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New Vaccine Post-Introduction Evaluation (PIE) Tool

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Contents

Abbreviations and acronyms

AD syringe	Auto-Disable Syringe
AEFI	Adverse Events Following Immunization
BCG	Bacille Calmette–Guérin (vaccine)
CDC	Centers for Disease Control and Prevention
cMYP	Comprehensive Multiyear Plan
DTP	Diphtheria-Tetanus-Pertussis (vaccine)
EPI	Expanded Programme on Immunization (WHO)
GAVI Alliance	formerly Global Alliance for Vaccines & Immunizations
HCW	Health-Care Worker
HepB	Hepatitis B
Hib	Haemophilus influenzae type b
ICC	Interagency Coordinating Committee
IEC	Information, Education and Communication
MDVP	Multi-dose Vial Policy (WHO/EPI)
MoH	Ministry of Health
NGO	Nongovernmental Organization
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
PCV7	7-Valent Pneumococcal Conjugate Vaccine
PIE	Post-Introduction Evaluation
UNICEF	United Nations Children's Fund
VVM	Vaccine Vial Monitor
WHO	World Health Organization
YF	Yellow Fever

Acknowledgements

This Post-Introduction Evaluation tool has been derived from existing materials, reports and experiences from hepatitis B (HepB) vaccine evaluations globally, and from HepB and *Haemophilus influenzae* type b (Hib) vaccine evaluations in the WHO Regional Offices for Africa and Europe. We would like to thank those who contributed to these evaluations. The tool also draws heavily on other existing vaccine management and related documents from the World Health Organization (WHO) and United Nations Children's Fund (UNICEF), and we also thank all those involved in the preparation of these documents. In particular we acknowledge the contributions from Gavin Grant, Terri Hyde and Linda Ojo Centers for Diseases Control and Prevention (CDC) and Rosalyn O'Loughlin London School of Hygiene and Tropical Medicine (LSHTM). The tool was used in four countries during 2007 and 2008, and this experience resulted in frequent revision of the document. We would like to thank all the participants in the evaluations in Ethiopia, Liberia, Sierra Leone and Ukraine; in particular for their valuable comments on improving the tool. Similarly, we would also like to thank those reviewers who dedicated their valuable time to providing comments and suggestions on how to improve the tool.

Preface

The WHO recommends that all countries which have introduced a new vaccine should evaluate the impact on their vaccination system. Until now, this evaluation consisted of a checklist, which was considered by some to be too limited to identify problems and provide useful information to the country. This new PIE tool is more comprehensive and is akin to a mini-review of WHO's Expanded Programme on Immunization (EPI). Because EPI reviews are typically conducted on a three to five year basis, a smaller review following the introduction of a new vaccine can help with timely identification of problems and can highlight strengths of introducing a new vaccine to the EPI system. Such a review, called a Post-Introduction Evaluation (PIE), is normally conducted 6–12 months following introduction.

This post-introduction evaluation tool is designed, to assist immunization managers in countries that have introduced a new or underutilized vaccine to provide a systematic method for evaluating the implementation of the introduction, and its impact on the existing immunization system in the country. Such evaluation will allow problems associated with the introduction of the vaccine to be identified early enough to be corrected and documented, so that they can be prevented in future introductions of new vaccine(s) and shared with other countries to prevent similar problems, and also to indicate the ease or complexity of the vaccine introduction. This document may also be useful for institutions or other professionals with similar assignments and/or objectives.

This post-introduction tool is not intended to facilitate disease surveillance or monitoring of the vaccine's impact on disease burden. Specific tools for this purpose are available for rotavirus vaccine , and other tools for monitoring the impact of Hib and pneumococcal vaccines on *Haemophilus influenzae* type b and *Streptococcus pneumoniae* disease will be available from WHO in mid 2010.

In developing this tool, we drew on experience from evaluations of the introductions of Hepatitis B and Hib vaccines in the past, as well as four recent field tests of the tool. We also relied heavily on existing guidelines and operational manuals. We have aimed to make the tool generic, and easily adaptable for different vaccines and in different settings. It is therefore important that before each evaluation, the tool is adapted to the specific country situation. Guidance on how to do this is provided in the text.

1. Overview

1.1 Introduction

This post-introduction evaluation (PIE) tool provides a systematic method for evaluating the impact of the introduction of a vaccine on the existing immunization system in a country. The PIE tool is designed for immunization managers in countries that have introduced a new or underutilized vaccine. WHO recommends that all countries which have introduced a new vaccine conduct a PIE. Conducting a PIE is not a new concept, and there are several examples of evaluations of Hepatitis B (HepB) and *Haemophilus influenzae* type b (Hib) vaccine introductions — those experiences have been incorporated into this tool. The purpose of the current tool is to provide a systematic method of performing the evaluation, that is comparable across countries, to facilitate the sharing of experiences. Numerous WHO and UNICEF guidelines and operational manuals have been consulted in the preparation of the tool, which is suitable for evaluation of all new vaccines but will require revision for each country's individual circumstances, and for the different vaccine formulations and presentations. This manual consists of an overview of the PIE, a description of what needs to be evaluated and what the evaluator should be looking for, and an explanation of how to synthesize the data and present the findings.

1.2 What are the goals of the manual?

The manual has four major objectives.

1) To provide health ministries and immunization partners with user-friendly tools to conduct a comprehensive evaluation of the impact of the introduction of a new vaccine on their immunization programmes.
2) To provide recommendations for rectifying typical problems associated with the introduction of a new vaccine.
3) To provide guidance for analysis of data collected during the evaluation.
4) To provide a template for a final report.

1.3 What is a PIE?

A PIE is a post-introduction evaluation of the overall impact of the introduction of a new vaccine(s) on a country's national immunization programme. It focuses on a range of programmatic aspects, such as pre-introduction planning, vaccine storage and wastage, logistics of administering the vaccine, and community receptiveness to the vaccine. A PIE can rapidly identify problem areas needing correction within the immunization programme either pre-existing or resulting from the introduction of a new vaccine, and provide valuable lessons for future vaccine introductions. The principles outlined in this manual are applicable to all newly-introduced vaccines and their current formulations and presentations. Although the tool was originally designed to evaluate the introduction of the pentavalent vaccine, field tests have shown, that with some adaptation, it is equally suitable for evaluating the impact of the pneumococcal and rotavirus vaccines.

1.4 When and where should a PIE be done?

Ideally, a PIE should be done between 6 and 12 months after introduction of the new vaccine. An evaluation carried out before six months may not allow enough time for issues to surface, for adequate data collection, and for potential problems to become evident. Similarly, an evaluation more than 12 months post-introduction runs the risk of missing problems related to the introduction that could have been easily corrected, such as weaknesses related to training, vaccine handling and management, or vaccine distribution. Where possible, a PIE should be conducted in conjunction with other Expanded Programme on Immunization (EPI) evaluation activities, thereby optimizing the use of time and resources.

The evaluation should be performed at all levels of the health system. This manual focuses on nationwide introduction, but it can be used with minimal modification for a regional (or district) evaluation where phased introduction of a new vaccine has taken place. The minimum number of 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 upon the size of the country and the human and financial resources available to conduct the evaluation. However, provided the sites to be visited are representative of the selection criteria outlined below, a maximum of six regions (or provinces) should provide adequate information for the evaluators.

Table 1: Minimum number of visits by health administration level

Health administration level*	Minimum number of visits
Central level	1
Regional/provincial level	3
District level	6
Health-facility level	18

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

The decision regarding which provinces, districts and health facilities to select for evaluation will vary based on the particulars of a country, but should, where possible, be made in advance to allow for site planning. Every effort should be made to visit hard-to-reach sites so that the evaluation is geographically representative and takes equity issues into account. It is also important to select sites that represent a range of programme performance, as this will provide the evaluators with a variety of illustrations. The following are examples of possible selection criteria.

- A mix of regions/districts based on immunization programme performance (e.g. best, moderate, worst).
- Geographically diverse and representative regions/districts, and within those districts, health facilities selected on the basis of performance (e.g. best, moderate, worst).
- A variety of health facilities visited (i.e. including large and small health clinics, rural sites, urban sites, and outreach sites).
- A variety of sites that include those with high numbers of internally displaced persons, or ethnic minorities.

The selection criteria that are used should be documented in the final report.

1.5 How is a PIE conducted?

The PIE is conducted by using questionnaires, checklists, observation of practices and recording reviews, at all levels of the health service, including cold and dry vaccine storage areas and points of vaccine administration, such as health facilities. Questionnaires incorporating the observation checklists are presented in Appendix 2. Each question in the questionnaires is coded by vaccine to make it easy to adapt the questionnaire for different vaccines. For example, to conduct a rotavirus vaccine PIE all the generic- and rotavirus-specific questions would be included. Appendix 3 includes a list of key findings to help with data synthesis, and Appendix 6 includes a description of common problems that may be encountered with the introduction of a new vaccine, and proposes solutions. The process has three components: desk review and adaptation of the tool; fieldwork, and compilation of data reporting and formulation of recommendations.

Desk review and adaptation of the tool

Pre-planning is crucial for a successful PIE. Appendix 1 contains a checklist of pre-PIE activities that should be performed before commencing the PIE. A desk review is an important part of the evaluation and should be conducted prior to the fieldwork. 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 for the PIE. Before beginning the fieldwork, a briefing should be given to all participants informing them of the findings of the desk review. It would also be useful to have the Ministry of Health (MoH) provide the team with their assessment of the introduction — what worked, what worked less well, what constraints were encountered. The team should then review the PIE questionnaires together, so that everyone has a clear idea of the objectives of the fieldwork, and is using the same methodology to administer the questionnaires to ensure consistency of data between the teams.

Table 2: Example of data and documents for PIE desk review

Data/documents	Examples
Documents relating to the current immunization system	• National immunization plan, comprehensive multiyear plan (cMYP), and plans for sustaining financing • New vaccines introduction plan • GAVI application — where applicable • National policy documents on adverse event following immunization (AEFI) monitoring; injection safety and waste disposal • Immunization recording forms, records, supervisory checklists • Report of last EPI review (if within past five years) • Vaccine management assessment and cold-chain assessments conducted in past five years
Materials relating to the new vaccine introduction	• Training materials and a summary of trainings conducted • Advocacy and information, education and communication (IEC) materials • Overview of resources allocated for introduction — financial and human — and mechanism for transfer from central to lower levels • Disease burden information by country, if available
Data relating to the current immunization system	• National monthly coverage data, by district if possible • National monthly surveillance data (e.g. meningitis), by district if possible • National vaccine shipment logs • National monthly vaccine wastage rates

Fieldwork

Fieldwork consists of visiting at least three regions, six districts, and 18 health facilities, and administering questionnaires to staff at each level, and to mothers or caretakers at the health-facility level. Questions are targeted specifically to the function of each level of the health service. At the central, regional and district levels, interviewees typically include heads of EPI, while at the health- facility level they may include a combination of EPI supervisors/senior nurses and health-care workers. Immunization sessions, the cold-chain system, waste-management procedures and other daily functional activities are observed, and records, such as temperature records, registries, forms and databases are reviewed. Parents or guardians of children who have been vaccinated are also interviewed. Table 3 summarizes the fieldwork and outlines the questionnaires found in Appendix 2, which are used at each level of the health system.

Table 3: Summary of fieldwork by health administration level

Health administration level	Questionnaire	Number to visit	Type of people to interview	Observations required
Central	Appendix 2.1	1	Person responsible for national EPI, data manager and central cold-store manager	Central cold store, and dry storage area
Regions	Appendix 2.1	At least 3	Person responsible for EPI and cold-store manager	Regional cold store, and dry storage area
Districts	Appendix 2.1	At least 6 (2/Region)	Person responsible for EPI and cold-store manager	District cold store, and dry storage area
Health facilities	Appendix 2.2	At least 18 (3/District)	Health-care worker	Cold and dry storage areas, immunization session
	Appendix 2.3	At least two mothers per health facility or a group interview	Mothers/carers of children who have just been vaccinated	Vaccination cards

The PIE should be conducted in such a way that those being interviewed are not frightened of, or intimidated by, the evaluators. This is particularly important for health-facility personnel and mothers. The team should explain who they are, why this region/district or health facility was selected, and what the objectives of the evaluation are. Feedback to those interviewed should be given at the end of the visit, and advice should be given about how to correct any inappropriate practices or misinformation observed. In the same way, correct practices observed should be commended. Before leaving the field, the team should present preliminary findings and recommendations to the regional or district office, based on their observations and interviews in that area. All interviewees should be thanked for their assistance.

Compilation of data, reporting and recommendations

Section 3 outlines the process of compilation and reporting of data, and the formulation of recommendations. Sharing findings with MoH officials and key partners such as the Interagency Coordinating Committee is important, so that action can be taken on the recommendations.

1.6 Who should conduct a PIE?

Approximately six to nine local health personnel are required to conduct the PIE effectively within a 10-day time period. A PIE team leader should be selected, and all team members should have knowledge of the EPI programme, programme monitoring, and data analysis. Some team members should have more specific expertise, such as logistics, the cold-chain system, or good practice in vaccine delivery. It is useful to include a mix of local immunization partners, such as MoH, WHO and UNICEF, and nongovernmental organizations active in immunization services. Historically, external WHO staff and other international partners have participated in PIEs, although this is not essential. The team should be divided into a number of smaller two to three person field teams, which would expect to visit about four to six health facilities each. Preferably, each field team should consist of at least one member of staff from the MoH and one from a partner organization. Where possible, health workers should evaluate regions other than the one in which they work.

When in the field, teams should identify a district officer from the MoH to accompany the team on the health-facility visits, so that the key findings of each visit are observed first-hand by those responsible for their correction and implementation.

1.7 How much does it cost to conduct a PIE?

Since the PIE has been designed for countries to self-administer (either alone or in combination with other routine evaluations), budget costs should not exceed US$ 10 000 but will vary depending on individual country circumstances. The WHO African Region reported costs ranging from US$ 4000 to US$ 10 000. Costs may include allowances for personnel, training, transport and supplies. Planning for a PIE should form part of the vaccine introduction plan developed prior to vaccine introduction.

