

WHO/V&B/03.19
ORIGINAL: ENGLISH

The immunization data quality audit (DQA) procedure



Vaccines and Biologicals

World Health Organization

WHO

WHO/V&B/03.19
ORIGINAL: ENGLISH

The immunization data quality audit (DQA) procedure



Vaccines and Biologicals

World Health Organization

**The Department of Immunization, Vaccines and Biologicals
thanks the donors whose unspecified financial support
has made the production of this publication possible.**

This publication was produced by the
Vaccine Assessment and Monitoring Team
of the Department of Vaccines and Biologicals

Ordering code: WHO/V&B/03.19

Printed: November 2003

This work is in progress. The data quality audit tool is being performed by independent private companies for the Global Alliance for Vaccines and Immunization (GAVI) and its application has been approved by the GAVI Board for the implementation of the GAVI reward scheme in January 2002. This technical document does not describe the current reward scheme. It may need to be adapted according to further policies.

This publication is available on the Internet at:

www.who.int/vaccines-documents/

Copies may be requested from:

World Health Organization

**Department of Immunization, Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland**

• *Fax:* + 41 22 791 4227 • *Email:* vaccines@who.int •

© World Health Organization 2003

All rights reserved. Publications of the World Health Organization can be obtained from Marketing and Dissemination, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 2476; fax: +41 22 791 4857; email: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to Publications, at the above address (fax: +41 22 791 4806; email: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

The World Health Organization does not warrant that the information contained in this publication is complete and correct and shall not be liable for any damages incurred as a result of its use.

Contents

<i>Abbreviations and acronyms</i>	<i>v</i>
1. Introduction	1
1.1 Goal and objectives of the immunization data quality audit	1
1.2 Purpose of the manual	2
1.3 Terminology	2
1.4 Brief description of the DQA results	3
1.5 Scope of the DQA	4
2. Preparations	5
2.1 Before the audit	5
2.2 Fundamentals	5
3. National level	8
3.1 Discussion with the managers of the immunization programme	8
3.2 National vaccine store	10
3.3 Monitoring immunization safety	10
3.4 Data processing office	10
3.5 Selection of districts	11
3.6 Reporting completeness and timeliness	12
3.7 Preparation for the field visits	13
4. District level	15
4.1 Discussion of immunization system	15
4.2 District vaccine store	15
4.3 Data processing office	16
4.4 District summary and discussion	19
5. Health unit evaluation	21
5.1 Getting started	21
5.2 Data collection and analysis	21
5.3 Discussion of results	26
5.4 Completion of the logbook and spreadsheet for each health unit	27
6. Creative accounting	28

7. The final report	30
7.1 Preparation	30
7.2 Presentation and discussion.....	30
7.3 Completion of the report	31
Annex A: Example national analysis workshop, June 2003	32
Annex B: Quality questions	38
Annex C: The logbook	54
Annex D: Data entry and DQA workbook guidelines.....	57
Annex E: Sampling guidelines.....	74
Annex F: Information for the sample of child health cards	81
Annex G: Vaccine wastage	86
Annex H: Core indicators	88

Abbreviations and acronyms

AD	auto-disable (syringes)
AEFI	adverse event following immunization
CBR	crude birth rate
CI	confidence interval
DOR	drop-out rate
DQA	data quality audit
DTP1	diphtheria–tetanus–pertussis vaccination, first dose
DTP1<1	DTP1 given to children under one year of age
DTP3	diphtheria–tetanus–pertussis vaccination, third dose
DTP3<1	DTP3 given to children under one year of age
DTP3>1	DTP3 given to children over one year of age
EPI	Expanded Programme on Immunization
GAVI	Global Alliance for Vaccines and Immunization
HIS	health information system
HMIS	health management information system
HU	health unit
ICC	Interagency Coordinating Committee
IMR	infant mortality rate
JRF	joint reporting form
measles<1	measles vaccine given to children under one year of age
NE	not eligible
QI	quality of the system index
TT2+ (PW)	TT2+ for pregnant women
TT2+	tetanus toxoid (vaccine/vaccination), two or more doses
VF	verification factor
VPDs	vaccine preventable diseases
VVM	vaccine vial monitor

1. Introduction

In the WHO document *EPI Information System Global Summary*, September 1998, a featured article analysed six routine child immunization coverage estimates reported from 217 countries and territories worldwide. The article examined the consistency and reliability of the reported values over the period 1991 to 1996. Although not exhaustive or definitive in detecting inaccuracies, the analysis identified 30% of the reported values as “outliers”. This magnitude of potential inaccuracy combined with the fact that 24% of the expected 6000 reports were missing, indicates that the quality of country immunization coverage estimates does need to be assessed in more detail.

The Global Alliance for Vaccines and Immunization (GAVI) initiated, in 2000, a massive programme to improve the immunization of children worldwide. This initiative uses doses of diphtheria–tetanus–pertussis (DTP) vaccine given to children under one year of age as an important criterion for funding and for measuring performance. It is required, as part of the terms of agreement with countries that receive support, that there is external verification of reported immunization with three doses of DTP (DTP3) given to children under one year of age. The Immunization Data Quality Audit (DQA) provides the mechanism for determining whether the reporting system of a country is reliable, in order to make reported increases in coverage trustworthy. Furthermore, GAVI aims at strengthening the management of immunization services to improve quality of data; therefore the DQA also aims at being used as a capacity building tool to improve the immunization monitoring and reporting systems.

1.1 Goal and objectives of the immunization data quality audit

The goal of the DQA is to assure that management of immunization services and the allocation of GAVI funding for immunization services are based on sound and accurate data. The specific objectives of the DQA are to:

- assess the quality, accuracy, timeliness and completeness of administrative immunization reporting systems, and to
- audit the reported DTP3 vaccinations given to children under one year of age (DTP3<1) in a specific calendar year and then estimate the national verification factor (VF, recounted/reported vaccinations) for use in the allocation of Vaccine Fund shares.

These objectives are achieved by examining data and the information system in operation at all administrative levels– from collection of data at the point of vaccination to the periodic compilation of data at national level, and by providing practical feedback to managers on how to improve the quality of their administrative immunization reporting system.

Not all data can be checked during the DQA, and therefore samples of the health infrastructure will be chosen for audit and review.

1.2 Purpose of the manual

This manual has been created to provide the auditors with a step-by-step guide for conducting the DQA. Assessing the quality is not an easy task, as it requires a review of the processes of recording, compiling and reporting. It also requires knowledge of the country's immunization programme and system of operation.

Internal auditors can routinely conduct part or all of the DQA and modify it as desired. However, when conducted for GAVI, it is essential that the external auditors adhere to the procedures as outlined in this manual and use the developed tools in a consistent manner.

1.3 Terminology

The term “the audit year” is used for the year preceding the one during which the audit is conducted. It must be a completed calendar year. Calendar year reporting is considered complete when the official date for submission to WHO/UNICEF headquarters (15 May) has passed. The reporting frequency, either monthly or quarterly, is often referred to as the reporting period.

“District” is used to define the third administrative level (N.B. the first is the national level), an intermediate level where immunization data are aggregated before being reported upwards (the total number of districts is reported on the first page of the WHO/UNICEF Joint Reporting Form). It may be labelled differently within the country.

The term “health unit” (HU) is used to represent the operational level for vaccinations, that is, where vaccinations take place and where the first compilation and reporting of immunizations is made. It may include hospitals, nongovernmental organization (NGO) services, or general practitioners (GPs), if these entities provide immunization services reported to the national level (normally the Ministry of Health).

The “individual recording form” is the generic term used to refer to the format health units used to record individual vaccinations. It can be, for example, a tally sheet, a register of immunizations, a Child Register, or a listing of immunizations. Likewise the “ledger book” is the term that refers to whatever book, register or sheet is used to record the receipt and use of vaccine stock.

1.4 Brief description of the DQA results

The quantitative results of the DQA are presented in tables and charts using an Excel workbook. For each of the three administration levels (national, district, and health unit) there are four sections in the summary page that can easily be printed:

1. **Performance indicators.** Performance indicators include the DTP drop-out rate (i.e. difference between DTP1 and DTP3 immunizations), DTP vaccine wastage, and the DTP3<1 coverage rate.
2. **Report availability.** Presents the proportion of reports that can be retrieved (availability is an indication of reporting completeness) at national and district level.
3. **Quality of the system index (QI).** The quality of the system index is based upon a series of questions regarding the practices of recording, reporting, and storing the data, monitoring and evaluation, denominator issues and system design (see Annex B for a complete listing of the questions). The QI is presented in a “radar graph” based on average values of each component by normalizing the values of each index to a scale from 0 to 5.
4. **Accuracy estimate of the DTP3<1 data.** The accuracy chart compares the reported DTP3<1 values (and recounted values at the health unit level) by source of the data. The DQA *verification factor* for DTP3<1 is a statistical estimate provided with a confidence interval. The factor is the ratio of recounted DTP3<1/reported DTP3<1. As an audit tool, the DQA is not meant to provide a statistically valid estimate of the total number of DTP3<1 doses given in a country (coverage). This is because there is no attempt to improve completeness by estimating the doses not reported. At the same time, reported doses that cannot be verified are treated as not given.

See examples in Annex A for chart examples and summary page of each administrative level. The formulas for the statistics are also given in Annex A.

In addition to the above-mentioned audited indicators, the auditors will check and discuss a number of additional indicators referred to as the *core indicator set*. All these indicators should be reported in the WHO/UNICEF Joint Reporting Form (JRF) and the auditor’s task will be to check and document the values reported at the time of the audit and discuss any differences (see Annex H).

The auditors keep a logbook containing all the descriptive information obtained during the DQA, for example, the dates of interviews, persons interviewed, and answers to the series of questions for the QI along with relevant explanations. The logbook also contains documentation of all data collected and the information source of all data used for the audit. A list of the information to be recorded in the logbook is shown in Annex C.

It is anticipated that, during the DQA, both the health workers and the auditors will discover issues and problems. These issues and problems are then discussed to provide immediate practical feedback and identify solutions.

1.5 Scope of the DQA

All data collected during the DQA and information discussed with the country's health workers during the DQA, including the quality questions for the QI, refer to the monitoring of immunization data. The external auditors should therefore not collect information or discuss issues of other areas of the immunization services in the country.

2. Preparations

2.1 Before the audit

Two Ministry of Health officers who work in the immunization programme (alternatively in the health information system) should be identified to assist and work with the auditors. These officers should be involved in all preparations and in all activities of the DQA. The Interagency Coordinating Committee (ICC) should be aware of the DQA process and assist as needed. Two vehicles for fieldwork during the two-week period will be required and organized by the auditing company. District immunization managers should be aware of the possibility that the DQA auditors may be coming to their district, and likewise health units need to be aware that the DQA auditors may come. Within each district visited, one district officer is required to assist the auditors.

One or two weeks before the official DQA, the auditors will randomly select four districts based upon data supplied by the immunization programme. For this sampling, the following data is required: national total value for DTP3<1 for the audit year and for each district: district name, reported DTP3<1 for the audit year and number of health units operating in the district during the audit year. When a district cannot be visited because of conflict, security or natural disaster, this should also be noted. More information about the sampling process is given below (section 3.5).

2.2 Fundamentals

The immunization reporting system is assumed to be an integral part of the health information system/health management information system (HIS/HMIS) not an independent system. If the immunization reporting system is separate, then the official source of immunization data for international reporting to WHO/UNICEF needs to be identified before the evaluation begins. Situations of dual reporting and/or compilation should be discouraged. Reporting systems that are not duplicated but have districts separating immunization data from other health information and sending it directly to a national immunization office should also be discussed and evaluated. Resources are scarce and should be optimized rather than spent to keep a separate immunization information system in operation.

If time is available at health unit level, four antigen/dose combinations should be evaluated (reported and recounted values): these are DTP1<1, DTP3<1, measles given to children under one year and tetanus toxoid doses 2+ (TT2+) given to pregnant women. Only DTP3<1 is considered vital to the audit and has to be done. "All other DTP" vaccinations (DTP1>1, DTP3>1 and all DTP2) are required in order to calculate annual totals for DTP vaccinations at health unit level in order to estimate the overall wastage of DTP vaccine at the health unit.

