionnaire	6-12 (2 per province)	Person responsible for COVID-19 vaccination programme	Vaccine stock records, immunization data records
	Annex A.4 Vaccine storage observation	6-12 (2 per region or province)	District cold store manager	District cold store or other private cold storage facilities, dry storage areas
Health facilities and other vaccination sites	**Annex A.3** Health facility/site questionnaire	18-36 (3 per district)	Health-care worker	Vaccine management, service delivery
	Annex A.4 Vaccine storage observation	18-36 (3 per district)	Health-care worker	Cold and dry storage areas
	Annex A.5 Vaccine session observation	18-36 (1 per health facility)	N/A	Vaccination session

	Annex A.6 Health workers priority group questionnaire	At least 36 (at least 2 health workers per facility/site)	Health workers who have just been vaccinated	Vaccination cards
	Annex A.7 Other priority group questionnaire	At least 36 (at least 2 health workers per vaccination site; aim to conduct a similar number of interviews across sites selected)	Individuals in other priority groups who have just been vaccinated	Vaccination cards

The number of health personnel required to conduct the PIE effectively within a 10-day time period will depend on the number of sites selected and whether multiple teams will visit sites simultaneously. A cPIE team leader should be selected, and all team members should have knowledge of the COVID-19 vaccination programme, its target populations, programme monitoring, and data analysis. It is useful to include a mix of local immunization partners WHO, UNICEF, other key in-country immunization partners and nongovernmental organizations active in COVID-19 immunization services. Historically, external staff from WHO/UNICEF and other international partners have participated in PIEs following the introduction of other vaccines, and virtual technical assistance from such partners should be considered. Additionally, Considering the COVID-19 transmission risk at the time of the evaluation, virtual platforms can also be considered for conducting some components of the cPIE including the orientation training at the beginning of the evaluation and the national and subnational interviews, as appropriate.
Data are collected on the following 9 principal evaluation areas (in alignment with the Guidance on National Deployment Planning and Vaccination for COVID-19 Vaccines):[4]

- Regulatory preparedness
- Planning, coordination, and service delivery
- Costing and funding
- Supply chain and waste management
- Human resource management and training
- Vaccine demand
- Vaccine safety
- Monitoring and evaluation
- COVID-19 surveillance