1.8 How long should a PIE take?

With advance planning and adequate resources, the PIE can be completed within 10 days. An initial team meeting 1–2 days before the weekend to finalize the tool will allow for travel to the field over the weekend, and maximize weekdays in the field. 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. It should be noted that, in many countries, vaccination sessions only take place in the mornings, so it is necessary to plan the timetable with this in mind. However, delays, such as waiting for the appropriate person to become available for an interview, must be accounted for, and some time should be spent giving feedback, particularly if any practices need correcting. An overview of a typical 10-day evaluation timeline is outlined in Table 4. If fewer than 10 days are available, the timetable may be modified.

Table 4: Implementation timeline

Days 1–2	• Team meeting to review objectives and ensure consistent interpretation of PIE tools • Adaptation of tools for country situation • Meet with MoH, EPI officials and key partners
Day 3	• Travel to field (preferably at the weekend if travel times are long)
Days 4–7	• Field visits to regions, districts and health facilities
Days 8–9	• Return from field • Data compilation and analysis • Writing report and recommendations
Day 10	• Reporting to MoH and ICC • Finalization of report and recommendations

10 Tips to ensure a 10-day PIE

- ☑ Ensure that the visit does not coincide with national holidays or mass immunization campaigns
- ☑ Confirm availability of staff for interview in advance, particularly in regions and districts
- ☑ Inform key interviewees about purpose and intent of meeting prior to visit to ensure they are adequately prepared to provide the requisite information
- ☑ Review new vaccine introduction plan prior to visits
- ☑ Finalize adapting PIE tools to country specificities prior to Day 1. Day 1 should be used to fine-tune any last-minute changes
- ☑ Coordinate health-facility site visits to coincide with immunization session days
- ☑ Include visit to at least one regional cold store on the itinerary
- ☑ Confirm that at least half of the selected sites provide full EPI services
- ☑ Arrange transportation in advance
- ☑ Anticipate delays by PLANNING AHEAD

2. Evaluation areas

Data are collected on 10 principal evaluation areas, listed below. Each one is then described in more detail, highlighting what the evaluator should be looking for during interviews and site visits.

1) Planning and introduction.
2) Coverage, drop-out, recording and reporting.
3) Cold-chain management.
4) Vaccine management, transport and logistics.
5) Monitoring and supervision.
6) Training and knowledge of health-care workers.
7) Injection safety and waste management.
8) Vaccine wastage.
9) Adverse events following immunization.
10) Advocacy, communication and acceptance.

2.1 Planning and introduction

Countries funded by the GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunizations), which is a public-private global funder, are required to prepare a vaccine introduction plan. Countries that have not used GAVI support to introduce a vaccine are also encouraged by WHO and its partners to prepare a vaccine introduction plan as part of their planning process. Evaluators should review the document for the following:

- to determine if the country has followed their plan, and if not, determine reasons for deviation from the plan;
- to compare key milestones outlined in the plan with results of the PIE, noting in particular:
  - whether cold and dry storage capacities were sufficient and vaccine and immunization supply forecasts were accurate;
  - how well the training coincided with the launch of the vaccine; for example, whether all workers were sufficiently trained in a timely manner;
  - whether information and educational materials and supplies were available at the time of launch;

– how well the catch-up campaign worked (if one was used);

– in the case of pentavalent introduction, whether the policy on what to do with excess diphtheria-tetanus-pertussis (DTP) vaccine following the introduction was adhered to;

– in the case of pentavalent, how well the national guidelines for transitioning those children who had already begun their vaccination with DTP was adhered to.

If there is no introduction plan in place, the key milestones listed above can still be evaluated by documenting what preparations were carried out.

Budgeting should be part of the planning process. For GAVI-eligible countries, GAVI provides time-limited support for new and underutilized vaccines against a co-financing contribution from the country. At the end of the co-financing period, the country is expected to take on the full cost of the vaccine. The sustainability of the funding should be determined by the evaluator responsible for the evaluation at national level;

- to determine whether a budget line exists at the central level for vaccines, including the new vaccines (for GAVI- and non-GAVI-eligible countries);
- to determine whether there are plans for increasing co-funding over time (in GAVI-eligible countries).

2.2 Coverage, drop-out, recording and reporting

A new vaccine should be introduced according to WHO's or the manufacturer's recommended schedule. Table 5 outlines the recommended schedules for Hib, pneumococcal and rotavirus vaccines. Schedules for other vaccines can be obtained from the WHO at http://www.who.int/immunization/policy/immunization_tables/en/index.html.

Table 5: Immunization schedule of selected new and underutilized vaccines

Vaccine	Doses in primary series	Interval between doses			
		Age at 1st dose	1st to 2nd	2nd to 3rd	Booster dose
Haemophilus influenzae type b	3	6 weeks (min.) with DTP-1, 24 months (max.)	4 weeks (min.) with DTP-2	4 weeks (min.) with DTP-3	No WHO recommendation
Pneumococcal conjugate (PCV)	3	6 weeks (min.) with DTP-1	4 weeks (min.) with DTP-2	4 weeks (min.) with DTP-3	No WHO recommendation
Rotavirus					
• Rotarix®	2	6 weeks (min.), 12 weeks (max.)	4 weeks (min.) and no later than 24 weeks of age	Not applicable	No booster dose
• RotaTeq®	3	6 weeks (min.), 12 weeks (max.)	4 weeks (min.)	4 weeks (min.) and no later than 32 weeks of age	

Coverage

The primary indicator of vaccine coverage is the proportion of eligible children receiving all doses of the recommended schedule. The use of administrative data to determine estimates for vaccine coverage provides both direct and timely evidence of programme performance; such data should be readily available as part of routine programme data. Table 6 shows how immunization coverage is calculated. In order to have an accurate picture of how immunization coverage has been affected by the introduction of the new vaccine, coverage and drop-out rates for the current time period need to be compared with coverage and drop-out rates for a comparable period from the previous year. For example, if the PIE is being conducted in August, coverage and drop-out rates from the previous year should be adjusted to reflect the period January to August as well.

With non-combination vaccines, such as pneumococcus and rotavirus vaccines, coverage should be monitored individually by dose and, where possible, compared with a vaccine that follows the same schedule. Because pneumococcus and rotavirus vaccines are not given in combination with DTP, comparisons of coverage can be made within the same year. Data sources for coverage may include the following: 1) MoH administrative data; 2) immunization survey data; 3) health-facility immunization registries.

Table 6: Estimating and comparing coverage of selected vaccines from administrative data

Indicator	Calculation	Example
Pentavalent vaccine coverage	No. children receiving Penta-1 (or 2, or 3) vaccine x 100 No. of surviving infants compared with No. children receiving DTP1 (or 2, or 3) **in previous year** x 100 No. of surviving infants	Penta-3 460 000 x 100 = 93% 495 000 Compared with DTP-3: 440 000 x 100 = 92% 480 000
PCV vaccine coverage	No. children receiving PCV-1 (or 2, or 3) x 100 No. of surviving infants compared with No. children receiving DTP1 (or 2, or 3) **in current year** x 100 No. of surviving infants	Pneumo-3: 396 000 x 100 = 80% 495 000 Compared with DTP-3: 460 000 x 100 = 93% 495 000

Drop-out rates

Drop-out rates, i.e. the difference in the percentage of children who start, and those who complete the schedule of a particular vaccine, are important in measuring vaccine uptake and programme inefficiencies, and can sometimes be easier to measure than coverage. While immunization coverage measures the level of access that populations have to immunization services, the drop-out rate measures the perceived quality of services.

Table 7 outlines how vaccine drop-out rates are calculated using pentavalent (DTP-HepB-Hib) and pneumococcal vaccines as an example.

Table 7: Estimating and comparing drop-out rates of selected vaccines from administrative data

Indicator	Calculation	Example
Pentavalent drop-out rate	(Penta 1 – Penta 3) x 100 / Penta 1	(500 000–460 000) x 100 = 8% / 500 000
Pneumococcal drop-out rate	(Pneumo 1 – Pneumo 3) x 100 / Pneumo 1	(450 000–380 000) x 100 = 16% / 450 000

Records and forms

Table 8 lists records and forms that should be available for review by site. The records should be reviewed for:

- completeness, consistency and accuracy of data entry;
- timeliness of data entry;
- updating to accommodate the new vaccine.

Table 8: Records and forms

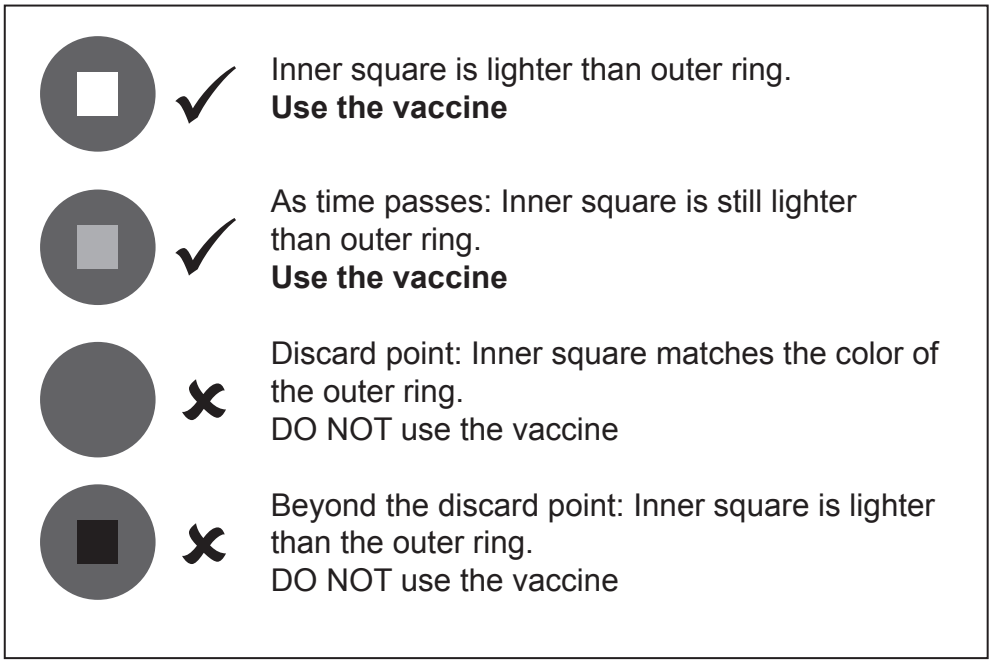
	Central	Region/District	Health Centre
Immunization logbook, tally sheet, register, recording and reporting forms			✓
Child health card			✓
Site/supervisory visit report	✓	✓	✓
Wastage report	✓	✓	✓
Monthly coverage report	✓	✓	✓
Monthly summary report	✓	✓	✓
Quarterly summary report	✓	✓	
Database updated with new vaccine	✓	✓	
AEFI case report and investigation forms		✓	✓
Vaccine storage records, including temperature records	✓	✓	✓

2.3 Cold-chain management

Some vaccines, such as rotavirus, HepB, Hib, and DTP might lose effectiveness if they are frozen. Therefore, it is imperative that any vaccine containing these antigens be transported and stored at temperatures of 2°C–8°C at all times, and that they are never frozen. It is therefore important that this issue be evaluated.

- Ask whether storage capacity and number of refrigerators have been adequate to accommodate the new vaccine and if any problems were encountered.
- Check for appropriate placement of vaccine(s) in refrigerators.
  - Vaccine(s) should not be stored in the bottom third of the refrigerator.
  - Vaccine(s) should not come into direct contact with the sides of the refrigerator.
  - There should be space between vaccine boxes to allow air circulation.
- Record the temperature reading on the thermometer at the time of the visit, and determine whether it has remained between +2°C and +8°C during the previous month by reviewing the temperature chart.
- Note if the temperature has been monitored and recorded daily (morning and evening), including weekends and holidays.
- Check whether the power supply for cold stores and refrigerators is adequate, and that a backup plan exists to maintain the cold chain for the vaccines in the event of power outages.
- Check if food or drinks are stored in the refrigerator. Refrigerators should store vaccines only.
- All vaccines are sensitive to heat. Check the vaccine vial monitor (VVM) if one is present to determine whether the vaccines have been exposed to heat (see VVM reading chart below).

Vaccine Vial Monitor (VVM) Reading



2.4 Vaccine management, transport and logistics

Adequate vaccine stock management at all levels ensures that: 1) health facilities do not experience shortages of stock; 2) overstock and expiration of vaccine do not occur. Table 9 provides examples for calculating minimum and maximum stock levels. Please note that the quantities used are examples and should not be taken as recommended quantities for any level.

- Look at vaccine forecast at the central level and determine if forecast meets demand.
- Review stock ledger at provincial, district and health-facility level.
- Ask the clinic/district if they experienced any stock-outs in the past six months due to a shortage of supply being received from the higher level. If yes, ask for how long it lasted.
- Look at ordering practices. Are supplies bundled, i.e. is there a syringe and needle for each vaccine dose and an appropriate diluent where applicable?
- Check the expiration dates of all vaccines stored. Those with the closest expiration date should be at the front of the shelf to be used first. Any expired vaccine should be discarded, and the quantities recorded appropriately in the vaccine stock records.
- Check if vaccines are inappropriately frozen. If so, discard and record the quantities appropriately in the vaccine stock records.
- Check if any reconstituted vaccines present in the refrigerator have been there longer than the recommended time. If so, discard, and record the quantities appropriately in the vaccine stock records.

Table 9: Example for calculating minimum and maximum stock levels

Minimum	Amount
Number of doses required for a given period (e.g. 3 months)	1 000
Percentage desired as minimum stock	25%
Minimum stock (doses) = 1 000 x 25%	250
Maximum	**Amount**
Number of doses required for a given period (e.g. 3 months)	1 000
Minimum stock (doses)	250
Maximum stock (doses) =1 000 + 250	1 250

2.5 Monitoring and supervision

A field evaluation should examine the monitoring of immunization coverage. At central and regional levels, the database should be updated to accommodate the new vaccine. At regional and health-facility levels, accurate recording of vaccinations compared against target populations provides health workers with the information necessary to make adjustments to their programme, to increase coverage and reduce drop-out rates.