An ideal timetable is shown in Table 1. The DQA starts with a discussion of the collection and reporting procedures in place within the country, continuing with interview of health officials and collection of quantitative and qualitative data. The first full day is spent at the national level. Half a day is scheduled for each district office and each health unit.

Two evaluation teams are formed, each with one external auditor and one national counterpart. Each evaluation team proceeds to the first district and selects health units. After completing the audit of the sampled health units in the first district, the team proceeds to the second district and repeats the process. The last day at the national level is reserved for preparation and presentation of the overall results.

An Excel workbook file specific for the DQA has been created to provide templates for the necessary analyses and calculations. It may be possible to transfer the required data from country computer files. Otherwise the data will have to be entered by the auditors from existing tables of information or reports. A listing of the required data from each level is summarized in Annex D for reference. Also in Annex D is the worksheet reference where data are to be entered into the workbook's worksheets.

The logbook should be started the first day and should contain all notes from all meetings. There is no set format but for quantitative input it is recommended that the format used in the workbook be duplicated in the logbook to facilitate a later transfer of the data (see Annex C for the optimal format to use). A loose-leaf clip file is used so that each external auditor can continue to create final up-to-date records while travelling. Given the large amount of data and intensive interviews, daily updates are imperative in order to keep an accurate record.

Table 1: DQA timetable, ideal timing*

Corresponding chapter in this manual	Saturday to Thursday workweek	Monday to Sunday workweek	Activity
3.1 3.2; 3.3; 3.4 3.5; 3.6	Saturday	Monday	Protocol visit at national level Collection of data Preparation for districts
4.1 4.2; 4.3.2; 4.3.3; 4.3.4 4.3.1 4.4 (4.4.1–5)	Sunday	Tuesday	Travel to district 1 Protocol visit at district Collection of data Selection of health units Discussion of results
5.1 5.2 (5.2.1–11) 5.3 (5.3.1–5); 5.4	Monday	Wednesday	Health units 1 and 2
	Tuesday	Thursday	Health units 3 and 4
	Wednesday	Friday	Health units 5 and 6
	Thursday Friday	Saturday Sunday	(make up time) Travel to district 2
4.1 4.2; 4.3.2; 4.3.3; 4.3.4 4.3.1 4.4 (4.4.1–5) 5.1 5.2 (5.2.1–11) 5.3 (5.3.1–5); 5.4	Saturday	Monday	Protocol visit at district Collection of data Selection of health units Discussion of results Health unit 1
5.1 5.2 (5.2.1–11) 5.3 (5.3.1–5); 5.4	Sunday	Tuesday	Health units 2 and 3
	Monday	Wednesday	Health units 4 and 5
	Tuesday	Thursday	Health unit 6 Travel to national headquarters
6; 7.1–7.3	Wednesday	Friday	Preparation of results Submission of draft report
7.3	Within 3 weeks of completion	Submit final report to country and GAVI secretariat	

* This is an ideal timetable; dates should be adapted to meet local constraints or difficulties. It is expected however that the DQA will be completed within 16 in-country days (including debriefing and draft report). Other visits may also be necessary, e.g. visits to regional/provincial level, visits to subdistricts and maybe other protocol visits at national or regional/provincial level.

3. National level

3.1 Discussion with the managers of the immunization programme

At the beginning of the DQA, the auditors meet with the national managers for the immunization programme including the appointed local counterparts. The auditors begin with a brief summary of the objectives, the timetable and a description of the results from the DQA.

The initial discussion then focuses on the general system of collection, compilation and reporting procedures used in the country's immunization reporting system. It includes the following topics:

- The flow of information from the point of collection to the national level. If a separate national office for immunization reporting exists, then where and how does this system separate from the main HIS/HMIS? Copies of the collection and reporting forms (including the child health card) and their specific names are obtained at this time. The frequency of reporting and the deadlines for reporting are also documented.
- The district reported and tabulated figures for DTP3<1 vaccinations are compared from the three sources relevant to the DQA. Differences and the reasons given for them are documented. The sources are:
 - the reported vaccinations (country totals) on the WHO/UNICEF Joint Reporting Form (JRF) for the audit year and the district totals used to obtain these national values;
 - the most recent national district annual tabulation of reported DTP3<1 vaccinations by district for the audit year;
 - the tabulated value for eligible districts used in the sampling process.

If the JRF reported figures are different from current/most recent tabulation, the difference is to be clarified and documented in the final report; however, no adjustment is done to the district data to recover an eventual difference. The district values used to get the last available annual country total will be used for the calculation of the verification factor. Even if the DTP3<1 figures may indicate that the district selection was done not using the best figures (most recent figures etc.) the auditors are not allowed to re-sample the districts. Any differences etc. should be carefully documented in the logbook.

It is important for the auditors to be prepared to adjust the discussion according to the country's specific system, e.g. the regional/provincial level reporting to the national level. The flow of information, reports etc. may in such cases be from regional/provincial level to the national level, with district reporting (only) to the regional/provincial level. Sampling (and national level data) will in such cases be based on the regional/provincial reporting (with two regions/provinces sampled).

Part of this discussion should take place at regional/provincial level to obtain, for example, explanation about any differences between figures from region/province and (selected) four districts.

This initial discussion flows into the specific questions to be answered for the QI (see Annex B). The questions are divided into five sections. Questions in the first and second section relate to the integration of immunization data with other routinely collected health data, numerator issues, denominator issues, and feedback and monitoring of the data, and are thought best answered during the initial discussion. The third section concerns recording of vaccine data and process for handling reports. The fourth and fifth sections contain questions regarding the practices of processing, analysis and storing of vaccination data. These are thought best answered at the vaccine store and at the data processing office, respectively. However, the order can be modified to suit the country situation.

All answers to the QI questions are recorded carefully in the logbook (they are later transferred to the worksheet "Nat-Anal", Item 2). For the denominator issues, additional information and clarifications must be documented.

- If the definition is different from the recommended WHO definition, record the exact definition used and the reason(s) for using it.
- If coverage rates over 100% were obtained, record why the managers believe it occurred.
- If denominator values do not differ between the audit year and the previous year, record why this occurred.
- Document how the denominator value was obtained. Record the formula. Include the values of all demographic statistics used (crude birth rate, infant mortality rate, net growth rate, etc.).
- Document the source and calendar year for each statistic used in the calculation of the denominator. Record results of more recent surveys, other research and health statistics that provide evidence of change in the demographics.

When finished with the discussion, the auditors can proceed to the vaccine store and the data processing office. To be efficient with time, one auditor could go to the vaccine store while the other starts the work at the data processing office.

3.2 National vaccine store

While visiting the national vaccine store, the current ledger book and the ledger book for the audit year are examined. The balance of DTP vaccine at the beginning and end of the year are obtained from the latter. The former is examined in order to determine whether the records are up to date for both DTP and TT vaccine. This information is part of the QI.

A national DTP vaccine wastage rate (“global” vaccine wastage or “system plus administrated” vaccine wastage) cannot be calculated from the sole verification of the ledger book. What can be estimated/calculated at the national level is the “system wastage” (see Annex G), corresponding to unopened vial wastage, or wastage occurring at the store. Information about all DTP doses “damaged” during the audit year and thus discarded from the national vaccine store is collected as well as balance of DTP vaccine at start and end of the audit year and all receipts to national store during the audit year.

National system wastage calculation needs to be fully documented and auditors must be able to discuss and present correct wastage calculations (Annex G).

3.3 Monitoring immunization safety

At the national level, the auditors should enquire to check whether reporting and monitoring mechanisms of immunization safety are well designed and implemented. These include the routine reporting and investigation of adverse events following immunization (AEFI) and the monitoring of injection supplies appropriate to the immunization policy (safety boxes, AD syringes and/or non-AD disposables). At district and health unit level, the auditors should check whether the system is operational. A number of quality questions cover the topic, and a specific paragraph on the issue should be included in the final report.

3.4 Data processing office

The data processing office is where the immunization reports are kept and the processing of the reports occurs. The final questions for the QI are answered at this time.

After the QI answers have been obtained, the data from the most recent tabulation containing the districts’ annual reported vaccinations for the audit year and the year previous are entered into the DQA Excel workbook (“Nat-Inp” worksheet). Information (numbers) for “Reports received” for each district (or region/province if this is the reporting level) are also retrieved or calculated from a national tabulation/file for the audit year and year previous. The data is then entered into this worksheet along with district denominators for the two years. (For surviving infants: see discussion about denominators above). If the processing is computerized, it should be possible to retrieve computer data files that can be read directly into the DQA workbook, otherwise the data will need to be entered manually. **NB: remember to do a virus scan and check.**

In the case of regional/provincial level reporting to the national level, denominators for individual districts may not be available at the national level. The auditors should then collect information about the selected four districts' denominator from the two sampled regions/provinces. Regional/provincial denominators should be recorded at national level in worksheet Nat-Inp for the audit year and year previous. If the district denominator is available and used at national level, the auditors should record this in the logbook for all districts in the two sampled regions/provinces, and later, when districts have been sampled, transfer the information to the relevant quality questions for the selected districts. What is important is to discuss consistency for denominators used at all levels.

3.5 Selection of districts

The selection of four districts was done before the DQA started. The districts were selected by sampling all districts with probability proportionate to size, using systematic random sampling. Size was estimated by the value of the reported DTP3<1 for the audit year. The data – the district names, their DTP3<1 values for the audit year, indication if the district

has conflict or security problems and is thus not eligible (NE), and the sampling – were entered to the worksheet labelled “Nat-Samp”. The random number table is used for the selection. Non-eligible districts are eliminated from the selection process.

The DQA is statistically based on a representation of the country's immunization data collected at 24 HUs with six HUs selected from each of the four sampled districts. Experience shows that in some countries some districts have less than six HUs reporting on immunization activities. In such cases those districts with less than six HUs reporting immunization data for the audit year will be regarded as non-eligible and therefore not included in the district sampling process. Such districts will be part of the national tabulation and therefore included in the worksheets Nat-Samp and Nat-Inp, but regarded as “NE” in worksheet Nat-Inp. This needs to be considered when analysing and discussing the reported DTP3<1 by source at national level and the VF/CI (in worksheet Nat-Anal). **The auditing company will have to discuss this issue with the country at the time of receiving country data for district sampling prior to the auditors' arrival in the country.**

Should the majority of districts in a country each have less than six HUs operating (immunization reporting in the audit year) the sampling will be discussed between the auditing company, the country, the GAVI secretariat and WHO.

DTP3<1 vaccinations given during nationally managed campaigns (including those at refugee camps or on so-called school days etc.) should normally not be included in district reports or the national tabulation for routine immunization. These should therefore not be included in the JRF administrative figure and will thus not be verified by the DQA. However, in some cases such immunizations are reported and included in the national figure. They are therefore to be included in the worksheets Nat-Samp and Nat-Inp, but regarded as NE, provided the figure is not included in any district's reported figure. This needs to be considered when analysing and discussing the reported DTP3<1 by source for the national level and reporting “completeness” at national level (in worksheet Nat-Anal). See instructions in Annex D for worksheet (Nat-Anal and Nat-Inp) entry.

The sampling is done following the guidelines in Annex E.

A district can be selected twice. If a district is selected twice, two sets of “district worksheets” with six health units’ worksheet will be needed. district data will only be collected once, but entered twice for “District no. 1” and “District no. 2”. Six health units will be selected for each “district” by selecting four health units from each stratum (see section 4.3.1).

There may be a country that has two points of aggregation; health unit data is aggregated at the district level, district data is aggregated at the province level, and only province data is available at the national level. In such a case, two provinces will be randomly selected before the start of the DQA. Once in country, another random selection of two districts within each province will be done.

The country will submit all provincial aggregated/tabulated data to the auditors for sampling instead of district data as mentioned above. The auditors will randomly select two provinces following the guidelines in Annex E using the Nat-Samp worksheet, with all the provincial data entered as “district” data. Once in the country, the auditors will collect all national level data from the national office and enter in worksheet Nat-Inp and Nat-Anal (again entering provincial data instead of “district” data, e.g. denominator, reports received). District information in worksheet Nat-Dist-Rep will be entered when the two teams meet up again at national level. The auditors will split up into the two teams and travel to the two selected provincial head quarters. Here each team will collect all districts’ information (district name and DTP3<1 for the audit year) from the selected province and select two districts (for each province) following the guidelines in Annex E (using a copy of the worksheet Nat-Samp). For each selected district collect district information at the provincial office and enter in worksheet Nat-Dist-Rep. From here the auditors travel to the district level. For instructions about how to use the workbook/worksheets see Annex D.

3.6 Reporting completeness and timeliness

The auditors will record information about the reporting completeness and timeliness at the national level. Report completeness for the audit year and year before is expressed in the worksheet Nat-Anal (cell M7/8) based on the number of reports from each district that the auditor can obtain at the national level from a tabulation (written or computerized) of reporting completeness (worksheet Nat-Inp cells I44.. and O44..) and the maximum number of reports expected. The availability of sampled district reports will be recorded in the worksheet Nat-Dist-Rep. The completeness figure will be compared with the one provided by the national level on the Joint Reporting Form.

The auditors should discuss the importance of recording and monitoring reporting completeness and timeliness at all levels with the programme manager and programme staff. Monitoring completeness is defined as the monitoring of whether reports have been received (see definition in Annex A), but the manager should also look whether the report is complete (all fields filled in) and contains information from all HUs reporting to the district. Only through a comprehensive monitoring system is it possible to capture all immunizations and provide appropriate feedback.

3.7 Preparation for the field visits

The teams determine the best itinerary for the audit of the four selected districts. It is suggested that large districts are visited first because of the travel time to health units, which may be longer, and the extra time available over the weekend can be used if needed.

A separate page for each district is started in the logbook. The four-district worksheet set is automatically labelled in the workbook (Dist-Data, Dist-HU-Samp, Dist-HU-Rep and Dist-Anal). The evaluation teams discuss whether there are any insecure areas within the selected districts, and document this in the logbook. For the selected districts, the auditors require all the district reports for the audit year. The auditors should discuss the importance of having reports signed and dated in the district reports. The national deadline for reporting (monthly or quarterly) is noted and DTP3<1 vaccinations from each report are entered in the Nat-Dist-Rep worksheet. The district's annual total of DTP3<1 vaccinations from the most recent national tabulation is entered for each district (in Nat-Dist-Rep cell F8/9/10/11 from worksheet Nat-Inp). Discuss any difference between the annual DTP3<1 vaccinations from the national tabulations (Nat-Dist-Rep cell F8/9/10/11) and from the district reports at national level (Nat-Dist-Rep cells M8/9/10/11); document the reasons for this in the logbook and in the final report. Any differences may have an impact on the verification factor confidence interval (VF/CI). See also section 3.1.

When this exercise is finished, the workbook file is shared and copied so that each evaluation team goes into the field with identical copies (see Annex D with DQA Excel workbook instructions).

The auditors should review the quality questions (Annex B) and determine whether the wording needs to be modified or whether some questions are deemed not applicable because of the specific system in operation in the country. If translation into local language in the districts and health units is anticipated, the national officers need to discuss between themselves uniform wording and uniform understanding of the questions before proceeding to the field.

The minimum items needed for the field are listed in Table 2. The auditors need to fill out the identification and immunization sections of 22 child health cards as per the instructions in Annex F in order to conduct a small exercise with the health workers at each HU. Two identical complete sets are required, as each assessment team goes to the field with one set of 22 cards. Note that there is a two-year calendar in Annex F to assist with this exercise. The copies of the individual recording forms will be used to complete this exercise in the HUs. One set of the random number tables will be required for each district for the sampling of HUs. **NB: If selection of districts is based on two selected provinces the auditors will need two sets of random number tables to enable selection of two districts within the province as well.**

Table 2: Items needed for the field for each evaluation team

No.	Items
22	Child health cards (or copies) prepared as shown in Annex F
40	Copies of individual recording forms
2	Sets of random number tables (3 sets if province)
	Stapler, paper clips, computer paper, spare diskettes
	Computer and printer
	DQA workbook file

4. District level

4.1 Discussion of immunization system

The initial meeting should include the medical officer in charge of the district health services and staff responsible for the immunization programme. The auditors start by describing the objectives and activities of the DQA. The timetable shown in Table 1 is also reviewed. The district medical officer in charge appoints one district officer to assist in obtaining the necessary district data and to accompany the auditors during the health unit visits.

The discussion should flow into obtaining answers to the QI questions (see Annex B). The auditors follow the same format at the district level as was followed at the national level. All answers with their clarifications are recorded in the logbook. Later the answers are transferred to the Dist-Anal worksheet, item 3. The first questions in the QI, those relating to feedback and monitoring, and denominator issues, are best asked at this time. As at the national level, the answers to the denominator issues need to have additional information recorded in the logbook.

Make every attempt to collect data from the district office. A district with inaccessible records (e.g. the staff is not available or refuses to cooperate, the district's record office is "locked" or the staff "with the key" not available etc.) will be treated as a respondent with zero information, which will have a serious impact on the national verification factor. Discuss such a situation with the national counterpart and district staff (senior medical officer) and make another attempt to collect the data from the district office, or appropriate action. Record this in the logbook.

4.2 District vaccine store

Information about the receipt of DTP vaccine during the audit year and about the completeness of the current ledger book is collected at the vaccine store.

As for the national level, a district DTP vaccine wastage rate ("global" vaccine wastage or "system plus administrated" vaccine wastage) cannot be calculated. What can be estimated/calculated at the district level is the "system wastage" (see Annex G). Information about all DTP doses "damaged" during the audit year and thus discarded from the district vaccine store is collected as well as balance of DTP vaccine at start and end of the audit year and all receipts to district store during the audit year.

The district system wastage calculation needs to be fully documented and auditors must be able to discuss and present correct wastage calculations (Annex G).

4.3 Data processing office

In the data processing office, the remaining questions of the QI are asked. These questions generally relate to the receipt, processing, storage and tabulation of the reported immunization data. In addition, the data required for the selection of health units and for the analysis at the district level are retrieved and entered into the workbook (worksheets Dist-Data, Dist-HU-Samp and Dist-Anal). This includes the most recent district tabulation of DTP1<1, DTP3<1, denominator and reported annual DTP3<1 by health units for the audit year. If the annual value of DTP3<1 vaccinations is not available by health unit, the data will have to be obtained by adding from the individual health unit reports. The Dist-Data and Dist-HU-Samp worksheets explain this process. District tabulations for DTP1<1, DTP3<1 and denominator for the year before the audit year are also required.

The districts' monthly/quarterly reported DTP3<1 for the audit year and number of HUs reporting for each reporting period are retrieved and entered in worksheet Dist-Anal.

4.3.1 Selection of health units

The data required for selection of health units is the annual DTP3<1 by health unit. As mentioned earlier, a district with less than six HUs is not eligible for sampling and will therefore not have been selected at the beginning of the audit. Health units that have to be included are all those having sent at least one report to the district during the audit year (even if the health unit was not functioning the whole year).

In some cases DTP3<1 vaccination has been reported by/through "reporting units", which are not included in health units' standard reports, for example outreach or refugee camp exercises managed by or carried out by district staff. Such reporting units should be added as part of the health unit's DTP3<1 if the value is included in the district's tabulation for the HU *and* the individual recording forms (tally sheets etc.) are available at the HU (to be recounted). If the DTP3<1 vaccinations given at, for example, outreach sessions or refugee camp sessions are recorded and reported and individual recording forms stored at either the district office or a subdistrict office, the figure is included as a separate reporting unit in the selection of HUs but regarded as NE.

A stratified sample of six health units (two per stratum) will be taken. Each stratum will be defined by the health units contributing to 1/3 of the total number of DTP3<1 vaccinations of the district. Two health units are selected randomly from each stratum. The steps in the selection are (see Annex E for detailed guidelines):

- Valid reasons (such as safety concerns, special authorizations needed, restricted area, e.g. military zone) for ignoring any health units in the selection process are discussed. Do not ignore a health unit because of distance from the district headquarters or because of the size or type of HU (private/NGO, etc.). Compare the information with that obtained at the national office. Ensure that the discussion is recorded in the logbook. HUs to be ignored should be identified with NE.

-
- The data is entered/copied to the Dist-Data and/or Dist-HU-Samp worksheet, and six health units are selected using the guidelines in Annex E and the instructions on the worksheet. A seventh HU is selected as “reserve”, using the guidelines in Annex E.
 - A health unit cannot be selected twice.

Twelve health units will be selected with four in each stratum (plus two reserve health units) if a district is selected twice (with two sets of district worksheets, Dist-Data, Dist-HU-Samp, Dist-HU-Rep and Dist-Anal). The first two selected health units from each stratum are used for “District no. 1” and the last two for “District no. 2”. The first selected reserve health unit is used for District no. 1 and the second for District no. 2.

Once selected, the best itinerary given the location of the (six “regular” selected) health units should be determined. Plan for one half day at each health unit. If there is not enough time to visit all the health units selected because of long hours of travel time, then drop the last health unit selected in the third stratum (smallest contribution to the total DTP3<1) and re-plan the itinerary. The evaluation team and the accompanying district officer should make arrangements to meet independent of the district office for the health unit visits. This is to ensure that the trips to the health units are not delayed in the mornings by routine work or unforeseen emergencies.

For each of the six (regular) selected health units, a separate page is started in the logbook. The health unit’s worksheet is automatically labelled. All reports from the selected (seven) health units for the audit year are retrieved and, for each selected HU, the following data is entered into the worksheet Dist-HU-Rep: the district’s annual tabulated DTP3<1 and the reported number of DTP3<1 from each reporting period (month/quarter). For each of the six (regular) selected health units, the DTP3<1 vaccination total from the district’s tabulation is automatically updated in the health unit’s worksheet (HU-Anal) from the district’s worksheet (Dist-HU-Samp). There should be discussions on differences between the (seven) health unit’s total DTP3<1 vaccinations from:

- the summation of its reports found at district level (Dist-HU-Rep cell E16/29/42/55/68/81/94);
- from the district tabulation (Dist-HU-Rep cells I9/18/27/36/45/54/62 and, if HU sampling was based on a district tabulation with HU annual totals, in worksheet Dist-HU-Samp cell F37/38/39/40/41/42/43).

The reasoning given for any difference should be documented in the logbook and in the final report. It is important for the district to prepare and file an annual tabulation for all reporting HUs.

Change in district borders

A particular situation may be encountered if, because of changes in district borders, one or more health units fall outside this district at the time of selection. In this case, it is assumed that the information for the audit year is still at the sampled district level and, therefore, all health units should nevertheless be included for sampling. If one or several of the health units now outside the district are selected, they should be visited (in the other district), and the normal audits undertaken there. This may require additional authorization from a “new” district.

Reserve health unit sampled

An additional health unit will be randomly chosen in the district, named as reserve HU. If one regular health unit cannot be visited due to weather conditions, non-passable roads etc., it will be replaced by the reserve health unit, which should not be visited under normal conditions. The reserve HU should be visited if and only if one health unit could not be visited because of reasons that could not be predicted at the time of the HU selection. For calculations, it will replace the missing HU, whichever stratum it was, and all necessary data entered in the regular “missed-out” health unit’s worksheet and also in worksheet Dist-HU-Samp and Dist-HU-Rep. Detailed documentation of the process in the logbook and in the final report is necessary.

Districts with “subdistricts”

In some countries HUs report to a subdistrict, which accumulates the HU reports and reports to the district.

Selection of HUs will, in such countries, be based on the availability of information at district and subdistrict level. In principle, the first two subdistricts will be selected following the normal sampling procedure at district level. From each subdistrict, three HUs will be selected, again following normal sampling procedure. Information for the workbook and logbook will be collected at district, subdistrict and HU level, which will add the two visits to the subdistrict level to the auditors’ schedule. (See Annex E for detailed guidelines.)