- Check whether there is a cumulative immunization coverage chart on the wall, and that it is completed up to the last month.
- Confirm that the health worker understands the information on the graph and can interpret it to take corrective action.
- Verify whether the registers, cards, tally sheets, and monthly records and reports are filled in correctly, and that copies of the monthly reports are available at each level.

Active supportive supervision, particularly in the first several months of new vaccine introduction, greatly increases the chances for the success of the programme. Determine whether intensive supervision during the first six months was planned for and implemented at the various levels.

- Confirm supervision at the central, provincial/district and health-facility level.
- Record frequency of visits and verify with written reports.
- Record the main findings from the supervisory visits.
- Evaluate whether recommendations made during supervisory visits have been implemented.

2.6 Training and knowledge of health-care workers

Well-timed and coordinated training of all levels of staff involved in a new vaccine introduction is vital to the success of the programme. "Cascade" training is a common training approach which allows rapid dissemination of information. However, this approach runs the risk of dilution by the time it reaches field staff. The following aspects of staff training are examined in the questionnaires.

- Whether training took place before, during, or after vaccine introduction.
- Whether the health-care workers currently responsible for vaccinating with the new vaccine were the ones that received the training.
- Whether the staff felt appropriately trained, and whether enough time was dedicated to training.
- Whether content material was appropriate, and whether trainers were knowledgeable.
- Whether national guidelines are understood.
- Whether new products and samples of vaccine vials requiring reconstitution were available for demonstration at the time of training.
- Whether trainees had an opportunity to try out the new skills acquired.

Health-care workers responsible for administering the new vaccine are a key component in the success or failure of a vaccination programme, and strongly influence the success of the programme. Discussions with health-care workers should demonstrate knowledge in several key areas.

- Basic knowledge of the disease targeted by the new vaccine, and the potential impact of routine childhood immunization on disease burden (e.g. meningitis, pneumonia, diarrhoea).
- Knowledge of clear take-home messages for parents and guardians, e.g. when to return for the next dose, normal side-effects and management, severe adverse events in the event of which the child should be taken to the health facility or nearby hospital.
- Vaccine safety and the public's perception of safety which could influence vaccine demand.
- Transport, storage, preparation and administration of vaccine, including an understanding of the impact of inappropriate storage and handling; familiarity with vaccine reconstitution (if applicable), and use and disposal of auto-disable (AD) syringes.

2.7 Injection safety and waste management

Waste-management policies may vary from country to country; the evaluator should find out if a waste-management policy exists and modify questions in the PIE tool to be consistent with the national policy. During observation of the immunization session, PIE team members should:

- Assess the skills of the health-care worker in administering the vaccine. The site of vaccination should be cleaned with water if visibly dirty. Pentavalent vaccine is given intramuscularly at the anterolateral (front outer) part of the thigh. Vaccines should not be administered to the buttocks.
- Observe use and disposal of AD and reconstitution syringes and vials. All needles and syringes should be used only once. Used needles and disposable syringes must be immediately discarded into the safety box without recapping.
- Ask if personnel dedicated to waste disposal are on site or at the central level.
- Observe whether safety boxes are sent for incineration, or burning and burial at the end of the session, or only when they are full.
- If possible, observe whether all empty or used vials are counted (to verify use and wastage).
- Find out if waste disposal is onsite. If offsite, a policy for frequent transport should be in place and enforced.
- The waste-disposal area should be fenced off; if burial pits are used they should be deep — at least two metres deep.
- There should be no loose vials or syringes in the waste-disposal area.

2.8 Vaccine wastage

Wastage, particularly in the first few months following introduction, may be increased because of low uptake, overstocking (due to inaccurate vaccine demand forecasting), poor handling or inappropriate storage. Conversely, vaccine wastage might decrease considerably if a newly introduced vial contains a smaller number of doses (e.g. a change from a 10-dose DTP vial to a single-dose pentavalent [DTP-HepB-Hib] vial). WHO guidelines for maximum acceptable wastage rates by vaccine presentation are listed in Table 10 and further information is available at the following link (http://www.who.int/immunization_delivery/systems_policy/logistics_projected_wastage/en/index.html). The evaluator should ask district and provincial personnel about their wastage rate.

- Ask how wastage is determined.
- Compare wastage rate of new vaccine with other vaccines of the same type and vial size.

Table 10: Vaccine Wastage

Vaccine type	Dose per vial	Wastage rate	Wastage factor*
All	1	5%	1.05
Lyophilized	10–20	50%	2.00
Lyophilized	2	10%	1.11
Liquid	10–20	25%	1.33
Liquid	2	10%	1.11

* Calculated as 100/(100 – wastage rate)

2.9 Adverse events following immunization

An adverse event following immunization (AEFI) is a medical incident, usually severe, that occurs after an immunization and is believed to be caused by the immunization. Programmes providing immunization services should include a system for AEFI detection, reporting, investigation and management. Management includes corrective action, relevant communication and evaluation of the system. The evaluator should inquire about any possible AEFIs.

- Ask whether any AEFIs have been reported to the facility. If so, ask what they were and how they were handled?
- Find out whether case report forms and investigation forms are on site and used to report AEFIs to the higher levels.

2.10 Advocacy, communication and acceptance

Advocacy and communication efforts are linked to community acceptance of the new vaccine. Messages and methods for their dissemination need to be tailored to the target audience.

- Ask about promotional launch efforts for the new vaccine, particularly at the central level.
- At central level, ask what steps were taken to make sure that the messages and information are both relevant to, and understood and accepted by, their target audiences. Include evidence of pre-testing of messages.
- Look for evidence of health information and education efforts, such as posters, flyers and brochures, and assess their accuracy and relevance to the target audience.
- Ask about the use of community-based information dissemination channels (e.g. community and religious leaders, outreach workers, traditional birth attendants, and other community peers).

To evaluate community acceptance, interview 2–5 parents or guardians of children who have just received the new vaccine, at each clinic visited, to seek anecdotal evidence of vaccine acceptability (Appendix 2.3). Groups of caretakers can also be interviewed. If no children have been vaccinated when the evaluator is onsite, general questions can be asked of parents to elicit knowledge and acceptance of the vaccine. Health-care workers should also be asked to describe their experience of administering an additional vaccine, as their acceptance will influence the acceptability by the caregivers.

- Ask what injection the infant received.
- Ask if parents or guardians heard about the new vaccine and the disease that it prevents.
- For vaccines requiring an additional injection at an immunization visit, such as yellow fever or pneumococcal conjugate vaccine (PCV), ask if the additional injection influenced the decision whether or not to receive the vaccination. Evaluate the health-care worker's reaction to delivering an additional vaccine.

3. Data synthesis and reporting

A list of key findings (Appendix 3) has been developed to assist in summarizing the major findings of the PIE. The majority of key findings are drawn from the health-facility questionnaire and observation checklist. These indicators were selected based on their ability to highlight key aspects of the evaluation (good or bad), and in particular to prioritize important aspects of the vaccine introduction that need correction. The team may choose to include all or some of the suggested key indicators, or alternatively select others that they consider most relevant to the findings of the evaluation.

3.1 Data analysis

At the end of each interview and site visit, the team members should discuss and summarize the findings of each visit, identify key indicators for each questionnaire and checklist, and highlight the strengths and weaknesses of the vaccine introduction process at that site. The findings from the interviews at each level of the health service, and the observations at clinics should be summarized to provide an overview of the vaccine introduction process. The data may be entered into spreadsheets in the field, and then compiled for the final analysis. An example of a spreadsheet is in Appendix 5. Some key findings, such as those suggested in Appendix 3, should be used to give a summary of the vaccine introduction. For example, if it was observed that six out of 18 health facilities have inadequate waste-disposal sites, the key finding would report that 67% of sites had clean, closed-off waste-disposal areas. Other key findings can be chosen as appropriate.

3.2 Recommendations

Recommendations should be specific and achievable; they should be based on the PIE findings and should be geared towards improving the EPI system. Where possible, they should include: 1) person(s) responsible for following up on the recommendation; 2) proposed time frame for implementation of each recommendation; 3) expected outcomes and indicators. All recommendations should be compatible with existing national policies. Appendix 6 provides a list of common problems and proposed solutions that may help in formulating recommendations. The focus should be on problems that were consistently noted across several site visits.

3.3 Presentation of findings at national level

Findings should be presented in a clear and concise manner, including an overview of findings and recommendations using the template in Appendix 5. Positive findings should be highlighted at the beginning and at the end of the document, with constructive recommendations relating to any difficulties encountered presented in the middle. Findings should be presented to MoH and immunization Interagency Coordination Committee (ICC) members to provide an opportunity for discussion and clarification. Sharing the findings early is an important step in ensuring that corrective action is taken as soon as possible. A plan that outlines a timeline, and the entity responsible for taking corrective action, should be put in place to ensure that the recommendations are implemented. The country should be asked to report to the ICC 6–12 months following the PIE, regarding their progress on implementing the recommendations of the PIE. The presentation should be followed by a detailed written report as outlined in Appendix 7.

The PIE will also provide useful information to other countries planning new vaccine introduction, since they are likely to encounter similar issues. Therefore, a copy of the report should be sent to the appropriate WHO Regional Office so that the findings can be shared with other countries in the region, as well as to WHO Headquarters for sharing more widely.

4. Reference documents / websites

- **Immunization practices**
  - xi) http://www.who.int/immunization_delivery/systems_policy/training/en/index1.html.
- **Effects of freezing — preventing vaccine freezing in the cold chain (2003)**
  - i) http://www.path.org/vaccineresources/service-delivery.php.
  - ii) http://www.who.int/vaccines-documents/DocsPDF05/795.pdf.
  - xii) http://www.path.org/publications/details.php?i=953.
- **AEFI**
  - i) http://www.who.int/vaccines-documents/DocsPDF05/792.pdf.
- Reference for monovalent Hib administration
  - i) http://www.who.int/immunization_training/resources/hib_training_cvp.pdf.
- **WHO vaccine stock management and wastage**
  - i) http://www.who.int/vaccines-documents/DocsPDF06/826.pdf.
  - ii) http://www.who.int/immunization_delivery/systems_policy/logistics_projected_wastage/en/index.html.
  - ii) http://www.who.int/immunization_delivery/systems_policy/logistics/en/index2.html.
- **Cleaning injection sites**
  - i) http://www.who.int/bulletin/volumes/81/7/en/Hutin0703.pdf.
- **Multi-dose vial policy**
  - i) http://www.who.int/immunization_delivery/new_vaccines/22.WHO_V&B_00.09.pdf.
- **WHO ensuring the quality of vaccine**
  - i) http://whqlibdoc.who.int/hq/2002/WHO_V&B_02.16.pdf.
  - ii) http://www.afro.who.int/ddc/vpd/epi_mang_course/pdfs/english/Mod%209.pdf.
- **Coverage**
  - i) http://www.who.int/vaccines-documents/DocsPDF02/www721.pdf.
- **Vaccine management assessment(WHO/IVB/05.02)**
  - i) http://www.who.int/vaccines-documents/DocsPDF05/796_Final_version.pdf.

5. Appendices

All appendices are available in word or excel format at the following link: http://www.who.int/nuvi/reference/en/index.html

Appendix 1: Checklist of pre-PIE activities

Activity	Timeline	Comment
Confirm PIE participants	1 month before	Should include key in-country partners, e.g. WHO, UNICEF and other key technical immunization partners.
Select the regions/districts/ health facilities to be visited	2 weeks before	Recommended that a minimum of three regions, six districts and 18 health facilities be selected. Selection should include both well performing and poorly performing areas in terms of immunization services and show some geographic diversity (e.g. urban and rural).
Form PIE teams	1 week before	Each team should be composed of at least one staff member each from the Ministry of Health and a partner organization.
Notify selected regions/ districts/health facilities that they will be visited	1 week before	Important to ensure that immunization staff are present at the time of the visit and that immunization sessions will be carried out in the clinics on the days visited. If appropriate, cold stores may be visited on Saturdays to optimize time available. National or regional holidays should be avoided.
Organize per diems for team members	1 week before	If not organized can delay travel to the field.
Allocate teams to regions/ districts/health facilities	1 week before and confirm on Day 1 of PIE	One team needs to be allocated to conduct the interviews at the central level (National MoH, central cold store).
Organize transport and accommodation for field locations	1 week before and confirm 2 days before day of travel. Flights may need to be booked sooner	Allow adequate travel time; if possible, arrange for everyone to return from the field the same day so that all the teams can start compiling the report.
Gather the documents and data listed in Appendix 2.1	1 week before	A desk review component is an important part of the evaluation and should be conducted prior to the fieldwork. The documents listed in Table 2 should be sent to PIE participants in advance.
Allocate time on Day 1 for all participants to review the tool together to ensure a common understanding	1 week before, plan timetable and itinerary	Allow at least one half day for this activity. Prior to going into the field, teams should have a clear agenda with confirmation of whom they will be visiting.
Arrange a feedback meeting with the MOH, ICC, WHO and other partners	1 week before	It may take time to organize this meeting so is better done in advance.
Finalize and review data input tool with participants	Day 1	All teams should be equipped with data input tools (e.g. EXCEL spreadsheet, laptop computer, etc.) so that data can be merged when teams re-convene. If using an EXCEL spreadsheet, it is helpful to programme dropdown menus for consistency.

Appendix 2: Questionnaires

Layout and adapting the questionnaires

Each question in the questionnaire is accompanied by an abbreviation, explained below. When customizing a questionnaire for a particular country, the questions appropriate to the vaccine that is being introduced should be chosen. For example, if conducting a rotavirus vaccine PIE, all GEN, CENT, C&R, DIST and ROTA questions would be selected. The questions would then be adapted as appropriate for the country concerned.

Where the words '**new vaccine**' appear, they should be replaced with the name of the new vaccine being evaluated.

Abbreviation	Explanation	Comment
GEN	Generic PIE questions — should be included in all evaluations	
CENT	Questions to be asked at the central level only	These questions are shaded in grey
C&R	Questions to be asked at the central and regional level only	These questions are shaded in grey
DIST	Questions to be asked at the district level only	These questions are shaded in grey
PENTA	Pentavalent (DTP-HepB-Hib) vaccine	To be asked only if the new vaccine is pentavalent vaccine
PNEUMO	Pneumococcal	To be asked only if the new vaccine is the multi-dose, preservative-free pneumococcal vaccine
ROTA	Rotavirus vaccine	To be asked only if the new vaccine is rotavirus vaccine. Rotarix® is specific to prefilled oral syringe w/ reconstitution buffer RotaTeq® is specific to prefilled oral dropper

Separate adaptation of the tool will be required in some situations, such as the following.

1) Vaccine preparations that are used infrequently, such as monovalent Hib.
2) New vaccine presentations of pneumococcal and rotavirus vaccine that are expected to be developed in the future, e.g. fully liquid rotavirus vaccine.
3) Switches between vaccine formulations, such as between:
   - Hib monovalent and tetravalent or pentavalent Hib-containing preparations;
   - liquid and lyophilized pentavalent (DTP-HepB+Hib) vaccine to fully liquid pentavalent vaccine (DTP-HepB-Hib);
   - Rotarix® and RotaTeq®;
   - a lower valent pneumococcal conjugate vaccine to higher valency pneumococcal vaccines.
4) Evaluation of two vaccines that were introduced simultaneously.
5) Evaluations of vaccines that are not given as part of the routine infant immunization schedule.

6) Evaluation of the incremental cost of introducing a new vaccine or switching from one preparation to another. Some cost questions are included in the questionnaires, but additional information will be required, and guidance from a health economist is advised.

7) Understanding and practice of health-care workers on the practice to follow with multi-dose preservative-free liquid vials of a vaccine.

Appendix 2.1 — Questionnaire for central/regional/district

Appendix 2.2 — Questionnaire for health facility

Appendix 2.3 — Questionnaire for mothers or caregivers

Appendix 2.1: Questionnaire — central/regional/district

Date of interview: _____ Name of interviewer: _____

This questionnaire was conducted at: (insert name of country, region or district)

☐ Central level:_____

☐ Regional level: _____

☐ District level: _____

Name(s) and title(s) of person(s) interviewed (please list all persons that you interviewed):
EPI manager/person responsible for vaccinations (or their deputy) should be interviewed

Name: _____ *Title:* _____

Name: _____ *Title:* _____

Name: _____ *Title:* _____

Contact details of most senior person:

*Telephone:*_____ *E-mail address:* _____

Name of new vaccine(s) being evaluated:

New vaccine preparation: (e.g. fully liquid, liquid lyophilized, manufacturer)

_____

New vaccine presentation: (e.g. prefilled syringe, 1-dose vial, 2-dose vial)

_____

Documents to request at beginning of interview:

Document / data	Document received	Document reported to exist but not available at time of interview	Document unavailable
Copy of national immunization schedule (central level only)			
Introduction plan for new vaccine			
Training materials/reference documents utilized at new vaccine training			
Vaccine management guidelines			
Media campaign/social mobilization/education materials (e.g. brochures, posters, pamphlets)			
Vaccine stock records			
Supervisor's book/site-visit reports (regional and district level only)			
Injection safety/waste-management policy document			
Wastage reports			
AEFI protocol/reporting form			
AEFI logbook/registry			
Surveillance data/bulletin on disease targeted by new vaccine			
National coverage and drop-out rates (central level)			

Abbreviation		Central/Regional/District Questionnaire
	BACKGROUND INFORMATION	
GEN	1. Date new vaccine introduced at national/regional/ district level **Note:** *If interviewing region or district, put date for appropriate area.*	(DD/MM/YYYY) _____ / _____ / _____
GEN	2. Was the new vaccine introduced nationwide or was it a phased introduction?	☐ National introduction (all regions and districts at once) ☐ Phased introduction (explain) _____
GEN	3. What is the population of children less than one year of age in this country/region/ district? **Note:** *If not available for <1 year, get for <2 or <5 years.*	Number of children <1 year of age _____ Source/Year_____
CENT	4. What factors influenced the decision for introduction of the new vaccine?	**Check all that apply** ☐ Strong political will ☐ Strong paediatrics association ☐ Introduction by neighbouring countries ☐ Disease burden data available nationally ☐ Visit by international adviser ☐ Other influences (specify)
CENT	5. Was the national immunization advisory committee supportive of the decision to introduce the new vaccine?	☐ Yes ☐ No ☐ Don't know If no, what were their reasons: _____
CENT	6. What is the national immunization schedule? **Note:** *Ask for a copy of the schedule for all EPI vaccines (central level only).*	Copy of schedule received ☐ Yes ☐ No
CENT	7. Was the immunization schedule changed when the new vaccine was introduced? If yes, why?	☐ Yes ☐ No ☐ Don't know If yes, reason _____
CENT	8. What is the schedule for the new vaccine? **Note:** *See WHO schedule recommendation for the new vaccine in PIE manual and note if there are any differences.*	**Insert age that dose is given** Schedule: Dose 1 _____Dose 2_____ Dose 3 _____Dose 4_____
GEN	9. What disease(s) does the new vaccine prevent? **Note:** *For pentavalent ask about all five antigens.* *Hib and pneumococcal vaccines prevent some, not all, meningitis and pneumonia. Rotavirus vaccine prevents some, not all, mild and severe diarrhoea.*	
ROTA	10. Are there age restrictions to administering the rotavirus vaccine? **Note:** *Correct answer is between 15–32 weeks.*	☐ Yes ☐ No ☐ Don't know If yes, please specify: Age at last dose_____ Age at last dose_____

Abbreviation		Central/Regional/District Questionnaire
ROTA	11. Is there a required minimum interval between doses? **Note:** *Correct answer is 4 weeks.*	☐ Yes ☐ No ☐ Don't know If yes, length of interval _____
	PRE-IMPLEMENTATION PLANNING AND VACCINE INTRODUCTION PROCESS	
GEN	12. Do you have a central/regional/district new vaccine introduction plan or timeline for introduction activities? **Note:** *For example, if someone from the district only has a national plan, just check national plan. If they have a national and a district plan check both.*	☐ Yes national plan/timeline ☐ Yes, regional plan/timeline ☐ Yes, district plan/timeline **Interviewer please ask for a copy at time of interview. Review later to ensure essential components are included.** ☐ No. If no, why not? _____
CENT	**Ask only if response to question 12 was "yes"** 13. Did you receive support or use guidelines to develop your introduction plan/timeline?	☐ Yes. If yes, specify support? _____ ☐ No. If no, why not? _____ ☐ Don't know _____
	TRAINING	
GEN	14. Please describe staff training for the new vaccine introduction, if any.	Target audience for the training ☐ Doctors ☐ Nurses ☐ Health-care workers ☐ Other (specify) Type of training ☐ Cascade ☐ Region-by-region ☐ Other (specify) Was training conducted before vaccine introduction ☐ Yes ☐ No If yes, how long before _____ Was training conducted after vaccine introduction ☐ Yes ☐ No If yes, how long after _____ ☐ How long was the training? _____ Who conducted the training at each level? Regions: _____ District:_____ Health facilities: _____ Other comments on training: _____
GEN	15. How were the trainings financed?	

Abbreviation		Central/Regional/District Questionnaire
GEN	16. What specific training was given on the administration of the new vaccine?	☐ Correct implementation of the MDVP for preservative-free multi-dose vaccines (pneumo) ☐ Specific age limitations for administering the vaccine (rota) ☐ Correct use of single-dose vial (rota — not like OPV multi-dose vial) ☐ Correct administration (rota — oral not injection) ☐ Correct technique (rota — inside infant's mouth towards the inner cheek) ☐ How to reconstitute vaccine ☐ Other, specify ☐ Don't know
GEN	17. Do you think there are any ways in which the training could be improved for next time?	☐ Yes ☐ No ☐ Don't know If yes, please describe_____
GEN	18. What educational and reference materials were provided to participants at time of training? **Ask for samples.**	
	VACCINE COVERAGE	
GEN	19. Was the immunization database updated to accommodate information on the new vaccine?	☐ Yes ☐ No ☐ Don't know
GEN	20. What formula do you use to calculate vaccine coverage? Include the source of the numerator (doses administered) and denominator (target population). (See Table 6).	**Formula** Numerator source _____ Denominator source _____ Correct formula used ☐ Yes ☐ No
GEN	21. What was DTP-1 and DTP-3 vaccine coverage in the year before the new vaccine introduction? **Note:** *Use year before new vaccine introduction or closest administrative period. Use OPV-1 and OPV-3 or OPV-1 and OPV-2 for rotavirus vaccine evaluation.*	DTP-1 coverage _____ year _____ DTP-3 coverage _____ year _____ Calculate drop-out rate: (DTP1 – DTP3)/DTP1 x 100 = _____%
GEN	22. What is the coverage of the first and last dose of the new vaccine for the most recent administrative period? **Note:** *If coverage is unknown for new vaccine because PIE is done before administrative data are available, record anecdotal reports or look at number of doses of new vaccine used versus number of doses of DTP used.*	New vaccine first dose (NV1) coverage _____ New vaccine last dose (NVL) coverage _____ Calculate drop-out rate: (NV1 – NVL)/NV1 x 100 = _____% *(See Table 7)*
GEN	23. Is coverage of the new vaccine higher or lower than DTP? **Note:** *Use OPV for rotavirus vaccine evaluation.*	New vaccine first dose versus DTP-1 ____% Higher ____% Lower ☐ No change New vaccine last dose versus DTP-3 ____% Higher ____% Lower ☐ No change
GEN	24. Is the drop-out rate for the new vaccine higher or lower than the DTP drop-out rate? **Note:** *Use OPV for rotavirus vaccine evaluation.*	New vaccine drop-out rate versus DTP drop-out rate ____% Higher ____% Lower ☐ No change
GEN	25. Is there a cumulative immunization coverage chart on the wall? Do you know how to interpret the data to increase coverage?	

Abbreviation		Central/Regional/District Questionnaire
CENT/REG	26. In the last year, what proportion of regions/districts/ health facilities sent all monthly immunization summary forms completed and submitted on time?	Percentage of regions/districts/health facilities submitting reports on time every month Percentage reports complete _____ (Of reports received, how many have all key information completed for every month)?
COLD-CHAIN MANAGEMENT		
GEN	27. Discuss any changes you had to make in the cold chain before introduction of the new vaccine. **Note:** *Try to distinguish cold chain expansion/ replacement of equipment that is part of normal cold-chain rehabilitation from changes made specifically to accommodate the new vaccine.*	
GEN	28. Were any problems with the cold chain identified after the introduction of the new vaccine? If yes, what were the problems and how have the problems been addressed?	☐ No problems ☐ Inadequate space ☐ Frozen vaccine ☐ Malfunctioning refrigerators ☐ Power supply/fuel shortage ☐ Other (specify)
GEN	29. Do you use freeze watch monitors during vaccine transportation?	☐ Yes ☐ No ☐ Don't know
VACCINE MANAGEMENT, TRANSPORT & LOGISTICS		
GEN	30. Do you have immunization policy guidelines for vaccine management? If yes, have they been updated to include the new vaccine? **Please provide a copy at time of interview.**	☐ Yes ☐ No
GEN	31. How do you forecast vaccine requirements?	
GEN	32. Did the estimated needs change with introduction of the new vaccine?	☐ Yes ☐ No ☐ Don't know If yes, why? _____
GEN	33. How are vaccines ordered?	
GEN	34. Please describe how vaccines are transported to the regions/districts/health facilities.	
GEN	35. How often do you send out vaccine shipments and supplies from your level to the next level?	
GEN	36. Did the frequency of deliveries change with introduction of the new vaccine? If yes, by how much?	☐ Yes ☐ No ☐ Don't know If yes, Frequency of delivery before introduction _____ times/year Frequency of delivery after introduction _____ times/year Reason for change? _____
GEN	37. Please describe how the transportation of vaccines to outreach sites has changed with the introduction of the new vaccine.	
GEN	38. What effect did the new vaccine have on dry storage space requirements?	

Abbreviation		Central/Regional/District Questionnaire
GEN	39. What were the costs associated with increased transport or cold-chain requirements?	Please state how many of the following were required: Extra trucks/cars rental or purchase _____ Extra logistic staff _____ Extra petrol _____ Extra cold-chain space _____ Other costs (specify) _____
GEN	40. Who paid for these extra costs?	
PENTA	41. What policy was established for the remaining quantities of DTP after introduction of pentavalent vaccine? Note: *Check if this policy is included in the vaccine introduction plan.*	Check all mentioned ☐ No policy ☐ DTP used until finished ☐ DTP to be sent to district ☐ DTP destroyed ☐ DTP to be sent to province/national level ☐ Other (specify) _____ ☐ Don't know
PENTA	42. Did you have a time gap between using up DTP vaccine stock and receiving pentavalent vaccine? If yes, for how long?	☐ Yes ☐ No If yes, how many weeks _____
GEN	43. Did you run out of any vaccines, including the new vaccine, or vaccine supplies in the past six months?	☐ Yes, vaccines (specify)_____ ☐ Yes, vaccine supplies (specify) _____ ☐ No If yes, how many weeks _____ If yes, reason for stock out _____
GEN	44. Have you had any vaccine expirations in the last six months? If yes, what did you do with the expired stock?	☐ Yes ☐ No If yes, action taken_____
GEN	45. Have you had any vaccine with the vaccine vial monitor (VVM) in stage III or IV in the last six months? If yes, what did you do with these vaccines?	☐ Yes ☐ No If yes, action taken_____
GEN	46. Are vaccine orders/deliveries tied to injection supplies (i.e. bundling)? Note: *Look at stock records to get this information.*	☐ Yes ☐ No Verified by checking stock records ☐ Yes ☐ No
ROTA	For Rotarix® only 47. How do you store Rotarix® vaccine?	☐ Keep the different components boxed together in the 25-dose box in the refrigerator If yes, why _____ ☐ Store the different components separately in and outside of the refrigerator If yes, why _____ ☐ Don't know
	WASTE MANAGEMENT & INJECTION SAFETY	
GEN	48. Describe the waste-disposal policy/plan at each level.	
GEN	49. Does each level generally follow these guidelines?	☐ Yes ☐ No ☐ Don't know
GEN	50. Did you have to make changes to your waste-disposal system for introduction of the new vaccine? If yes explain.	