District selected twice

The district will only be visited once by one auditor team, but the district data will be entered into two different sets of worksheets and six health units selected for “each” set.

4.3.2 Completeness of reporting

The auditor will assess both the completeness of health unit reporting and the availability of the selected health unit’s reports at the district level. They will record information about the health unit reporting completeness and timeliness at the district level from the district charts or tabulations and check report availability for the six selected health units, when entering the DTP3 information from these selected HUs. They will compare the report availability with the completeness and timeliness of the HUs as monitored by the district.

Additionally, the auditor will provide to the district officer the district report availability as retrieved at the national level (included in the analysis chart for the district). They will discuss the need for the district to both date and sign the district reports including the copy remaining at district level.

4.3.3 DTP vaccine wastage, coverage and drop-out rate

The district's DTP vaccine system wastage is estimated/calculated based on the district's vaccine stock ledger book and entries for the audit year. The balance of DTP vaccine at beginning and end of audit year and all issues are recorded in the logbook and worksheet (Dist-Anal, section 2), as well as all doses discarded due to damage (e.g. breakdown in the cold chain, expired vaccine, accidents etc. – see Annex G). All entries are carefully recorded in the logbook with explanation. The vaccine stock ledger must be complete for this calculation.

The district denominator for infants is also entered in the worksheet (Dist-Anal item 1). DTP1<1, DTP3<1 and district denominator for children for the year previous to the audit year are also required in order to calculate change in reported DTP3<1, DTP3<1 coverage and drop-out rate from DTP1<1 to DTP3<1.

It is important to capture all vaccinations in the audit year, including outreach, health days, campaigns etc. These may not be included in the normal reporting system and “allocated” to a specific health unit, but obviously are a part of the valid vaccinations in the district. In some cases such vaccinations may not even be recorded or filed at district level, but only recorded or filed at national level.

4.3.4 Data accuracy and consistency

The district's most recent annual tabulation (or totals) of DTP3<1 and monthly/quarterly reported figures for DTP3<1 will automatically be compared with the national level figures. The figures from the most recent national tabulation of the district's DTP3<1 as well as the district's monthly or quarterly reports of DTP3<1 at the national level were entered at the national office (worksheet Nat-Dist-Rep). The worksheet will present these values in different charts, and differences will be discussed with the district officers during the final meeting with the district staff.

4.4 District summary and discussion

The district summary page (Dist-Anal) should be printed out once all the data has been entered and the computed values, charts and tables are completed. Page one contains the performance indicators, the report availability, a chart of the QI components, and the consistency of the reported DTP3<1. The remaining pages contain the actual data used in the creation of the first page. At this point, the audit team should regroup with the district officers for a discussion of the printed results. Comments and suggestions on ways the district could improve should be discussed and entered into the logbook. Some guidelines to remember during this discussion follow.

4.4.1 Performance indicators

The change in annual DTP3<1 (between the audit year and the year previous), the DTP3<1 coverage rate, the drop-out rate from DTP1<1 to DTP3<1, and the district DTP vaccine system wastage are included as performance indicators. The computation of the DTP vaccine system wastage is based on the district vaccine stock ledger. If the vaccine stock ledger is inappropriately maintained (i.e. some ledger book entries are missing), vaccine stock management becomes difficult and accurate calculations for district vaccine wastage a problem.

4.4.2 Completeness and timeliness of reporting

The district should ensure that the reports are completed and sent on time. If the problem lies with submission, the discussion should focus on how to ensure that the reports get to the national office in time. Reporting periods when no report was compiled or sent should be documented and the reasons for non-reporting should be discussed. The number of HU reports retrieved at district level for each reporting period (as entered in worksheet “Dist-Anal” row 83) gives an indication of the degree of missing vaccination data. It is important to focus on the importance of exhaustive reporting, i.e. all immunizations must be reported from HU to district and from district to national level (system/procedure/process for handling late reporting, data integrity and consistency).

4.4.3 The quality of the system

The questions for the quality of the system are formulated so that the “yes” answer always indicates a higher quality system. The index score is the percentage of the items answered yes. The target is 100% for each component since questions not applicable are to be deducted from both the numerator and denominator. All clarifications should be documented clearly in the logbook. It is important to discuss each “no” answer not only for verification but also to promote a constructive discussion toward improvement. The chart in worksheet Dist-Anal presents the scoring on a comparable scale from 0 to 5 for all four components.

4.4.4 Data accuracy and consistency

The total annual DTP3<1 vaccinations from the district reports are compared to those obtained from the district tabulation, reports found at national level and the national tabulation. Differences should be discussed and the reasons given documented in the logbook.

4.4.5 Results from the health units

The results from the health unit visits will be given to the district officer who accompanies the team and as feedback to the district’s senior medical officer and colleagues (e.g. the district health management team). If this is not possible due to time constraints, the district officer will be asked to do it on behalf of the team.

5. Health unit evaluation

5.1 Getting started

At a meeting with the officer in charge of the health unit and all of the health workers who give or record vaccinations, the district officer should introduce the evaluation team and the purpose of the visit. The evaluation team should then ensure that objectives of the DQA are clearly understood. Checks on the quality of the system, the accuracy of compilation and the completeness of reporting will be made. The results will be discussed and shared with the health workers. As much of the normal operation of the health unit as possible should continue.

During the discussion and analysis at the health unit, all information should be entered into the logbook. This includes notes from the discussion, answers with clarifications for the QI and all data gathered and analysed at the health unit. Calculators may be used to do the computations. Formulas are given in Annex A.

Make every attempt to collect data from a health unit. A health unit with inaccessible records (e.g. the staff is not available or refuses to cooperate, the health unit is "locked" etc.) will be treated as a respondent with zero information, which will have a serious impact on the national verification factor. Discuss such a situation with the national counterpart and district officer, and make another attempt to collect data from the health unit with notification to the staff from the unit (from district officer/office). Record this in the logbook.

5.2 Data collection and analysis

The sequence given below follows the numbering of the QI questions. The strategy is to start with a general discussion and then proceed to walk around the health unit while checking specific points regarding the recording, monitoring and storage of the vaccination data. Finally, in a quiet room, each health worker who gives vaccinations will do the child health card exercise while at the same time the auditor validates the reported values. When these two activities are finished, the findings (including errors found) are explained to the health workers. The order of the discussion can obviously be changed to complement the situation in the health unit. The following is just a summary of the activities and discussion. It is expected that the auditor will use the list of questions and instructions contained in annexes B, C, D, F and G.

5.2.1 *Initial discussion*

The introductory discussion with the officer in charge of vaccinations in the health unit should blend into the evaluation. A quiet room that doesn't disrupt the normal activities of the health unit should be chosen for the final part of the evaluation. Each health worker who gives or records vaccinations will be asked to do a short exercise involving the child health cards, one at a time starting with the officer in charge of immunizations, once the audit team reaches the quiet room.

5.2.2 *Storage of reports*

As a first stop in the walk around the health unit, the auditor should see where old reports and forms are stored. The last feedback report on vaccination data from the district office is retrieved and the date documented.

The forms from the audit year that will be necessary for the evaluation are discussed at this time, namely:

- all report forms containing vaccination data;
- all individual recording forms;
- the ledger book containing vaccine stock information;
- the book/card containing syringes and safety boxes stock information.

If there is an assistant available, he/she can be asked to retrieve the forms while the evaluation process continues. If there is no assistant available, the audit team should assist in the retrieval at this time and then proceed.

All efforts should be made to retrieve records and forms.

5.2.3 *Monitoring performance*

The auditors examine any charts or tables that show vaccination data. Monitoring charts should be up-to-date, preferably on display, and include monthly coverage as well as drop-out rates.

5.2.4 *Supervision*

If there is a visitor's book or any type of register that records supervision visits from the district officers, the auditor should see it to document the date of the last visit of the district officer in charge of immunizations. The purpose of the visit should also be recorded in the logbook.

5.2.5 *Vaccine and syringe supplies stock records*

The auditors are shown the place where the vaccines and injection safety supplies are stored and examine the current ledger book. The most recent records for DTP and TT vaccine and syringe supplies are examined to determine whether they are up to date.

5.2.6 *Current recording of vaccination data*

In the place where child vaccinations are given, the auditor should see the current individual recording forms in use for recording and counting vaccinations. The number of DTP3 vaccinations given to children under one year (DTP3<1) during the last immunization day are counted and recorded.

If there are children waiting for a vaccination, the auditor observes up to five vaccinations. Certain issues are considered during the observation, and then discussed after the observation is finished.

In the place where tetanus vaccinations are given, the auditor looks at the individual recording forms and records the number of vaccinations given (of doses two and more to pregnant women – TT2+) at the last immunization session.

5.2.7 *Child health card exercise (not done if immunization session can be observed)*

Once in the quiet room, the child health card exercise is explained to each health worker separately, starting with the officer in charge. The cards represent children arriving at the HU on the day of the evaluation. The health worker is to examine a card, determine what vaccinations should be given, and make the appropriate marks/recordings on the provided sample copy of the individual recording form. Then on the back of the form, the health worker writes down the date that the child should return for his/her next vaccination. The dates should obviously correspond to the dates of the health unit's planned vaccination sessions. The cards are given one at a time by the national officer while the auditor completes the steps in the evaluation process (sections 5.2.8 through 5.2.11). Others should leave the room or be quiet so that the health worker can concentrate. The schedule of vaccination sessions and a calendar from the vaccination room or the one found in Annex F can be used during the exercise.

5.2.8 *Transcription of DTP vaccine stock*

From the ledger book for the audit year, the beginning and end of year balance of DTP vaccine and dates, with the amounts of DTP vaccine received normally from the district vaccine store, are transcribed to the logbook. Ensure that if the data is recorded in vials, the number of doses per vial remained constant throughout the year. If not, make appropriate note in the logbook and calculate the correct amount in doses. The values obtained are used to calculate DTP vaccine wastage ("global wastage") at the HU. If any time periods are missing, the dates are noted. The auditor needs to discuss the situation at the health unit before recording receipts and other DTP vaccine issues. Sometimes a large issue or return may be seen. In rare situations, a health unit may return vaccines to their supplier or assist another unit. These clarifications need to be recorded in the logbook and subtracted from the receipts. (Record in the logbook, receipts, issues and reasons for such events as returning a quantity to the district store.) Breakage, expiry or other system wastage/damage or loss must also be recorded in the logbook.

When a health unit also acts as a subdistrict store, there should be two ledger books. This concept should be explained – the vaccines should also be stored as separate as possible. Issues related to the store should be treated like any other issue in the store’s ledger book. If there is only one ledger book, try to sort out the vaccine receipts for the health unit. Explain to the unit what should be happening and say that the data will be recorded as missing. The district and national levels should be informed during the de-briefing of the need for two stock ledgers in such situations.

When health units have no fridge, they obtain their vaccines and use them immediately. They should still maintain a record of what they receive and use. If they receive at the start of each immunization day, there is more data to collect, but at least it is straightforward. If they actually return unused vials at the end of each day, this also needs to be recorded. Each relevant entry needs to be recorded in the logbook – then monthly totals made from it for the spreadsheet.

All receipts and issues (doses used) at the health unit for its DTP vaccinations must be calculated by month from the logbook and entered into the worksheet HU-Anal. This includes system wastage, such as expired vials/doses, breakage, losses, but not quantities returned to the district store or sub-store for whatever reason or quantities temporarily stored for another health unit, when the other unit’s fridge is out of order, or there is flooding, lack of power etc. By entering the calculations of the DTP vaccine supplied from district store, the doses issued (or used) for the health unit’s DTP vaccinations and doses of DTP administered into the worksheet HU-Anal, the health unit’s global DTP vaccine wastage is automatically calculated (cell F7) provided the vaccine ledger book data/information is complete for the whole audit year. The formula is given in Annex G.

5.2.9 Transcription of data from the health unit reports

The auditors retrieve all the HU’s reports for the audit year and record vaccinations reported from each report in the audit year in the logbook. If the data are recorded in the same format as needed in the worksheet, data entry will be facilitated (see Annex D). The following data are required from each monthly/quarterly report: DTP1<1, DTP3<1, all other DTP (i.e. DTP1>1, DTP3>1 and all DTP2), measles<1 and TT2+ for pregnant women.

DTP3<1 from an annual tabulation for the audit year for the HU will also be recorded in the logbook and compared with the tabulation found at district level for data consistency.

DTP3<1 from the year previous to the audit year is also needed. This can be an annual tabulation if available at the HU or monthly/quarterly figures from the reports.

5.2.10 Completeness and timeliness of reporting

The auditor will provide to the health unit officer the HU completeness and timeliness (as monitored by the district) and the report availability as retrieved at the district level (included in the analysis chart for the HU). They will discuss the need for the HU to both date and sign the reports, including the copy remaining at HU level.

5.2.11 *Verification of reported data*

All the individual recording forms from the audit year used by the health workers in their compilation of their reported values are collected by reporting period. The auditor documents the time periods when some or all tally sheets/recording forms are missing, noting this information in the logbook.

The auditor recounts the vaccinations for DTP3<1 by report period using the available individual recording forms. Preferably DTP<1, measles<1 and TT2+ (PW) are also recounted, in this order, as time allows. If the first recount disagrees with the reported value, the recount is done again to ensure correctness. The recounted values are entered into the logbook and if it is different from the reported value, it is circled.

If there are two types of individual recording forms used in the health unit (e.g. tally sheets, "Under Five Register" or child registers) the recount is done primarily on the type which is used to produce the reported information. The other type may be used in case of missing period. In every case, it will be useful to compare the numbers found in both sources (at least one month) and discuss eventual differences.

In some cases a HU will use different individual recording forms/tally sheets and so on for the static clinic and outreach, health days, school sessions, campaigns etc. In such cases it is important to ask for all records and count all, making appropriate notes in the logbook. It may also be possible that the HU's reported figure for DTP3<1 vaccinations includes a campaign's vaccinations in the monthly/quarterly report, but the individual recording forms/tally sheets are not stored at the health unit. In such cases the auditors must ask for other available records (e.g. the child register) that may contain the information. Alternatively, they may check out the place where the individual recording forms are stored (e.g. travel back to the district office or visit a subdistrict office). It is important to have access to all individual recording forms to ensure best possible data/recording/reporting verification.

It is important that all records are properly dated in order to guarantee correct recount for the appropriate period. A tally sheet with, for example, date but no year may not be used as valid documentation for recount (unless it is absolutely clear that it is a unique mistake, for example if the sheet is the only one without date or year in a properly organized filing system). "Loose" tally sheets and non-standardized papers used for recording/tallying vaccinations may only be used for recounting if they are clearly recorded with date/year and separately "blocked" or partitioned individual vaccinations.

Short supplies of appropriate recording forms, reporting formats etc. should be discussed with the district officer and at the national level.

5.3 Discussion of results

5.3.1 *The child health card exercise*

The antigen/doses recorded by each health worker are counted and then compared to the correct values. The dates to return are checked using the HU's specific schedule for immunization sessions. The auditor goes through the cards with the health worker so that he/she realizes where and why mistakes were made. All reasoning given for mistakes should be recorded in the logbook. The ease or lack of ease that each health worker showed using the individual recording forms is also noted in the logbook.

5.3.2 *Completeness and timeliness of reporting*

The discussion should focus on how to ensure that the HU completes and submits the reports on time. If the problem lies with submission, the discussion should focus on how to ensure that the reports get to the district office in time. Reporting periods when no report was compiled or sent should be documented and the reasons for non-reporting should be discussed.

5.3.3 *Accuracy of compilation*

Differences between the reported and the recounted values should be investigated and the health workers should be asked for the reason(s) for such differences. The discussion should emphasize how to improve accuracy and the importance of accurate figures, particularly in the context of a performance based reward system. The auditor should compare all the HUs' reported DTP3<1 for the audit year (annual tabulation at HU, annual tabulation at district level, monthly/quarterly reports at HU and district level and recounted values) and discuss inconsistencies in reported and recounted figures. This discussion should highlight issues of over-reporting and under-reporting. The auditors document this discussion in the logbook, and if relevant describe the major findings in the final report. The VF is based on these figures (reported and recounted).

5.3.4 *Wastage of DTP vaccine*

The computation of DTP vaccine global wastage is based on reported values of DTP vaccinations given (all doses and ages) and the recorded receipts, issues and stock balances of DTP vaccine during the audit year. When some reports or some ledger book entries are missing, the value will obviously be affected, and this needs to be considered if the wastage is unrealistically high or low. It should be remembered that HUs might not be able to reduce wastage without changes in procedure from the district or national levels, for example, without less doses per vial or without reducing the number of immunization sessions.

5.3.5 *The quality of the system*

The questions to determine the quality of the system are formulated so that the "yes" answer always indicates a higher quality system. The index score is the percentage of the items answered yes. The target is 100% since questions not applicable are to be deducted from both the numerator and denominator. All clarifications should be documented clearly in the logbook. It is important to discuss each no answer with the health workers, not only for verification but also to promote a constructive discussion toward improvement.

The worksheet's "system index quality" chart presents the scores for the three components ("recording practices", "storing/reporting practices" and "monitoring/evaluation") in a radar graph based on a scoring scale from 0 to 5 to make the three components' scoring comparable.

5.4 Completion of the logbook and spreadsheet for each health unit

At the end of each day, all entries in the logbook need to be reviewed for completeness and legibility, and then rewritten as necessary. All final suggestions for improvement should be entered into a separate section of the logbook (with subheadings of district and HU name). The quantitative data in the logbook is now entered into the HU's analysis worksheet. The HU's data tables (item 1, 2, 3 and 4 of the worksheet HU-Anal) should be verified against the data in the logbook. The national officer can assist by doing this manual verification. Once verified, the HU analysis is complete.

Without daily updates and completion of the HU analyses, it will be impossible for the auditors to keep an accurate account. When all HUs have been visited, a printed copy of the HU worksheets is given to the district officer (if it is possible to make a printout at the last location before departing from the district officer). It will be his/her responsibility to present the findings to the rest of the district team.

6. Creative accounting

Two situations need to be distinguished and tackled differently:

- *Inflation* of the reported number of vaccinations (over-reporting).¹ This is revealed by the calculation of the verification factor (see formula, Annex A).
- *Fraud*, in terms of falsification of recording forms. This is not revealed by the calculation of the verification factor. If the auditors find evidence to support that this is the case, the recounted value for the HU should be set to zero. However, evidence of fraud has proven to be very difficult to measure objectively. As a general rule, if agreement is made with the national counterpart, the recounted value should be set to zero, and if not, the issue is to be discussed at national level and presented in the report.

Suspicion of cheating (or falsifying) with individual recording forms for DTP3<1 for the audit year can be based on the following:

- Recount other vaccinations – DTP1<1, measles<1 and TT2+(PW) – for the audit year, which may demonstrate that all recounted figures are lower than reported figures on a comparable scale, whereas the DTP3<1 recounted figure more or less matches the reported figure.
- Check reported figures for the year before the audit year as well as individual recording forms availability; and either spot-check, recounting DTP3<1 for e.g. three reporting periods/month, or recount the whole year. If needed, check other vaccinations too –DTP1<1, measles<1 and TT2+ (PW).
- Compare recounted figures for DTP3<1 from individual recording forms and the child register/under-five register or whatever register is used by the health unit to record children.
- All or most of the forms appear to have been prepared/written the day before (e.g. fresh ink, same pen used, same handwriting).
- All individual recording forms for the audit year are neatly stored, compiled or ready for the visit, whereas other records, forms, tables etc. are messily stored (e.g. not stored in the same place, not available, cannot be located).

¹ The situation encompasses all cases where a reported figure is higher than the true figure and supposes intentional change to convey a more favourable impression. On many occasions, however, inflation may be non-intentional. The reasons for this should be discussed and presented.

Additionally, common mistakes (intentional or not) include the inclusion of DTP3 >1 into infant figures, counting the number of doses spent during the day instead of number of immunizations given.

In addition, to prevent such a situation from occurring:

- warning upon arrival will be part of the briefing at national level;
- the DQA briefing paper sent by the GAVI secretariat when announcing a DQA includes a paragraph on the issue (reproduced below).

From: *How to Prepare for a Data Quality Audit briefing paper* (May 2002):

“Missing reports and records (especially tally sheets) was a common problem in the countries visited during the pilot DQA. It is very important that when reports or records are missing that you do not try and rewrite them based on other data sources. If they are missing it is best to report that they are missing. In the pilot DQA a few cases were found where reports and records had been rewritten especially for the DQA. We urge you not to do this because in such a situation where auditors encounter false or rewritten records and reports, they will not be included in the DQA, resulting in a “zero score” for that administrative level.”

The briefing paper is available at: http://www.vaccinealliance.org/home/Support_to_Country/Monitoring_Evaluatio/dqa.php

7. The final report

7.1 Preparation

After returning to the national office, the auditor teams discuss and share among themselves the results of their separate visits to the field before compiling the report for the national level. This includes combining into one the data from the two shared workbooks and the data from the logbook. See annexes D and E for guidelines.

Once the DQA workbook is complete, the national verification factor is calculated automatically. The verification factor is an unbiased estimate of the true value of the ratio (recounted vaccinations/reported vaccinations) (see formula in Annex A). The standard error of this estimate is also calculated, and a 95% confidence interval is provided. These statistics are presented with clarifications in the final report. The clarifications are:

- The percentage of the national DTP3<1 vaccinations reported by districts not eligible for selection. The exact reasons for ineligibility are documented.
- The percentage of the (visited) districts' DTP3<1 vaccinations reported by health units not eligible for selection. The exact reasons for ineligibility are documented.
- Review of main factors explaining the verification factor figure, with details of findings from all levels provided (what has contributed to a high/low figure). (NB: It is important to discuss HUs with a higher recounted value compared to the reported value.)

7.2 Presentation and discussion

The auditors should organize a presentation (preferably using Power Point) that summarizes the results found at the HU, district and national levels. Examples of the analysis summary for each administrative level should be described in detail. A list of the errors found at each level and the recommendations for improvement should be included. Finally, if the DQA is being conducted for the GAVI initiative, the verification factor is presented and discussed.

The comments and recommendations for improvement that were documented at the HU and district level should be examined for practicality during the discussion. Modifications and additional comments should be thoroughly documented by the auditors.

Within the GAVI context, the country might be asked to prepare a plan to improve the monitoring/reporting system, based on the audit recommendations. Well-presented and meaningful feedback and reporting are therefore crucial to the completion of this plan.

7.3 Completion of the report

A draft report should be submitted at the end of the audit. A short narrative summarizing the major results and the highlights of the discussion during the national presentation should be written. An electronic copy of the final workbook must also be included. (Due to the very large size of the DQA workbook this has to be done as a zipped file. Perform an anti-virus check before handing over the diskette and record this in the logbook.) The final report is to be ready and sent to the GAVI secretariat and the Ministry of Health within three weeks of the completion of the audit.