Abbreviation		Central/Regional/District Questionnaire
GEN	51. Did you have to make changes to your injection safety practices for introduction of the new vaccine? If yes, explain.	
	VACCINE WASTAGE	
GEN	52. What formula is used to calculate vaccine wastage and what is the source of the data. **Ask for wastage report.**	☐ Vaccine wastage not calculated Formula: Data source, numerator_____ Data source, denominator _____ Is provided formula correct? **(See Table 10)** ☐ Yes ☐ No Source of data: ☐ Stock books ☐ Summary sheets ☐ Other
GEN	53. What is the vaccine wastage rate of the new vaccine? **Note:** *If vaccine wastage rate is unknown for new vaccine because PIE is done before administrative data are available, record anecdotal reports or attempt part-year calculation.*	New vaccine wastage rate _____%
PENTA	54. What was the DTP wastage rate? **Note:** *Use year before new vaccine introduction or closest administrative period.*	DTP wastage rate _____%
PENTA	55. Has the pentavalent vaccine wastage rate changed when compared to DTP wastage rate (last administrative period)?	New vaccine wastage rate versus DTP wastage rate ____% Higher ____% Lower ☐ No change
GEN	56. Did you change anything about the way you administer vaccines, to reduce wastage of the new vaccine?	
	MONITORING AND SUPERVISION	
GEN	57. How often are supervisory visits made to the regional/district/health-facility level?	Regional level _____ District level _____ Health-facility level_____
C&R	58. Have you or a member of your staff or a partner organization made supervisory visits, to the districts/ health facilities since new vaccine introduction? If so, how often and by whom?	☐ Yes ☐ No If yes, how often _____ By whom _____ If no, why not? _____
GEN	59. How do supervisors give feedback to sites visited?	☐ Written ☐ Supervisory logbook ☐ Supervisory checklist ☐ Send site visit report ☐ Other (specify) _____ ☐ Oral ☐ Discussion with staff ☐ Other (specify) _____
GEN	60. What are the main issues that came up at the last two supervisory visits? Are they specifically related to introduction of the new vaccine? How have they been resolved?	a. _____ b. _____ c. _____

Abbreviation		Central/Regional/District Questionnaire
GEN	61. Are follow-up visits conducted at sites with inadequate performance and continuing problems?	☐ Yes ☐ No
DIST	62. Have you received a supervisory visit? If yes, when and by whom?	☐ Yes ☐ No When _____ By whom _____ Ask to see a copy of the visit report.
ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)		
GEN	63. Do you have a system and written protocol for monitoring and reporting AEFIs for all vaccines? Please describe the procedure. **Ask for a copy of the AEFI protocol and reporting form.**	☐ Yes ☐ No If no, why not _____ .
GEN	64. Do you have a crisis plan in place to manage AEFIs? Please describe.	
GEN	65. Did you make any changes to the AEFI protocol specifically for the new vaccine?	
GEN	66. Have you had any reported AEFIs for the new vaccine or another vaccine since the new vaccine was introduced? **Note:** *Verify using AEFI logbook/registry if available.*	☐ Yes ☐ No ☐ Don't know If yes, How many for the new vaccine _____ How many for a traditional vaccine (specify) _____ What were the AEFIs_____ How were they handled? _____
ADVOCACY & COMMUNICATION		
GEN	67. Did you have an official launch ceremony at the time of the new vaccine introduction? **Note:** *If yes, what did it involve, was it successful, did it get much media coverage, how long before the introduction of the new vaccine did it take place?*	☐ Yes ☐ No ☐ Don't know If yes, describe _____ If no, why not? _____
GEN	68. Did you use any media outlets to promote the new vaccine and inform/educate the community about the vaccine? **Note:** *Please ask for copies of any materials.*	Check all that apply: ☐ Radio ☐ Television ☐ Community groups ☐ Town crier ☐ Celebrity ☐ Government officials ☐ Other (specify) Main messages _____
GEN	69. Did you prepare or distribute any health education material for the community on the new vaccine? If yes, what were they? Who were the target audiences? When and how were they distributed? **Note:** *Please ask for copies of any materials.*	Check all that apply: ☐ Posters ☐ Brochures ☐ Flyers ☐ Clothing (t-shirts, hats etc.) ☐ Other (specify) Target audiences _____ Main messages _____

Abbreviation		Central/Regional/District Questionnaire
	SUSTAINABILITY	
CENT	70. Is there a budget line for vaccine purchases in the national budget?	
CENT	71. How are traditional EPI vaccines financed? **Note:** *List all sources that pay for the vaccine.*	
CENT	72. How is the new vaccine paid for? **Note:** *List all sources that pay for the vaccine.*	
C&R	73. Do you plan to introduce any more new vaccines in the future? If yes, which one(s) and when? **Note:** *If they say no, this is an opportunity to mention new vaccines, such as pneumococcal vaccine, rotavirus vaccine and HPV, that probably will be available in the future.*	
	SURVEILLANCE	
C&R	74. Do you have surveillance for the diseases which the new vaccine will prevent? Please describe. **Note:** *Include the number of sites, date started.* **Ask for a copy of the surveillance data/bulletin.**	
C&R	75. Have there been any problems with the surveillance?	☐ Yes ☐ No ☐ Don't know If yes, describe _____
	IMPACT ASSESSMENT	
C&R	76. Are you conducting, or do you plan to conduct, a vaccine impact assessment, i.e. a study to determine if the new vaccine is reducing disease burden?	☐ Yes ☐ No ☐ Don't know If yes, give details _____ If no, why not? _____
	GENERAL IMPRESSIONS	
GEN	77. How well was the new vaccine accepted? If there were any problems, please comment for each group. **Note:** *Was it considered to be a safe and effective, and needed vaccine?*	**New vaccine well accepted** Health-care workers ☐ Yes ☐ No Professional societies ☐ Yes ☐ No Community/public ☐ Yes ☐ No Government ☐ Yes ☐ No Media ☐ Yes ☐ No On what is your answer based? _____ Discuss any problems _____
GEN	78. Were there financial implications in introducing the new vaccine for each of the following areas?	**Ask about the financial implications of each of the following:** Cold chain ☐ Yes ☐ No If yes, specify: _____ Vaccine transport ☐ Yes ☐ No If yes, specify: _____ Wastage ☐ Yes ☐ No If yes, specify: _____ Communication materials/ media ☐ Yes ☐ No If yes, specify: _____ Training ☐ Yes ☐ No If yes, specify: _____ Other costs? ☐ Yes ☐ No If yes, specify: _____

Abbreviation		Central/Regional/District Questionnaire
GEN	79. What effect has the introduction of the new vaccine had on your EPI programme?	**Please check one that best describes the introduction:** ☐ Improved the EPI programme. Please explain _____ ☐ Made the EPI programme worse. Please explain _____ ☐ No effect. Please explain
GEN	80. In your opinion, was the introduction of the new vaccine a smooth process or problematic? Please explain.	**Please check one that best describes the introduction:** ☐ Very smooth. No problems ☐ Smooth, minor problems. Please explain _____ ☐ Somewhat smooth, some major problems. Please explain _____ ☐ Not smooth at all, some major problems Please explain _____
GEN	81. Many other countries will be introducing this and other new vaccines soon. What have you learned from this experience, and what advice do you have for other countries to ensure a smooth introduction?	
OBSERVATION OF VACCINE STORAGE AREA AT THE CENTRAL/REGIONAL/DISTRICT LEVELS		
GEN	82. Are all freezers and refrigerators clean and functioning properly?	☐ Yes ☐ No
GEN	83. Are there thermometers outside the freezers and refrigerators?	☐ Yes ☐ No ☐ Some
GEN	84. Are there thermometers inside the freezers and refrigerators?	☐ Yes ☐ No ☐ Some
GEN	85. Is the temperature inside the refrigerators currently between +2° and +8° C?	☐ Yes ☐ No ☐ Some
GEN	86. Is there a log of freezer and refrigerator temperatures?	☐ Yes ☐ No ☐ Some If yes, has temperature consistently been between +2° and +8° C for refrigerators in the last two months? ☐ Yes ☐ No ☐ Some
GEN	87. How often are temperatures recorded?	☐ Twice daily ☐ Daily ☐ No records ☐ Other (specify) _____
GEN	88. Are temperatures monitored and recorded on weekends and holidays? **Note:** *Check specifically for holidays in _____ (insert date of most recent holiday).*	☐ Yes ☐ No ☐ Sometimes
GEN	89. Are all vaccines arranged as "First expiry, First out"?	☐ Y ☐ N If no, why not? _____ ☐ Not applicable. Why? _____
GEN	90. Did you observe any expired vaccines?	☐ Yes ☐ No If yes, which vaccine, and how many? _____

Abbreviation		Central/Regional/District Questionnaire
GEN	**For vaccines with a VVM** 91. Did the VVMs that you observed indicate that vaccine is usable, i.e. Stage 1 or 2	☐ Yes, all vaccines usable ☐ No, some vaccines Stage 3 or 4 (unusable) Specify vaccine and proportion unusable _____
GEN	**For vaccines with a VVM** 92. Are vaccines with VVM in Stage 2 arranged so that they are used first?	☐ Y ☐ N ☐ Not applicable, no Stage 2
GEN	93. Are there spaces between the vaccine boxes/trays to allow air circulation?	☐ Yes ☐ No
GEN	94. Is injection equipment stored in good condition?	Other costs? ☐ Yes ☐ No Adequate space ☐ Yes ☐ No Clean and dry conditions ☐ Yes ☐ No Well organized (i.e. easily accessible) ☐ Yes ☐ No ☐ Other observation (specify) _____
NOTES AND COMMENTS		
GEN	If you were unable to visit the cold store or dry store area, please mention reason. Record any interesting positive or negative anecdotes or comments by immunization staff.	

Appendix 2.2: Questionnaire — health facility

Date of interview: _____ Name of interviewer: _____

This questionnaire was conducted at:

☐ Region: _____

☐ District: _____

☐ Health-facility name: _____

Type of health facility (check one):

☐ Health Centre/Clinic ☐ Health Post/Outpost ☐ Other (specify) _____

Name(s) and title(s) of person(s) interviewed (please list all persons that you interviewed):
EPI Senior Nurse/Health-care worker responsible for vaccinations (or their deputy) should be interviewed

Name: _____ *Title:* _____

Name: _____ *Title:* _____

Name: _____ *Title:* _____

Contact details of most senior person:

Telephone: _____ *E-mail address:* _____

★ Denotes Suggested Key Finding (see Appendix 3).

Documents to request at beginning of interview: (check appropriate boxes)

Document / data	Document received	Document reported to exist but not available at time of interview	Document unavailable
Introduction plan for new vaccine			
Training materials/reference documents utilized during new vaccine training			
Vaccine management guidelines			
Media campaign/social mobilization/education materials (brochures, posters, pamphlets, etc.)			
Vaccine stock records			
Supervisor's book/site visit reports			
Injection safety/waste-management policy document			
Wastage reports			
AEFI protocol/reporting form			
AEFI logbook/registry			
Sample child health card/immunization card			
Immunization logbooks, monitoring forms, tally sheets, vaccine registries			

Abbreviation		Health-Facility Questionnaire
PRE-IMPLEMENTATATION PLANNING		
GEN	1. Were you (interviewee) working at this health facility at the time of the new vaccine introduction?	☐ Yes ☐ No **Interviewer:** If "No", try to get a staff member who was present when the new vaccine was introduced to participate. If not, continue with the interview although it may not be possible to answer all questions.
GEN	2. When was the new vaccine first administered at this health facility?	(DD/MM/YYYY) _____ / _____ / _____ ☐ Don't know
TRAINING		
GEN	3. Please describe health-facility staff training for the new vaccine introduction, if any.	How many people from this health facility were trained? _____ Who from this health facility was trained? _____ How many of them are still working at this health facility? _____ How long was the training for health facility staff? _____ What were the key topics covered in the training? _____ Were there any opportunities to practice the new skills to administer the new vaccine correctly? _____ Did the person from this health facility who was trained, train others in the health facility? ☐ Yes ☐ No ☐ Don't know Was training conducted before vaccine introduction ☐ Yes ☐ No If yes, how long before? _____ Was training conducted after vaccine introduction ☐ Yes ☐ No If yes, how long after? _____ Who conducted the training for health-facility staff? _____ Other comments on training _____
GEN	4. What specific training did you receive on the administration of the new vaccine?	**Check all mentioned** ☐ Correct implementation of the MDVP for preservative-free multi-dose vaccines (pneumo) ☐ Specific age limitations for administering the vaccine (rota) ☐ Correct use of single-dose vial (rota — not like OPV multi-dose vial) ☐ Correct administration (rota — oral not injection) ☐ Correct technique (rota — inside infant's mouth towards the inner cheek) ☐ How to reconstitute vaccine ☐ Other, specify ☐ Don't know

Abbreviation		Health-Facility Questionnaire
GEN	5. Do you think there are any ways in which the training could be improved for next time?	☐ Yes ☐ No ☐ Don't know If yes, please describe_____
GEN	6. Are new vaccine introduction guidelines or educational and reference materials from the training available? **Ask to see samples.**	☐ Yes ☐ No ☐ Don't know ★ **Key Finding: Guidelines/training materials provided?**
GEN	7. Overall, were you satisfied with the training provided?	☐ Yes ☐ No ☐ Don't know ★ **Key Finding: Satisfaction with training?**
VACCINE COVERAGE		
GEN	8. What is the size of the target population for infant immunizations in this health facility? What is the source of this figure? **Note:** *If not available for <1 year, get information for <2 or <5 years.*	<1 year of age: _____ Source of data _____
GEN	9. What formula do you use to calculate vaccine coverage? Include the source of the numerator (doses administered) and denominator (target population). (See Table 6)	**Formula** Numerator source _____ Denominator source _____ Correct formula used ☐ Yes ☐ No
GEN	10. What was DTP-1 and DTP-3 vaccine coverage in the year before the new vaccine introduction? **Note:** *Use year before new vaccine introduction or closest administrative period. Use OPV-1 and OPV-3 or OPV-1 and OPV-2 for rotavirus vaccine evaluation.*	DTP-1 _____ year _____ DTP-3 _____ year _____ Calculate drop-out rate: (DTP1 – DTP3)/DTP1 x 100 = _____% *(See Table 7)*
GEN	11. What is the coverage of the first and last dose of the new vaccine for the most recent administrative period? **Note:** *If coverage is unknown for new vaccine because PIE is done before administrative data are available, record anecdotal reports or look at number of doses of new vaccine used versus number of doses of DTP used.*	New vaccine first dose (NV1) coverage _____ New vaccine last dose (NVL) coverage _____ Calculate drop-out rate: (NV1 – NVL)/NV1 x 100 = _____%
GEN	12. Is coverage of the new vaccine higher or lower than DTP? **Note:** *Use OPV for rotavirus vaccine evaluation.*	New vaccine first dose versus DTP-1 coverage rates ____% Higher ____% Lower ☐ No change New vaccine last dose versus DTP-3 coverage rates ____% Higher ____% Lower ☐ No change ★ **Key Finding: Percentage change in coverage rate**
GEN	13. Is the drop-out rate for the new vaccine higher or lower than the DTP drop-out rate? **Note:** *Use OPV for rotavirus vaccine evaluation.*	New vaccine drop-out rate versus DTP drop-out rate ____% Higher ____% Lower ☐ No change ★ **Key Finding: Percentage change in drop-out rate**
GEN	14. How often do you report immunization data to the district? **Ask to see a report.**	

Abbreviation		Health-Facility Questionnaire
GEN	15. Have immunization registries/child health cards, etc. been updated to include the new vaccine?	Check box if updated ☐ Vaccine registry/logbook ☐ Child health card ☐ Tally sheets/district reporting forms ☐ Vaccine stock forms ☐ Other (specify)
GEN	16. How many days a week does your site perform outreach immunization sessions, i.e. immunization sessions not conducted at the health facility?	☐ Outreach not performed _____ times per week
GEN	17. Are outreach data collected separately?	☐ Yes ☐ No
GEN	18. Do you include the new vaccine in the outreach immunization sessions?	☐ Yes ☐ No. If no, reason _____
GEN	19. What changes, if any, did you have to make to outreach sessions when you introduced the new vaccine?	☐ No changes required ☐ More vaccine carriers required ☐ Increased number of outreach sessions ☐ Other changes (specify)
COLD-CHAIN MANAGEMENT		
GEN	20. What is the source of power supply for cold storage?	☐ Check all that apply ☐ Cold storage box ☐ Refrigerator, kerosene ☐ Refrigerator, electricity ☐ Refrigerator, solar ☐ Refrigerator, mixed power source ☐ Other (specify) _____
GEN	21. The last time there was an interruption in your power supply, what did you do? (Includes lack of kerosene)	
GEN	22. Discuss any changes you had to make in the cold chain before introduction of the new vaccine. **Note:** *Try to distinguish cold-chain expansion/replacement of equipment that is part of normal cold-chain rehabilitation from changes specifically for the new vaccine.*	
GEN	23. Were there any problems with the cold chain recognized after the introduction of the new vaccine? If yes, what were the problems and have the problems been addressed? If they have been addressed, how were they addressed?	☐ No problems ☐ Inadequate space ☐ Frozen vaccine ☐ Malfunctioning refrigerators ☐ Power supply/fuel shortage ☐ Other (specify) ☐ How resolved? _____ ★ **Key Finding: Percentage health facilities observed or reported problems with the cold chain**

Abbreviation		Health-Facility Questionnaire
VACCINE MANAGEMENT, TRANSPORT & LOGISTICS		
GEN	24. Do you have immunization policy guidelines for vaccine management? If yes, have they been updated to include the new vaccine? Please provide a copy at time of interview.	☐ Yes ☐ No
GEN	25. How do you forecast vaccine requirements?	
GEN	26. How did estimated requirements change following introduction of the new vaccine?	☐ Yes ☐ No ☐ Don't know If yes, why? _____
GEN	27. Please describe how vaccines are ordered and delivered to the health facility.	Who orders? _____ How often are vaccines delivered? _____ Any problems with this?_____
PENTA	28. What did you do with remaining quantities of DTP after introduction of the new vaccine?	**Check all mentioned** ☐ No policy ☐ DTP used until finished ☐ DTP to be sent to district ☐ DTP destroyed ☐ DTP to be sent to province/national level ☐ Other (specify)
PENTA	29. Did you have a gap between using up DTP vaccine and receiving the new vaccine? If yes, for how long?	☐ Yes ☐ No If yes, how many weeks? _____
GEN	30. Have you had any vaccine expirations in the last six months? If yes, what did you do with the expired stock?	☐ Yes ☐ No If yes, action taken?_____
GEN	31. Have you had any vaccine with VVM in Stage III or IV in the last six months? If yes, what did you do with these vaccines?	☐ Yes ☐ No If yes, action taken?_____
GEN	32. Did you run out of any vaccines, including the new vaccine, or vaccines supplies in the past six months?	☐ Yes ☐ No ☐ Yes, vaccines (specify) ☐ Yes, vaccine supplies (specify) ☐ No If yes, how many weeks? _____ If yes, reason for stock out _____ ★ **Key Finding: Percentage of health facilities reporting vaccine or supply stock out in last six months**
GEN	33. Are vaccine orders/deliveries tied to injection supplies (i.e. bundling)? **Note:** *Look at stock records to get this information.*	☐ Yes ☐ No Verified by checking stock records ☐ Yes ☐ No
ROTA	For Rotarix® only 34. How do you store Rotarix® vaccine?	☐ Keep the different components all boxed together in the 25-dose box in the refrigerator If yes, action taken?_____ ☐ Store the different components separately in and outside of the refrigerator If yes, action taken?_____ ☐ Don't know

Abbreviation		Health-Facility Questionnaire
WASTE MANAGEMENT AND INJECTION SAFETY		
GEN	35. Did you have to make any changes to your waste-disposal system for introduction of the new vaccine? If yes, explain.	☐ Yes ☐ No If yes, explain_____
GEN	36. Have you experienced any problems with your waste-disposal system? **Observe site.**	☐ Yes ☐ No If yes, explain_____
VACCINE WASTAGE		
GEN	37. What formula is used to calculate vaccine wastage and what is the source of the data. **Ask for wastage report.**	☐ Vaccine wastage not calculated Formula: **(See Table 10)** Data source, numerator_____ Data source, denominator_____ Is formula provided correct? ☐ Yes ☐ No Source of data: ☐ Stock books ☐ Summary sheets ☐ Other ★ **Key Finding: Wastage report on site? ☐ Yes ☐ No**
GEN	38. What is the vaccine wastage rate of the new vaccine? **Note:** *If vaccine wastage rate is unknown for new vaccine because PIE is done before administrative data are available, record anecdotal reports or attempt part-year calculation.*	New vaccine wastage (this administrative period)_____ %
PENTA	39. What was the DTP wastage rate? **Note:** *Use year before new vaccine introduction or closest administrative period.*	DTP wastage (administrative period) _____ %
PENTA	40. Has the pentavalent vaccine wastage rate changed when compared to DTP wastage rate (last administrative period)?	New vaccine wastage rate versus DTP wastage rate ____% Higher ____% Lower ☐ No change
GEN	41. Did you change anything about the way you administer vaccines, to reduce wastage of the new vaccine?	
MONITORING AND SUPERVISION		
GEN	42. How many times in the past six months have you received a supervisory visit from district or regional level or from a partner agency? Was the visit documented? **Ask to see the supervisory book, copy of last report.**	Number of visits _____ Is there a written report of the visit? ☐ Yes ☐ No ★ **Key Finding: At least one documented visit**? ☐ Yes ☐ No
GEN	43. If yes, who visited, and what were the problems identified?	Who visited? _____ (job title) Problems identified _____

Abbreviation		Health-Facility Questionnaire
ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)		
GEN	44. Do you have a system and written protocol for monitoring and reporting AEFIs for all vaccines? Please describe the procedure. **Ask for a copy of the AEFI protocol and reporting form.**	☐ Yes ☐ No If no, why not? _____ ★ **Key Finding: AEFI system/protocol in place?**
GEN	45. Did you make any changes to the AEFI protocol specifically for the new vaccine?	
GEN	46. Have you had any reported AEFIs for the new vaccine or another vaccine since the new vaccine was introduced? **Note:** *Verify using AEFI log book/registry, if one.*	☐ Yes ☐ No ☐ Don't know If yes: How many for the new vaccine? _____ How many for a traditional vaccine? (specify) _____ What were the AEFIs? _____ How were they handled? _____
ADVOCACY, COMMUNICATION & ACCEPTANCE		
GEN	47. Did you have an official launch ceremony at this health facility at the time of the new vaccine introduction? **Note:** *What did it involve, was it successful, did it get much media coverage?*	☐ Yes ☐ No ☐ Don't know If yes, describe _____
GEN	48. Did this health facility provide any health education messages or materials to the community about the new vaccine at the time of introduction? **Ask to see copies of materials.**	**Check all that apply** ☐ None provided ☐ Posters ☐ Brochures ☐ Health education sessions ☐ Public meetings ☐ Other (specify) _____
GEN	49. Did you experience any resistance from the community regarding the new vaccine?	☐ Yes ☐ No ☐ Don't know
GEN	50. Do you remember any media focus (e.g. on radio, television or newspapers) on the new vaccine?	☐ Yes ☐ No If yes, describe _____
HEALTH-CARE WORKER KNOWLEDGE (ask HCW, not head of health facility)		
GEN	51. What is the immunization schedule for the new vaccine?	
ROTA	52. Are there infants who should not receive the vaccine? **Note:** *Age restrictions: maximum age for first dose, maximum age for last dose.*	☐ Yes ☐ No ☐ Don't know If yes, who? _____

Abbreviation		Health-Facility Questionnaire
ROTA	53. Please explain the correct way to administer the rotavirus vaccine.	**Check all mentioned** ☐ It is a single-dose vial so all is given ☐ It is given orally ☐ It is put inside the infant's mouth towards their cheek ☐ The vaccine needs to be reconstituted ☐ Other, specify _____
ROTA	54. Have you or other staff experienced any problems with administering rotavirus vaccine?	Record any problems mentioned
PENTA	55. What antigens are included in pentavalent vaccine?	**Check if mentioned — don't prompt but can tell afterwards** ☐ Diphtheria ☐ Pertussis ☐ Tetanus ☐ Haemophilus influenzae type B (Hib) ☐ Hepatitis B (HepB) List others mentioned _____
GEN	56. What disease(s) does the new vaccine prevent? **Interviewer:** For Penta ask about all five antigens *Hib and Pneumo vaccine prevents some, not all, meningitis and pneumonia.* *Rotavirus vaccine prevents some, not all, severe and mild diarrhoea.*	**Interviewer: Write exact response given** _____ _____ _____ _____ _____ _____ ★ **Key Finding: Percentage HCWs that knew what disease(s) the new vaccine prevents?**
GEN	57. What information do you provide to parents before and after vaccination with the new vaccine?	**Check if mentioned — don't prompt but can tell afterwards** ☐ Name of the vaccine ☐ Diseases it protects against ☐ Benefits to the child and the family ☐ Vaccine schedule/when to return ☐ Normal side effects? ☐ What side effects they should return for ☐ Bring vaccination card ☐ Other health messages (specify) Two or more mentioned? ☐ Yes ☐ No ★ **Key Finding: Percentage HCWs providing two or more accurate pieces of information to parents? ☐ Yes ☐ No**

Abbreviation		Health-Facility Questionnaire
	GENERAL IMPRESSIONS	
GEN	58. Were there any financial implications for the health facility involved in introduction of the new vaccine?	**Ask about the financial implications of each of the following:** ☐ Don't know Cold chain ☐ Yes ☐ No If yes, specify_____ Vaccine transport ☐ Yes ☐ No If yes, specify_____ Wastage ☐ Yes ☐ No If yes, specify_____ Communication materials/media ☐ Yes ☐ No If yes, specify_____ Training ☐ Yes ☐ No If yes, specify_____ Other costs? ☐ Yes ☐ No If yes, specify_____
GEN	59. What effect has the introduction of the new vaccine had on your EPI programme?	**Please check one that best describes the introduction:** ☐ Improved the EPI programme. Please explain _____ ☐ Made the EPI programme worse. Please explain _____ ☐ No effect. Please explain _____ ★ **Key Finding: Percentage sites reporting that new vaccine improved the EPI programme?**
GEN	60. In your opinion, was the introduction of the new vaccine a smooth process or problematic? Please explain.	Please check one that best describes the introduction: ☐ Very smooth. No problems ☐ Generally smooth, minor problems. Please explain _____ ☐ Somewhat smooth, some major problems. Please explain _____ ☐ Not smooth. Major problems. Please explain _____ ★ **Key Finding: Percentage sites reporting a smooth or very smooth introduction**
GEN	61. Many other countries will be introducing this and other new vaccines soon. What have you learned from this experience and what advice do you have for other health facilities to ensure a smooth introduction?	
	OBSERVATIONS AT VACCINATION SESSION	
GEN	62. Are (all) vaccines reconstituted correctly (e.g. measles, BCG, penta, rota)?	☐ Yes ☐ No ☐ Don't know (N = unsafe practice)
GEN	63. Are vaccines stored/handled properly during the session, e.g. clean, organized, vaccine vials outside carrier are in foam pad?	☐ Yes ☐ No ☐ Don't know (N = unsafe practice)