Annex A:

Example national analysis workshop, June 2003

Training Yemen - Audit year 2002

Start date of audit 21/06/03

A. Performance indicators – 2001 and 2002

Calendar year	Reported DTP3 <1	Change in reported DTP3 <1	DTP3 <1 coverage rate	% Districts DTP3 <1 coverage >=80%	% dropout DTP1 <1 to DTP3 <1	% Districts dropout <10%	% DTP vaccine system wastage	Quality of system index score
2001	619,715		56.1%	15.9%	18.1%	26.1%		
2002	768,708	148,993	66.4%	28.6%	14.3%	33.8%	0.0%	79.2%

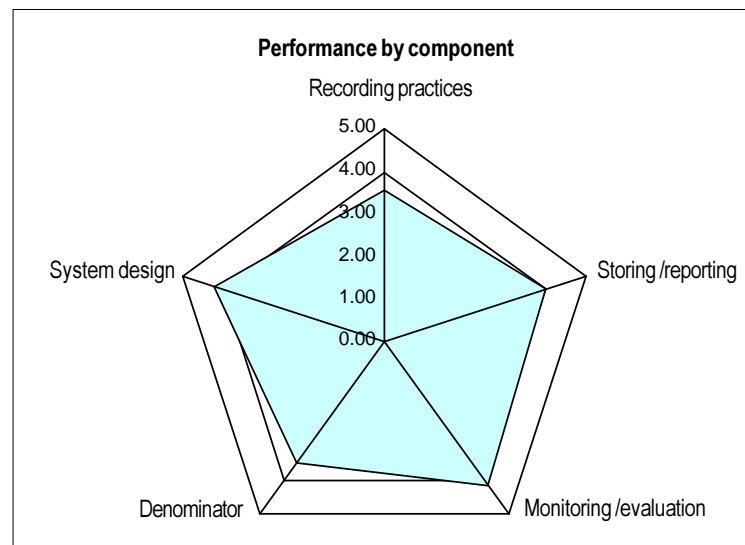
Based on most recent national totals

B. Report completeness at national level –2001 and 2002

Date on WHO /UNICEF report (JRF)	Districts report completeness rate at national level
14/03/02	86.4%
15/04/03	86.8%

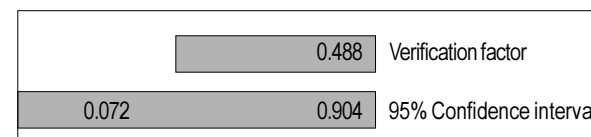
(For regions/provinces if this is entered in Nat- Samp/Nat- Inp)

C. Quality of the system index by component

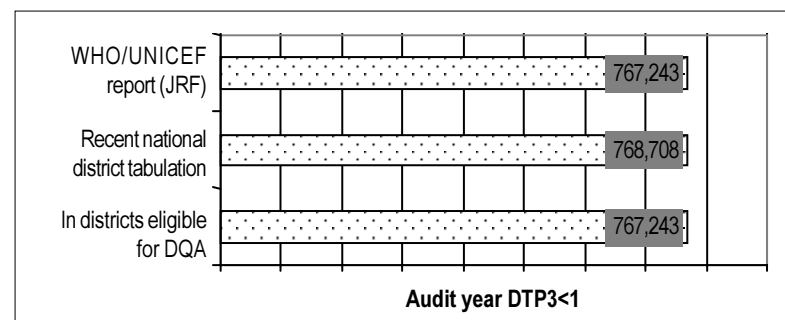


On a scale from "0" to "5".

D. Accuracy estimate of DTP3 <1 for the year 2002



Reported DTP3 <1 for the year 2002 by source



District Aden - Audit year 2002

Audit date: 22/06/03

A. Performance indicators – 2001 and 2002

Calendar year	Reported DTP3 <1	Change in reported DTP3 <1	DTP3 <1 coverage rate	% dropout DTP1 <1 to DTP3 <1	% DTP vaccine system wastage	Quality of system index score
2001	20,874		87.8%	5.0%		
2002	17,792	-3,082	73.4%	3.8%	0.0%	78.9%

Based upon annual totals at district office

B. Report availability – HU completeness 2002

National level	District level
% Districts reports found at Nat. level	Nos. HUs reporting in audit year Completeness of HU reporting
100.0%	67 93.7%

Based on HUs included in HU sampling

C. Quality of the system index by component

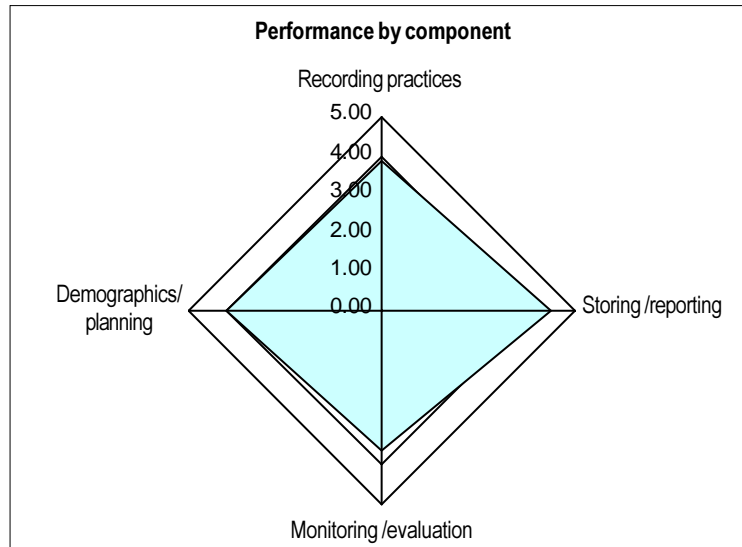
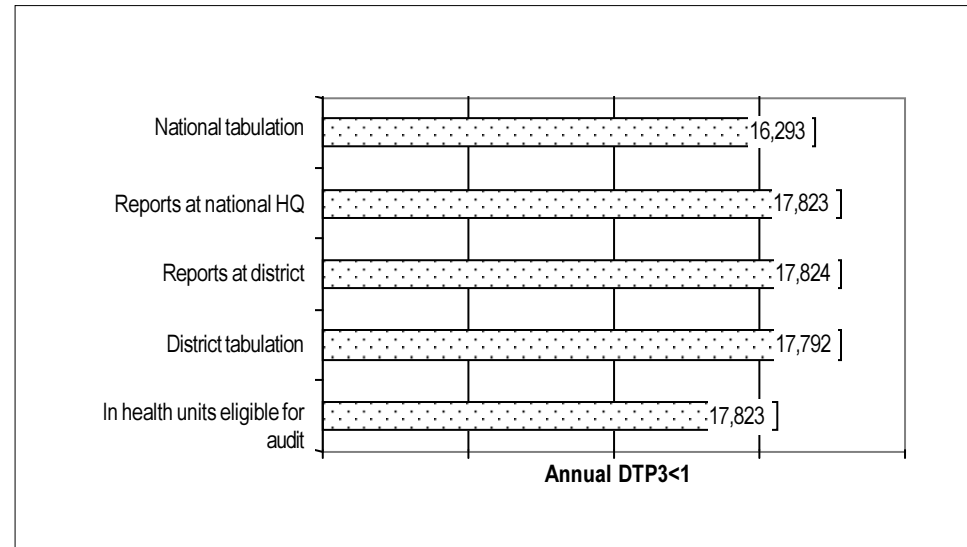


Chart based on a scale "0" to "5" for each component

D. Accuracy estimate of DTP3 <1 for the year 2002



Karaba, District Aden District - Audit year 2002

Audit date: 23/06/03

A. Performance indicators – 2001 and 2002

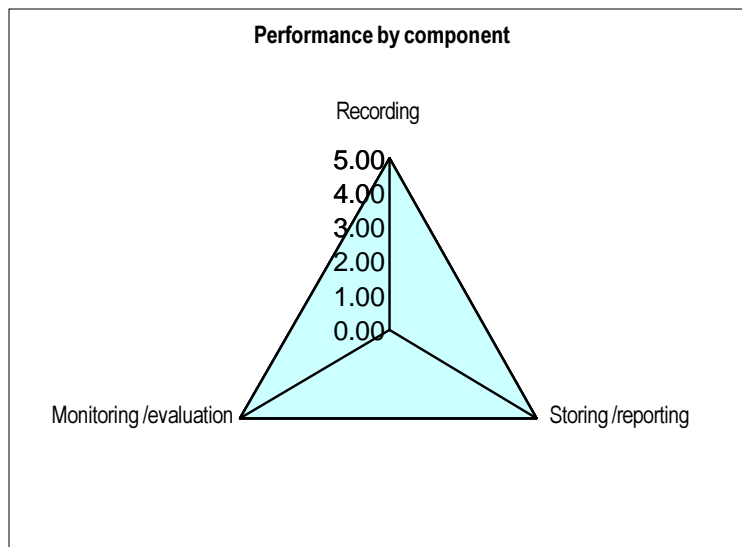
Calendar year	Reported DTP3 <1	Change in reported DTP3 <1	% dropout DTP1 <1 to DTP3 <1	% DTP vaccine wastage	Quality of system index score
2001	missing				
2002	88	missing	24.8%	missing	100.0%

Based on information found at health unit

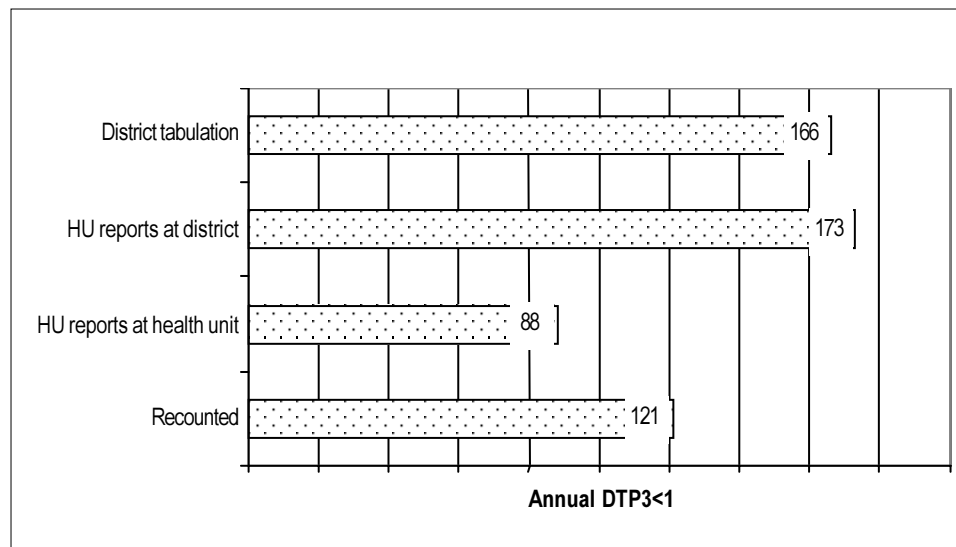
B. Report availability for year 2002

found at Nat. level	% of year's report found at district level	% of year's report found at health unit level
	100.0%	50.0%

C. System index quality by component year 2002



D. Annual DTP3 by source for year 2002



Formulae for calculating results

$$\begin{array}{l} \text{Quality of the system index} \\ \text{(Target 100\%)} \end{array} = \frac{\text{(count of yes)} \times 100}{\text{(count of yes + count of no)}}$$

$$\begin{array}{l} \text{On a scale from 0 to 5} \\ \text{(Target 5.00)} \end{array} = \frac{\text{(count of yes)} \times 5}{\text{(count of yes + count of no)}} \quad \text{(radar chart presentation)}$$

(See Annex B for breakdown into components – presentation in “Nat-Anal”, “Dist-Anal” and “HU-Anal”)

$$\text{Report availability} = \frac{\text{(number of reports retrieved)} \times 100}{\text{(number of reports expected)}}$$

$$\begin{array}{l} \text{Number expected at national level} \\ \text{Number expected at district level} \end{array} = \begin{array}{l} \text{(number of districts)} \times \text{(reporting periods in a year)} \\ \text{(number of HUs)} \times \text{(reporting periods in a year)} \end{array}$$

(District report availability for all districts – calculated in worksheet Nat-Anal cell M7/8 for reports found or presented in a table at national level).

(District report availability for selected district – calculated in worksheet Dist-Anal cell J8 for reports found at national level).

(HU's report availability for selected HU – calculated in worksheet HU-Anal cell J7 for reports found at district level and cell M7 for reports found at HU level).