Abbreviation		Health-Facility Questionnaire
GEN	64. Are appropriate administration techniques observed (e.g. pentavalent intramuscular injection in the thigh, and rota, oral, inside cheek)?	☐ Yes ☐ No ☐ Don't know (N = unsafe practice)
GEN	65. Are AD syringes used?	☐ Yes ☐ No (N = unsafe practice)
GEN	66. Are needles recapped (look in safety box for capped needles)?	☐ Yes ☐ No ☐ Don't know (Y = unsafe practice)
GEN	67. Are AD syringes disposed of in a safety box?	☐ Yes ☐ No ☐ Don't know (N = unsafe practice)
GEN	68. Is the policy on use of the open multi-dose vial observed?	Date opened marked on vial ☐ Yes ☐ No Open vial discarded at end of immunization session ☐ Yes ☐ No ☐ Other observation (specify) _____ ☐ Unknown (N = unsafe practice)
GEN	69. Summary: How many unsafe practices, based on questions above, were observed?	Number of unsafe practices_____ ★ **Key Finding: Percentage of sites with two or more unsafe practices observed**
OBSERVATION OF VACCINE STORAGE AREA		
GEN	70. Are all refrigerators clean and properly functioning?	☐ Yes ☐ No
GEN	71. Is there a thermometer outside the refrigerator?	☐ Yes ☐ No
GEN	72. Is there a thermometer inside the refrigerator?	☐ Yes ☐ No
GEN	73. Is the temperature inside the refrigerator currently between +2° and +8° C?	☐ Yes ☐ No What is the temperature? _____
GEN	74. Is there a log of refrigerator temperatures?	☐ Yes ☐ No
GEN	75. How often are temperatures recorded?	☐ Twice daily ☐ Daily ☐ No records ☐ Other (specify)
GEN	76. Are temperatures monitored and recorded on weekends and holidays? **Note:** *Check specifically for holidays in _____(insert date of most recent holiday).*	☐ Yes ☐ No ☐ Sometimes
GEN	77. Are vaccines arranged as "First expiry, First out"?	☐ Yes ☐ No If no, why not?_____ ☐ Not applicable. Why? _____
GEN	78. Did you observe any expired vaccines?	☐ Yes ☐ No If yes, which vaccine and how many? _____ _____
GEN	**For vaccines with a VVM** 79. Did the VVMs that you observed indicate that vaccine is usable, i.e. Stage 1 or 2	☐ Yes, all vaccines usable ☐ No, some vaccines Stage 3 or 4 (unusable) Specify vaccine and proportion unusable _____ ★ **Key Finding: Percentage of health facilities reporting with any VVM in Stage 3 or 4.**

Abbreviation		Health-Facility Questionnaire
GEN	**For vaccines with a VVM** 80. Are vaccines with VVM in Stage 2 arranged so that they are used first?	☐ Y ☐ N ☐ Not applicable, no Stage 2
GEN	81. Are there spaces between the vaccine boxes/trays to allow air circulation?	☐ Yes ☐ No
	HEALTH COMMUNICATION	
GEN	82. Are any posters or other literature about the new vaccine noted in the health facility?	☐ Yes ☐ No
	STOCK ROOM	
GEN	83. Is injection equipment stored in good condition	Adequate space ☐ Yes ☐ No Clean and dry conditions ☐ Yes ☐ No Well organized (i.e. easily accessible) ☐ Yes ☐ No ☐ Other observation (specify) _____
	WASTE DISPOSAL	
GEN	84. How are used AD syringes being disposed of? (If not observed, ask how boxes are disposed).	☐ Safety box ☐ Open bucket ☐ Other ☐ Other observations
GEN	85. How are used safety boxes disposed of? (If not observed, ask how boxes are disposed). **Note:** *Specify whether box is emptied and reused or destroyed with contents inside.*	☐ Incinerator ☐ Pit-burned ☐ Pit-exposed ☐ Pit-buried ☐ Above-ground area ☐ Box reused ☐ Other observation
GEN	86. Were discarded needles and syringes observed on the ground outside the facility?	☐ Yes ☐ No
GEN	87. Is waste-disposal site closed off?	☐ Yes ☐ No ★ **Key Finding: Percentage of health facilities with clean, closed-off disposal sites**
GEN	88. Describe any other observation of the disposal site.	
	NOTES AND COMMENTS	
	If you were unable to visit the cold store or dry store area, please mention reason. Record any interesting positive or negative anecdotes or comments by health-care workers.	

Appendix 2.3: Questionnaire — mother or caregiver

Date of interview: _____ Name of interviewer: _____

Region: _____ District: _____ Health-facility name: _____

Interview mothers/caregivers whose child has just received the new vaccine (can also talk to a group of mothers waiting to be vaccinated to get their impressions). Please modify questions as appropriate for the type of new vaccine introduced. Begin the interview by saying the following "I would like to ask you a few questions about the vaccines your child received today. The answers you give will help us learn more about how to introduce a new vaccine." (N.B. You may need someone conversant in the local language to ask the questions).

1. Do you have your child's immunization card with you today? If yes: May I please see it? **Note:** *If pentavalent vaccine is not used, ask for Hib, Hep B, and DTP separately.*	**Use card to answer the following** Card present ☐ Yes ☐ No **Vaccines received today** ☐ Pentavalent ☐ OPV ☐ Rota ☐ Measles ☐ Pneumo ☐ BCG ☐ Other (specify) _____ **Card updated?** ☐ Old card (not updated to include new vaccine) ☐ Old card (with new vaccine written in by hand) ☐ New card (updated to include new vaccine)
2. What vaccine(s) did your child receive today? **Note:** *Check if answers correct by looking at vaccination card or, if card not available, verifying with clinic record.*	**Check one box** ☐ Names all vaccines (answer correct) ☐ Names some vaccines (partially correct) ☐ Does not know ☐ Mentions specific health benefit of vaccine (e.g. for Hib vaccine says, "got vaccine to prevent meningitis or pneumonia") ☐ Mentions general beneficial effects of vaccines, e.g. "my child got vaccines to keep him healthy" ☐ Other (specify) _____
3. Do you know about the new vaccine for infants? **Note:** *Be country specific; give the time when the vaccine was introduced.*	☐ Yes ☐ No If yes, which disease(s) do they prevent? ☐ Does not know ☐ Answer correct ☐ Answer incorrect
4. If yes to question 3. How did you receive the message about the new vaccine? **Note:** *Radio, newspaper, television, health-care worker, friend, public meeting.*	
5. Do you know when to bring your child for his/her next vaccination? **Note:** *If answer is no or yes but incorrect, please advise mother when next vaccination is due.*	☐ Yes (answer correct) ☐ Yes (answer incorrect) ☐ No
6. Do you know what reaction your child may get following his/her vaccination today? **Note:** *This question is trying to differentiate between baseline knowledge and knowledge received at current vaccination session.*	☐ Yes (answer correct) ☐ Yes (answer incorrect) ☐ No **Interviewer:** *If answer is no or yes but incorrect, please advise mother of potential side effects, e.g. mild redness, pain, mild swelling at injection site, mild fever, drowsiness and irritability.*
7. Other comments or observations. Record any interesting positive or negative anecdotes or comments by mothers.	

Appendix 3: Suggested key findings

To help with analysis, several key findings indicated by a ★ in the health-facility questionnaire (Appendix 2.2) are suggested below. You may select all, some, or add your own findings to summarize your evaluation.

	Key Findings	Question No.
PRE-IMPLEMENTATION PLANNING		
	% reporting provision of new vaccine introduction guidelines	6
	% reporting satisfaction with training	7
VACCINE COVERAGE		
	% change in coverage rate (%)	12
	% change in drop-out rate (%)	13
COLD-CHAIN MANAGEMENT		
	% of health facilities observed or reported with cold-chain problems since the new vaccine introduction	23
VACCINE MANAGEMENT, TRANSPORT & LOGISTICS		
	% of health facilities reporting vaccine or supply stock out in last six months	32
VACCINE WASTAGE		
	% with wastage reports on site	37
MONITORING & SUPERVISION		
	% of sites reporting one or more supervisory site visits in last six months	42
ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)		
	% sites with AEFI procedure in place	44
HEATH-CARE WORKER KNOWLEDGE & PRACTICE		
	% HCW who knew what disease(s) the new vaccine prevents	56
	% HCW workers providing adequate information to parents	57
GENERAL IMPRESSIONS		
	% reporting that new vaccine improved the EPI programme	59
	% reporting a smooth or very smooth introduction	60
OBSERVATIONS AT VACCINATION SESSION		
	% of sites with two or more unsafe practices observed	69
OBSERVATION OF VACCINE STORAGE AREA		
	% with VVM Stage 3 or 4	79
WASTE DISPOSAL		
	% with observed clean, closed-off disposal site	87

Appendix 4: Summary spreadsheet

Summary spreadsheet for collating information from questionnaires 2.1, 2.2 and 2.3. See attached spreadsheet.

POST INTRODUCTION EVALUATION

COUNTRY

DATE:

This form needs to be adapted if questionnaire 2.1 is changed

[New Vaccine] PIE: Summary of central, regional and district level questionnaire

Instructions: Enter data from Central/Regional/district level questionnaires collected by your team. Focus on essentials only - the shorter the better. Leave shaded cells blank.

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
	BACKGROUND INFORMATION										
GEN 1.	1. Date new vaccine introduced at national/regional/ district level										
GEN 2.	2. Was the new vaccine introduced nation-wide or was it a phased introduction?										
GEN 3.	3. What is the population of children less than one year of age in this country/Region/ District										
CENT	**Central level interviews only** 4. What factors influenced the decision for introduction of the new vaccine?										
CENT	**Central level interviews only** 5. Was the national immunization advisory committee supportive of the decision to introduce the new vaccine?										
CENT	**Central level interviews only** 6. What is the national immunization schedule?										
CENT	**Central level interviews only** 7. Was the immunization schedule changed when the new vaccine was introduced? If yes, why?										
CENT	**Central level interviews only** 8. What is the schedule for the new vaccine?										
GEN	9. What disease(s) does the new vaccine prevent?										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
ROTA	10. Are there age restrictions to administering the rotavirus vaccine?										
ROTA	11. Is there a required minimum interval between doses?										
	PRE-IMPLEMENTATION PLANNING AND VACCINE INTRODUCTION PROCESS										
GEN	12. Do you have a central / regional / district new vaccine introduction plan or timeline for introduction activities?										
CENT	**Central level interviews only. Only ask if yes to question above.** 13. Did you receive support / use guidelines to develop your introduction plan / timeline?										
	TRAINING										
GEN	14. Please describe staff training for the new vaccine introduction, if any										
GEN	15. How were the trainings financed?										
GEN	16. What specific training was given on the administration of the new vaccine?										
GEN	17. Do you think there are any ways in which the trainng could be improved for next time?										
GEN	18. What educational and reference materials were provided to participants at time of training? **Ask for samples**										
	VACCINE COVERAGE										
GEN	19. Was the immunization data base updated to accommodate information on the new vaccine?										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
GEN	20. What formula do you use to calculate vaccine coverage? Include the source of the numerator (doses administered) and denominator (target population)										
GEN	21. What was DTP1 and DTP3 vaccine coverage in the year before the new vaccine introduction?										
GEN	22. What is the coverage of the first and last dose of the new vaccine for the most recent administrative period?										
GEN	23. Is coverage of the new vaccine higher or lower than DTP?										
GEN	24. Is the dropout rate for the new vaccine higher or lower than the DTP drop out rate?										
	25. Is there a cumulative immunization coverage chart on the wall? Do you know how to interpret the data to increase coverage?										
GEN	26. In the last year, what proportion of regions/districts/ health facilities sent all monthly immunization summary forms completed and submitted on time?										
	COLD CHAIN MANAGEMENT										
GEN	27. Discuss any changes you had to make in the cold chain before introduction of the new vaccine										
GEN	28. Were any problems with the cold chain identified after the introduction of the new vaccine? If yes, what were the problems and how have the problems been addressed?										
GEN	29. Do you use freeze watch monitors during vaccine transportation?										
	VACCINE MANAGEMENT, TRANSPORT & LOGISTICS										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
GEN	30. Do you have immunization policy guidelines for vaccine management? If yes, have they been updated to include the new vaccine? **Please provide a copy at time of interview**										
GEN	31. How do you forecast vaccine requirements?										
GEN	32. Did the estimated needs change with introduction of the new vaccine?										
GEN	33. How are vaccines ordered?										
GEN	34. Please describe how vaccines are transported to the regions/districts/health facilities.										
GEN	35. How often do you send out vaccine shipments and supplies from your level to the next level?										
GEN	36. Did the frequency of deliveries change with introduction of the new vaccine? If yes, by how much?										
GEN	37. Please describe how the transportation of vaccines to outreach sites has changed with the introduction of the new vaccine.										
GEN	38. What effect did the new vaccine have on dry storage space requirements?										
GEN	39. What were the costs associated with increased transport or cold chain requirements?										
GEN	40. Who paid for these extra costs?										
PENTA	41. What policy was established for the remaining quantities of DTP after introduction of pentavalent vaccine?										
PENTA	42. Did you have a gap between using up DTP vaccine stock and receiving pentavalent vaccine? If yes, for how long?										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
GEN	43. Did you run out of any vaccines including the new vaccine or vaccine supplies in the past 6 months?										
GEN	44. Have you had any vaccine expirations in the last 6 months? If yes, what did you do with the expired stock?										
GEN	45. Have you had any vaccine with vaccine vial monitori (VVM) in stage III or IV in the last 6 months? If yes, what did you do with these vaccines?										
GEN	46. Are vaccine orders / deliveries tied to injection supplies (i.e. bundling)?										
ROTA	**For Rotarix only** 47. How do you store this vaccine? What was the rationale for deciding whether to store the different components together or separately inside and outside of the refrigerator?										
	WASTE MANAGEMENT & INJECTION SAFETY										
CENT	**Question for Central level only** 48. Describe the waste disposal policy/plan at each level.										
GEN	49. Does each level generally follow these guidelines?										
GEN	50. Did you have to make changes to your waste disposal system for introduction of the new vaccine? If yes explain.										
	VACCINE WASTAGE										
GEN	51. What formula is used to calculate vaccine wastage and what is the source of the data.										
GEN	52. What is the vaccine wastage rate of the new vaccine?										
PENTA	53. What was the DTP wastage rate?										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
PENTA	54. Has the pentavalent vaccine wastage rate changed when compared to DTP wastage rate (last admin period)?										
GEN	55. Did you change anything about the way you administer vaccines, to reduce wastage of the new vaccine?										
	MONITORING AND SUPERVISION										
GEN	56. How often are supervisory visits made to the regional/district/health facility level?										
GEN	57. Have you or a member of your staff or a partner organization made supervisory visits, to the districts/health facilities since new vaccine introduction? If so, how often and by whom?										
GEN	58. How do supervisors give feedback to sites visited?										
GEN	59. What are the main issues that came up at the last 2 supervisory visits? Are they specifically related to introdeuction of the new vaccine? How have they been resolved?										
GEN	60. Are follow-up visits conducted at sites with inadequate performance and continuing problems?										
DIST	**Question for Districts only** 61. Have you received a supervisory visit? If yes, when and by whom?										
	ADVERESE EVENTS FOLLING IMMUNIZATION (AEFI)										
GEN	62. Do you have a system and written protocol for monitoring and reporting AEFIs for all vaccines? Please describe the procedure.										
GEN	63. Do you have a crisis plan in place to manage AEFIs? Please describe.										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
GEN	64. Did you make any changes to the AEFI protocol specifically for the new vaccine?										
GEN	65. Have you had any reported cases of AEFI for the new vaccine or another vaccine since the new vaccine was introduced?										
	ADVOCACY & COMMUNICATION										
GEN	66. Did you have an official launch ceremony at the time of the new vaccine introduction?										
GEN	67. Did you use any media outlets to promote the new vaccine and inform/educate the community about the vaccine?										
GEN	68. Did you prepare or distribute any health education material for the community on the new vaccine? If yes what were they? Who were the target audiences? When and how were they distributed?										
	SUSTAINABILITY										
CENT	**For central interviews only** 69. Is there a budget line for vaccine purchases in the national budget?										
CENT	**For central interviews only** 70. How are traditional EPI vaccines financed?										
CENT	**For central interviews only** 71. How is the new vaccine paid for?										
C&R	**For central and regional interviews only** 72. Do you plan to introduce any more new vaccines in the future? If yes which one(s) and when?										
	SURVEILLANCE										
C&R	**For central and regional interviews only** 73. Do you have surveillance for the diseases which the new vaccine will prevent? Please describe.										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
C&R	**For central and regional interviews only** 74. Have there been any problems with the surveillance?										
	IMPACT ASSESSMENT										
C&R	**For central and regional interviews only** 75. Are you or conducting, or do you plan to conduct, a vaccine impact assessment i.e. a study to determine if the new vaccine is reducing disease burden.										
	GENERAL IMPRESSIONS										
GEN	76. How well was the new vaccine accepted? If there were any issues please comment for each group.										
GEN	77. Were there financial implications of introducing the new vaccine for each of the following areas?										
GEN	78. What effect has the introduction of the new vaccine had on your EPI program?										
GEN	79. In your opinion was the introduction of the new vaccine a smooth process or problematic? Please explain										
GEN	80. Many other countries will be introducing this and other new vaccines soon. What have you learned from this experience and what advice do you have for other countries to ensure a smooth introduction?										
	OBSERVATION OF VACCINE STORAGE AREA AT THE CENTRAL /REGIONAL /DISTRICT LEVELS										
GEN	81. Are all freezers and refrigerators clean and properly functioning?										
GEN	82. Is there a thermometer outside the freezers and refrigerators?										
GEN	83. Is there a thermometer inside the freezers and refrigerators?										

Level	Question	Central	Regional	Regional	Regional	District	District	District	District	District	District
GEN	84. Is the temperature inside the refrigerators currently between +2 ° and +8° C										
GEN	85. Is there a log of freezer and refrigerator temperatures?										
GEN	86. How often are temperatures recorded?										
GEN	87. Are temperatures monitored and recorded on weekends and holidays?										
GEN	88. Are all vaccines arranged as “First expiry, First out”?										
GEN	89. Did you observe any expired vaccines?										
GEN	**For vaccines with a VVM** 90. Did the VVMs that you observed indicate that vaccine is useable i.e. stage 1 or 2										
GEN	**For vaccines with a VVM** 91. Are vaccines with VVM in stage 2 arranged so that they are used first?										
GEN	92. Are there spaces between the vaccine boxes/trays to allow air circulation?										
GEN	93. Is injection equipment stored in good condition										
	NOTES AND COMMENTS										
	If you were unable to visit the cold store or dry store area, please mention reason. Record any interesting positive or negative anecdotes or comments by immunization staff.										

Appendix 5: Summary spreadsheet

Summary spreadsheet for collating narrative information from the interviews and recommendations made. See attached spreadsheet.

Appendix 5: Narrative of the field evaluation in _____ region, district, health facility

Areas Evaluated			
Target Population (Year)			
Penta3 Coverage (Year)			
Penta DOR for (Year)			
DTP3 Coverage (Year)			
DTP3 DOR for (Year)			
Pre-implementation Planning and Training Strengths			
Pre-implementation Planning and Training Weaknesses			
Pre-implementation Planning and Training Recommendations			
Health Care Worker Knowledge Strengths			
Health Care Worker Knowledge Weaknesses			
Health Care Worker Knowledge Recommendations			

Advocacy, Communication and Acceptance Strengths			
Advocacy, Communication and Acceptance Weaknesses			
Advocacy, Communication and Acceptance Recommendations			
Coverage and reporting Strengths			
Coverage and reporting Weaknesses			
Coverage and reporting Recommendations			
AEFI reporting Strengths			
AEFI reporting Weaknesses			
AEFI reporting Recommdendations			
Monitoring and Supervision Strengths			
Monitoring and Supervision Weaknesses			
Monitoring and Supervision Recommendations			
Cold Chain Strengths			

Cold Chain Weaknesses			
Cold Chain Recommendations			
Vaccine management, transport, storage and wastage Strengths			
Vaccine management, transport, storage and wastage Weaknesses			
Vaccine management, transport, storage and wastage Recommendations			
Waste management and injection safety Strengths			
Waste management and injection safety Weaknesses			
Waste management and injection safety Recommendations			

Appendix 6: Common problems and solutions

Table 11 below lists some of the more commonly encountered problems relating to new vaccine introduction, and some general EPI problems. The circumstances leading to these situations may differ from one location to another and between countries. While the recommended steps are not exhaustive, they should serve as a starting point for corrective action, and may be useful in formulating recommendations following the fieldwork.

Table 11: Common problems encountered in an EPI programme when introducing a new vaccine and suggested solutions

Scenario	Suggested solutions
Vaccine coverage is >100%	☑ Frequently, the denominator population is incorrect. Investigate the denominator problem; this could be influenced by campaigns or outdated population statistics.
Immunization coverage for new vaccine is lower than rate for old comparable vaccine. **Note:** *Immunization coverage post introduction should be similar to that of other comparable vaccines. Vaccines that require an additional injection may have a lower rate of uptake in the first months because of requirement for additional injection. Combination vaccines may have higher uptake since no additional injection is required and there is increased awareness of the vaccine.*	☑ Look at data accuracy: - If the number of doses delivered (numerator) is higher or lower than estimated, immunization coverage estimates will be either too low or too high. - If the target population (denominator) is over- or underestimated, vaccine coverage estimates will be either too low or too high. ☑ Encourage routine review and analysis of coverage data during supervisory visits. ☑ Determine if there are any problems with community acceptance of the new vaccine. ☑ Determine if the lower coverage is due to supply issues.
Vaccines stored at inappropriate temperature (too hot or too cold). **Note:** *Vaccine freezing is one of the most common pitfalls faced by an immunization programme; many vaccines lose potency if frozen.*	☑ If refrigerator is not working well, it should be repaired or replaced. ☑ Verify that refrigerator temperature is monitored twice a day (including weekends). ☑ Ensure that staff are trained in basics of vaccine storage and refrigerator maintenance through supportive supervision or stock management. ☑ Freeze-watch monitors should be considered for all refrigerators and during transportation. ☑ Thermostat should maintain refrigerator temperature between +2° and +8° Celsius. Tape thermostat in position to avoid accidental movement. ☑ A backup power supply or plan should be available for when the primary source of power is lost (e.g. a generator or extra kerosene). ☑ Posters with temperature guidelines should be placed on all refrigerators. ☑ Staff should know how to conduct the shake test to determine if vaccine has been frozen. ☑ Staff should know how to read vaccine vial monitors (these are heat- sensitive indicators printed directly onto vial labels). During transportation and immunization sessions the ☑ vaccine must not be in direct contact with frozen ice packs. ☑ For short distance travel, vaccine should be packed with conditioned frozen ice packs (frozen ice pack kept at room temperature for 15–45 minutes until you can hear water when shaken). ☑ Recommend additional training as needed.

Scenario	Suggested solutions
Over- or under-stock of vaccine or vaccine supplies. **Note:** *Additional resources are available from WHO Vaccine Stock Management Guidelines (WHO/IVB/06.12) http://www.who.int/vaccines-documents/DocsPDF06/826.pdf.*	☑ Determine reasons for over- or under-stock, e.g. transportation/delivery delays. ☑ Recommend that supportive supervisory visits include observation of stock management activities. ☑ Recommend use of a stock report form. ☑ Ensure that staff know how to calculate minimum and maximum stock levels (see section 2.4). Minimum and maximum stock level should be established if none exists. ☑ Revise ordering practices to ensure vaccines are bundled.
Health-care worker knowledge attitude and practice gaps identified. **Note:** *This includes issues such as insufficient knowledge, unsafe vaccine practice, and incorrect administration of vaccine.*	☑ Conduct periodic refresher EPI courses for workers at all levels. ☑ Increase supportive supervision with written recommendations and follow-up checks. ☑ Use supervisory visits to conduct on-the-spot training. ☑ Update reference manuals to be available on site. ☑ Use training for new vaccine introduction to address/refresh other general EPI training needs.
Insufficient supervision at health facility and province/district.	☑ Recommend regular supportive supervisory visits to the health facility with written recommendations and follow-up checks. ☑ Recommend additional supervisory visits to health facility when a new vaccine is introduced. ☑ Recommend at least bi-monthly supervisory visits at the provincial/district level. ☑ Recommend use of supervisory checklists that contain topics specifically related to the introduction of the new vaccine.
Waste accumulating without appropriate disposal.	☑ Recommend a point person for vaccine waste management at provincial, district and health-facility level. ☑ Have a clear waste-management plan that is shared with all immunization workers. ☑ Recommend training on hazardous waste material disposal. ☑ Provide onsite incinerators where appropriate.
Vaccine wastage exceeds recommended rate.	☑ Where applicable, WHO's policy on multi-dose vials[1] should be used for multi-dose vials. ☑ If wastage occurs due to vaccine expiration or improper handling, provide recommendations to improve cold chain and vaccine management as outlined above.

[1] Multi-Dose Open Vial Policy states that certain vaccines (mostly liquid) can be stored for up to four weeks and reused pending certain conditions, such as expiration date, appropriate storage temperature and antiseptic techniques. However, for BCG, measles, yellow fever, and some formulations of Hib vaccines, once reconstituted, they ***must be discarded*** at the end of each immunization session or at the end of six hours, whichever comes first (http://www.who.int/vaccines-documents/DocsPDF99/www9924.pdf).

Appendix 7: Report outline template

Cover
New Vaccine: Post-Introduction Evaluation Date Country
Executive Summary (1 page)
• Background • Objectives • Summary of findings • Recommendations
Background (1 page)
• Rationale for introduction of new vaccine • Description of introduction
Methods (1–2 pages)
• Evaluation team members • Objectives of evaluation • Design of evaluation
Findings (3–5 pages)
Findings should match the major areas listed below. Observed strengths and weaknesses or areas of concern should be noted. 1. Pre-implementation planning 2. Coverage and reporting 3. Cold-chain management 4. Vaccine management, transport and logistics 5. Monitoring and supervision 6. Training and knowledge of health-care workers 7. Injection safety and waste management 8. Vaccine wastage 9. Adverse events following immunization 10. Advocacy, communication and acceptance
Recommendations (1–2 pages)
Each team should endeavour to make only a limited number of recommendations. These recommendations should be specific and, whenever possible, should include 1) person(s) responsible 2) proposed timeframe for implementation of each recommendation 3) expected outcome and indicators. All recommendations should be in accordance with existing national policies.
Appendices
• Itinerary • Team members • List of persons met • Data-collection instrument • Core indicator table • Presentation made to the ICC

The World Health Organization has provided technical support to its Member States in the field of vaccine-preventable diseases since 1975. The office carrying out this function at WHO headquarters is the Department of Immunization, Vaccines and Biologicals (IVB).

IVB's mission is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. The Department covers a range of activities including research and development, standard-setting, vaccine regulation and quality, vaccine supply and immunization financing, and immunization system strengthening.

These activities are carried out by three technical units: the Initiative for Vaccine Research; the Quality, Safety and Standards team; and the Expanded Programme on Immunization.

The Initiative for Vaccine Research guides, facilitates and provides a vision for worldwide vaccine and immunization technology research and development efforts. It focuses on current and emerging diseases of global public health importance, including pandemic influenza. Its main activities cover: i) research and development of key candidate vaccines; ii) implementation research to promote evidence-based decision-making on the early introduction of new vaccines; and iii) promotion of the development, evaluation and future availability of HIV, tuberculosis and malaria vaccines.

The Quality, Safety and Standards team focuses on supporting the use of vaccines, other biological products and immunization-related equipment that meet current international norms and standards of quality and safety. Activities cover: i) setting norms and standards and establishing reference preparation materials; ii) ensuring the use of quality vaccines and immunization equipment through prequalification activities and strengthening national regulatory authorities; and iii) monitoring, assessing and responding to immunization safety issues of global concern.

The Expanded Programme on Immunization focuses on maximizing access to high quality immunization services, accelerating disease control and linking to other health interventions that can be delivered during immunization contacts. Activities cover: i) immunization systems strengthening, including expansion of immunization services beyond the infant age group; ii) accelerated control of measles and maternal and neonatal tetanus; iii) introduction of new and underutilized vaccines; iv) vaccine supply and immunization financing; and v) disease surveillance and immunization coverage monitoring for tracking global progress.

The Director's Office directs the work of these units through oversight of immunization programme policy, planning, coordination and management. It also mobilizes resources and carries out communication, advocacy and media-related work.

Department of Immunization, Vaccines and Biologicals

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