(HU report availability for all HUs – calculated in worksheet Dist-Anal cell M8 from district's monthly/quarterly reports found at district level).

$$\text{Completeness of reporting} = \frac{\text{(number of reports received)} \times 100}{\text{(number of reports expected)}}$$

$$\begin{array}{l} \text{Number expected at national level} \\ \text{Number expected at district level} \end{array} = \begin{array}{l} \text{(number of districts)} \times \text{(reporting periods in a year)} \\ \text{(number of HUs)} \times \text{(reporting periods in a year)} \end{array}$$

Completeness is not calculated by the auditor but is asked at the national and district level.

$$\text{Timeliness of reporting} = \frac{\text{(number of reports received on time)} \times 100}{\text{(number of reports expected)}}$$

Timeliness is not calculated by the auditor but is asked at the national and district level.

$$\text{Dropout rate (DOR) DTP1<1 to DTP3<1} = \frac{(\# \text{ DTP1<1} - \# \text{ DTP3<1}) \times 100}{\# \text{ DTP1<1}}$$

(Target less than 10%)

$$\text{DTP vaccine system wastage} = \frac{\text{(doses of DTP wasted (unopened vials))} \times 100}{\text{(doses of DTP handled)}}$$

where:

unopened vial doses of DTP may result from a breakdown in the cold chain (turned vaccine vial monitor – VVM, frozen DTP etc), poor management (expired vaccine), loss or written off, or accidents (breakage etc), missing inventory.
Doses handled: (stock beginning of audit year) + (doses received during audit year)

DTP vaccine system wastage calculation is applicable for national and district level.

$$\text{DTP vaccine global wastage} = \frac{((\text{doses of DTP issued}) - (\text{doses of DTP administered}))}{(\text{doses of DTP issued})} \times 100$$

where:

doses of DTP issued (sometimes called “doses supplied”) = (stock beginning audit year) + (doses received during audit year) - (stock end of audit year).

Doses administered = total number of DTP vaccinations given to children during the audit year (all DTP).

DTP vaccine global wastage is calculated for all selected health units and includes both “system” and “administrated” wastage.

See Annex G for detailed explanation.

The verification factor:

Let

M = the number of clusters (districts) in the country

m = the number of clusters (districts) selected ($m < M$)

i = cluster indicator ($i = 1, 2, \dots, m$)

N = the number of **reported** vaccinations in the country

N_i = the number of **reported** vaccinations in the i^{th} cluster (largest of the national tabulation value and the value of the sum of district reports found at national level)

h = strata indicator ($h = 1, 2, \dots, L$)

N_{hi} = the number of **reported** vaccinations in the h^{th} stratum of the i^{th} cluster

The N_{hi} sum (three strata) is equal to the district tabulation value found at the district. Each stratum total (N_{hi}) is calculated summing the values of the health facilities annual totals (in the stratum) adjusted so that the strata totals equal the district tabulation.

j = HU indicator ($j = 1, 2, \dots, q$)

x_{hij} = the number of **recounted** vaccinations in the j^{th} HU in the h^{th} stratum of the i^{th} cluster

y_{hij} = the number of **reported** vaccinations in the j^{th} HU in the h^{th} stratum of the i^{th} cluster

Where the **reported** is given as the reported figure for the health unit found at district level or, if no value found at district level, the value found at the health unit.

The estimated number (or observed number) of vaccinations administered in the i^{th} cluster is given by the equation:

$$\hat{O}_i = \sum_{h=1}^L N_{hi} \left(\frac{\sum_{j=1}^q x_{hij}}{\sum_{j=1}^q y_{hij}} \right)$$

$$= \begin{aligned} & (\# \text{ of reported in Strata 1}) \frac{\# \text{ of Recounted in HU1+HU2 (in Strata 1)}}{\# \text{ of Recounted in HU1+HU2 (in Strata 1)}} \\ & + (\# \text{ of reported in Strata 2}) \frac{\# \text{ of Recounted in HU1+HU2 (in Strata 2)}}{\# \text{ of Recounted in HU1+HU2 (in Strata 2)}} \\ & + (\# \text{ of reported in Strata 3}) \frac{\# \text{ of Recounted in HU1+HU2 (in Strata 3)}}{\# \text{ of Recounted in HU1+HU2 (in Strata 3)}} \end{aligned}$$

The ratio of the recounted number of vaccinations to the reported number of vaccinations in the i^{th} cluster is given by the equation:

$$\hat{R}_i = \frac{\hat{O}_i}{N_i} = \frac{\text{Estimated \# of Vaccinations for the cluster}}{\# \text{ of Reported Vaccinations in the cluster}}$$

Then the national Verification Factor is:

$$\hat{R} = \frac{\sum_{i=1}^m \hat{O}_i}{\sum_{i=1}^m N_i} = \frac{\text{Sum of the Recounted Vaccinations over the 4 clusters}}{\text{Sum of the Reported Vaccinations in the 4 clusters}}$$

An approximation to the standard error of the estimated ratio of the recounted to reported number of vaccinations given in the country is given by the equation:

$$SE(\hat{R}) \approx \sqrt{\frac{\sum_{i=1}^m (\hat{R}_i - \hat{R})^2}{m(m-1)}}$$

Annex B:

Quality questions

National level

Breakdown of questions into the five components:

- Recording practices (7): Nos. 24, 24a, 25, 26, 27, 29, and 44a
- Storing /Reporting practices (5): Nos. 31, 32, 33, 34, and 35
- Monitoring and Evaluation (18): Nos. 17, 18, 18a, 18b, 18c, 19, 20, 21, 22, 23, 28, 28a, 28b, 28c, 36, 37, 42, and 43
- Denominators (10): 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14
- System design (13): 1, 2, 3, 4, 15, 16, 30, 38, 39, 40, 41, 44 and 45

It may be necessary to adapt the questions to the country's specific system, procedures and operations. For example, the reporting system may be from health unit to a subdistrict, from subdistrict to district, from district to province and from province to national level. Supervision and monitoring may follow a similar channel of responsibilities, or may be slightly different. Vaccine may be supplied through a supply channel from national level to districts and from districts to HUs, or from national level to a provincial store, which supplies HUs directly. Denominators may be set by national level or calculated at provincial or district level based on local demographic data, or, as experienced in some countries, based on a "household health register" updated annually.

Table B.1: Quality questions, national level

No.	Formulation	Comments/clarifications
1	Is there integrated reporting (immunization data with other health data) from health unit to district?	Integrated reporting = only one reporting system (one set of forms, reports, tabulations etc.)
2	Is there integrated reporting (immunization data with other health data) from district to national level?	See QQ no.1.
3	Are there official regulations regarding the reporting of immunization (health data) from all health units (including government, private, religious, NGO)?	Official = MoH or government statement. This could be as an official regulation, a directive, instructions or written on the forms and reports used or in an immunization manual, training handbook etc. This could include what to report, frequency of reporting, where to report to, reporting deadlines etc. The auditor should see it.
4	Are there written instructions for reporting forms currently in use?	This should include instructions on how to fill in the form, who to sign the form, how to distribute and archive the report etc. The auditor should see it.
5	Is the definition of the denominator for child immunizations consistent with the WHO definition?	See definition Annex B, p.15. If the country's definition is different from the official WHO definition, record the exact definition used and the reasoning for using it.
6	Were all district infant immunization coverage rates for the audit year under 100%?	Document all with rates over 100% with explanation "why".
7	Is the infant denominator used in the audit year different from the denominator used in the previous year?	If the denominator values are the same record "why"; the importance with this question is to demonstrate denominator changes with population changes.
8	Is the number of surviving infants (audit year) identical in the Joint Reporting Form and GAVI documents?	Look at the figures in the GAVI annual report – GAVI applications' and discuss any discrepancy.
9	Is the number of surviving infants (audit year) consistent with other health programmes?	look at other infant targeted programmes (Mother and Child Health programmes, nutrition, etc.).
10	Is the definition of the denominator for tetanus immunizations to pregnant women consistent with the WHO definition?	See definition at the end of Annex B. Ask for denominator definition for pregnant women only. If not available or if only available for Child Bearing Aged Women, score 0.
11	Were all district TT2+ coverage rates for pregnant women for the audit year under 100%?	If the country is not measuring coverage for pregnant women, this answer is not available (na). Document all with rates over 100% with explanation why.
12	Is the denominator (pregnant women) used in the audit year different from the denominator used in the previous year?	Score "Yes" or "No" even if QQ No.10 is "No". The importance with this question is to demonstrate denominator changes with population changes.

No.	Formulation	Comments/clarifications
13	For the audit year, is the denominator value (for infant immunizations) found at the four districts the same as that used at national level?	Record and check against the figure found for the four districts. Discuss any difference and discuss why. Answered after visit to the four districts.
14	Is the proportion of infants per strategy type known in the country?	Strategy: fixed, outreach, mobile. A proportion (%) should be known and if known, score 1. Ideally, it should be supported by written information.
15	Are DTP3 child vaccinations reported separately for children under one year of age?	
16	Are tetanus vaccinations doses 2+ reported separately for pregnant women?	
17	Is an up-to-date monitoring chart or table of the current year's immunization coverage displayed anywhere?	See the chart or table. The importance with this QQ is that the chart is up-to-date and "displayed" in a relevant office, room etc (e.g. Immunization Programme Manager, Operations officer etc). "
18	Is an up-to-date monitoring of the current year's immunization dropout rate displayed anywhere?	Can be on the same chart or table as coverage. The importance is to be able to say, at this moment of the year (the audit visit), what is the dropout rate? This can be DTP1–3 dropout or other dropout measure.
18a	Is an up-to-date monitoring chart or table of the current year's immunization reporting completeness (from the district) displayed anywhere?	Completeness: was the report received YES/NO. Discuss the completeness figure found in the Joint Reporting Form. Discuss completeness against availability of reports at national level.
18b	Is the timeliness of district reporting monitored?	
18c	Does the national office routinely stamp or write the date that the report from district (region/province) is received at national level on the report?	Needs to be answered as such by the programme manager (i.e. is the monitoring of timeliness systematic and organized). This must be the "first" date, the report was "seen" (received) at national level, not the date the report was (computer) processed.
19	Is there a routine feedback format for the next lower level?	Routine feedback = written summary or analysis of EPI data. Routine = regular (not ad hoc). Format = written if distributed or minutes of meeting if in form of a meeting. If "no" then the score for 20 and 21= "na".
20	Is the date of the last feedback form or report less than four months ago?	

No.	Formulation	Comments/clarifications
21	Does any routine feedback format contain some discussion of the data?	Feedback must be more than just a repetition of what was reported. Results and analyses should be interpreted. See the latest feedback.
22	Can the numerators reported to WHO/UNICEF (Joint Reporting Form) for the audit year be reproduced from an archive file?	This can be paper (hard) copy, floppy diskette, computer file etc. It is important that it clearly is an "archive" file with date for archive, production etc. Check numerators for DTP1<1 and DTP3<1.
23	Is there a publication in print or already available which includes immunization data from the audit year?	Publication = annual report, newsletter, set of tables, filed summary etc.
24	Are vaccines receipts and issues recorded in a vaccine ledger book?	If no ledger book, or inappropriate record keeping of vaccine receipts and issues, score "No". It is not sufficient to have bin-cards, but an appropriate cardex-system will suffice provided it is correctly maintained, stored and archived.
24a	Is the current ledger book up-to-date for DTP vaccine?	If QQ 24 is "No" score 0. Up to date = all receipts and issues entered within 24 hours. The auditor may check ledger against receipt and issue vouchers if time permits.
25	Is the current ledger book up to date for TT vaccine?	If QQ 24 is "No" score 0. Up to date = all receipts and issues entered within 24 hours. The auditor may check ledger against receipt and issue vouchers if time permits.
26	Is the receipt of DTP vaccine complete for the entire audit year?	If QQ 24 is "No" score 0. Complete = all receipts and issues recorded. If book seems incomplete discuss reasons why.
27	Were immunization forms sufficiently available in the visited districts during the current year?	Answered after visit to the four districts. If there is any shortage of any form that the national level should provide to the district level, score 0.
28	Is there a map of the country showing performance per district?	Map should be up to date, ideally on display, or easily retrieved from computer file. Performance: coverage, dropout, population not immunized...
28a	Is there a graph of number of vaccine preventable diseases (VPDs) per period of time in the country?	Broken down by VPD – should be up to date and for all vaccine preventable diseases. If one disease graphed and up to date, score 1.
28b	Are district vaccine stock-outs monitored?	The manager should be able to say (based on written information) whether one district has encountered a vaccine stock-out. If no vaccine stock-out reported, ensure that the monitoring is possible and done. (Check with stock-out reported by any visited district for discussion). Stock-out = interruption in vaccine supply (for any vaccine).
28c	Is there a monitoring of supervisory activities?	Should be able to say, (based on written information), when was the last time a district was supervised. Ideally, should follow a yearly plan.

No.	Formulation	Comments/clarifications
29	Have all the available district reports from the period previous to the last one been processed?	Processing = entering data into whatever system they use (electronic or paper). Ideally there should be written instructions about the process and procedures.
30	Is there a written procedure for dealing with late reporting?	Question: yes/no. The auditor should see it. If yes, discuss how far the procedure is implemented.
31	If the data processing is computerized: Is there a written backup procedure?	If not computerized score is "na". Read it.
32	If the data processing is computerized: Is the last date of backup within the past week?	If not computerized score is "na". Check the date written on the backup file or diskette file creation date.
33	If the data processing is computerized: If more than one computer has immunization data, is there either a functioning network or a written, well-organized method of data transfer?	If not computerized score is "na". Read it.
34	Does each district (region/province) have its own file or sub-file?	Files for the reports in paper.
35	Are the district (region/province) reports filed by year and reporting period?	Be flexible: the best practice will enable the easy retrieval of any given report.
36	Is there a list of tabulation formats that are or can be created?	Standard format of various reports that users can select from.
37	Is the date of printing/production on every tabulation/chart?	
38	Did the monthly (quarterly) reports from the districts (region/province) for the audit year use the same form/format?	If there was an official change in the report format, a four-month flexibility should be allowed (mix of old and new forms for a maximum of four-months).
39	Is there a written procedure/process (specific form or as part of the monthly (quarterly) reports) for submission of aggregate reports of adverse events following immunization (AEFIs) from regional/provincial, district or health unit level?	If there is no surveillance of AEFIs, this is to be highlighted in the report. "Aggregate" reporting. Not a case-by-case reporting. Specify the level of reporting in the logbook.
40	Does the reporting form to the higher level from the health units and districts (regions/province) allow for calculation of vaccine wastage?	Should include number of doses administered by the health units and number of vials used (including those wasted) at each level. The importance with this QQ is for the national level to monitor and calculate vaccine wastage for the country and for individual districts (regions/province). For districts to monitor and calculate vaccine wastage for HU, see Annex G.

No.	Formulation	Comments/clarifications
41	Is there a recording system (ledger book, stock form or paper) which allows the monitoring of receipt/issuing of syringe supplies (AD syringes and/or non-AD disposable syringes)?	The monitoring system should be appropriate to the immunization safety policy, e.g. if both AD and non-AD disposable syringes are used, the two types of supplies should be recorded separately.
42	Was the vaccine wastage rate (DTP) reported in the JRF for the audit year?	
43	Is the vaccine wastage rate calculation (JRF or actually found at the time of the audit) at national level done according to correct calculation?	Correct wastage calculation at national level should include the wastage of all reporting units (including doses damaged), not only reported doses administered/doses issued. See Annex G. If no calculation (in JRF or the one provided) score "No".
44	Does the vaccine ledger book (national level) allows for monitoring of separate batch numbers and expiry dates of vaccine?	Ledger book or cards, cardex system etc. This QQ does not depend on the answer to QQ 24. The importance with this QQ is to demonstrate recording and monitoring of vaccine batch number with expiry date (could be recorded as "lot").
44a	Is the batch number and expiry date recorded for all vaccines and up to date?	If no system/procedure/form for recording/monitoring of vaccine batch number and expiry date score is "na" (QQ 44 is "No"). Check DTP for the score.
45	Does the (standard) reporting form for district reporting to national level have a "box"/"space" for reporting number of health unit reports included in the district's report?	If "yes" score "1" but check whether this information is filled in by the four selected districts. If not remember to discuss this with the national office and the four districts.

District level

Breakdown of questions into the four components:

- Demographic/planning (10): 1–10
- Monitoring and evaluation (11): 11–21
- Recording practices (9): 22–30
- Storing /Reporting practices (8): 31–38

It may be necessary to adapt the questions to the country's specific system, procedures and operations. For example the reporting system may be from health unit to a subdistrict, from subdistrict to district, from district to province and from province to national level. Supervision and monitoring may follow a similar channel of responsibilities, or may be slightly different. Vaccine may be supplied through a supply channel from national level to districts and from districts to HUs, or from national level to a provincial store, which supplies HUs directly. Denominators may be set by national level or calculated at provincial or district level based on local demographic data, or, as experienced in some countries, based on a "household health register" updated annually.

Table B.2: Quality questions, district level

No.	Formulation	Comments/clarifications
1	Is there a target number of children that the district strives to vaccinate during a calendar year or reporting period?	Obtain the target value and previous year's annual total. Discuss how realistic the value is and record in the logbook (even if the target is unrealistically high/low, as long as they have set a target they score a 1).
2	Is there a target number of pregnant women that the district strives to vaccinate during a calendar year or reporting period?	If the national policy is for "women of childbearing age" score is "na". Obtain the target value and the previous year's annual total. Discuss how realistic the value is and record, (even if the target is unrealistically high/low, as long as they have set a target they score a 1)
3	Is the denominator (for infant immunizations) used in the audit year different from the denominator used in the previous year?	Record in the logbook. If same value discuss and record the district's reason for this.
4	For the audit year, is the denominator value (for infant immunizations) found at the district level the same as the one found at the national level?	Record and check against the figure found at national level (region/province if no figure at national level). Discuss any difference and record "why". If there is a difference and if the district has more qualified data, then score 1.
5	Is the proportion of infants per strategy type known for the district?	Strategy: fixed, outreach, mobile. A proportion (%) should be available and known
6	Is there an up-to-date microplan for the district (current year)?	Microplan should include the planning process to increase routine immunization coverage. It may be integrated with other health services.
7	Is the denominator (for TT2+ immunizations for pregnant women) used in the audit year different from the denominator used in the previous year?	Score "Yes" or "No" even if QQ No.10 national level is "No". The importance with this question is to demonstrate denominator changes with population changes. Record the values.
8	Has the same denominator for child immunizations been used on different tabulations, reports, charts, tables etc., as observed by the auditors during the visit?	
9	Has the same denominator for child immunizations been used on different programmes (check nutrition, malaria programmes, etc)?	Generally the health worker will know.
10	Is there a district map of catchment area showing HU providing immunization strategies?	Ideally, the map should include denominator, target, strategy type.
11	Is there an up-to-date chart /table of the current year's immunization coverage displayed anywhere?	The importance with this QQ is to have a chart on display for the district staff in charge of the immunization programme, which is up to date. A chart on display in e.g. a store-room is not useful. If there is a chart/table but "hidden" in a drawer scores 0. Discuss and encourage to display and use the chart.

No.	Formulation	Comments/clarifications
12	Is the completeness of the immunization reporting from HU recorded and monitored at district level?	
13	Does the district record and monitor reporting timeliness for HU immunization reporting?	
14	Is an up-to-date monitoring of the current year's immunization dropout displayed anywhere?	Can be on the same chart or table as coverage. The importance is to be able to say, at this moment of the year (the audit visit), what is the dropout rate? This can be DTP1–3 dropout or other dropout measure.
15	Is there a routine feedback format for the next lower level?	Feedback = written summary or analysis of immunization data (district to sub/district or district to HU). Routine = regular (not ad hoc). Format = written if distributed or if in form of a meeting is minutes of meeting.
16	Are there regular meetings with health unit workers to discuss immunization performances?	Such meetings should occur outside supervisions and involve workers from several health units.
17	Is there a monitoring of health unit vaccine wastage?	
18	Are supervision activities monitored?	A written schedule of supervision that includes visiting every health unit within a specific period of time. Supervision must include immunization. Record should include list of HUs, date visited and by whom. Check core indicator.
19	Is there any publication of tables or charts produced for the audit year (or in the process of being produced)?	Publication = annual report, newsletter, set of tables, filed summary etc.
20	Is there a monitoring of health unit vaccine stock-outs?	The manager should be able to say (based on written information) whether one health unit has encountered a vaccine stock-out. If no vaccine stock-out reported, ensure that the monitoring is possible and done. Stock-out=interruption in vaccine supply (for any vaccine).
21	Is there a system for investigation of individual reports of adverse events following immunization from the district to the higher level functioning/operational?	If no official system implemented yet (no instructions) score is "na".
22	Are vaccines receipts and issues recorded in a vaccine ledger book?	If no ledger book, or inappropriate record-keeping of vaccine receipts and issues, score "No". It is not sufficient to have bin-cards, but an appropriate cardex-system will suffice provided it is correctly maintained, stored and archived.

No.	Formulation	Comments/clarifications
23	Is the current ledger book up to date for DTP vaccine?	If QQ 22 is "No" the score for this QQ is 0. Up to date = all receipts and issues entered within 24 hours, but be understanding if all HUs have specific day for collection.
24	Is the current ledger book up to date for TT vaccine?	If QQ 22 is "No" the score for this QQ is 0. Up to date = all receipts and issues entered within 24 hours, but be understanding if all HUs have specific day for collection.
25	Is the receipt of DTP vaccine complete for the entire audit year?	If QQ 22 is "No" the score for this QQ is 0. Complete = entries for each month (normally). If book seems incomplete discuss reasons why.
26	Were immunization forms sufficiently available in the visited health units during the current year?	Answered after visit to the health units. If any shortage of any form that the district level should provide to the health unit level, score 0.
27	Does the district office stamp or write the date the report from HU is received at district level on the report?	Needs to be answered as such by the district medical officer or person in charge of immunization services (i.e. is the monitoring of timeliness systematic and organized). This must be the "first" date, the report was "seen" (received) at district level, not the date the report was (computer) processed.
28	Did the monthly (quarterly) reports from the health units all use the same form/format for the current year?	If there was an official change in the report format, a four-month flexibility should be allowed (mix of old and new forms for a maximum of 4 months)
29	Did the Individual Recording Form (tally sheets) from the 6 health units use the same form/format for the current year?	If no tally sheet check registers This question is answered after the visit to the health units
30	Is there a system (ledger book/stock card) for monitoring the receipt/issuing of injection supplies (AD and/or non-AD disposable syringes)?	Monitoring system = appropriate recording.
31	Have all the available Health unit reports from the period previous to the last one been processed?	Processing = entering data into whatever system they use (electronic or paper). Ideally there should be written instructions about the process and procedures.
32	Is there any procedure/system for dealing with late reporting?	Information coming late should be sent to the national level. The explanation provided should be in line with national guidelines. If no national guidelines, the system should be functional.
33	Does each health unit have its own file or sub-file and are the papers inside filed by date?	Storage should facilitate retrieval and monitoring (and be well organized). If the storage is filed by date only (not by health center), score YES if any report search is easy.
34	Is there a written backup procedure?	If not computerized score "na". See the procedure.

No.	Formulation	Comments/clarifications
35	Can the official immunization tabulations for the audit year be reproduced from an archive electronic file?	If not computerized score "na". Official immunization tabulations = final summary of audit year data. (Take only DTP3<1.) Archive electronic file = stored file from hard disc/diskette.
36	Is the last date of backup within one week of the assessment?	If not computerized score "na". Check disc for last saved date; look at the file creation date.
37	If more than one computer has immunization data, is there either a functioning network or a written, well-organized method of data transfer?	If not computerized score "na". See the method.
38	Is the date of printing/production on every tabulation/chart or, if the data is archived, the date the archived file was created?	If not computerized score "na". Check.

Health unit level

Breakdown of questions into the three components:

- Recording practices (18): numbers 1–18
- Monitoring and evaluation (8): numbers 19–27
- Storing /reporting practices (4): numbers 28–31

It may be necessary to adapt the questions to the country's specific system, procedures and operations. For example, the reporting system may be from health unit to a subdistrict, from subdistrict to district, from district to province and from province to national level. Supervision and monitoring may follow a similar channel of responsibilities, or maybe slightly different. Vaccine may be supplied through a supply channel from national level to districts and from districts to HUs, or from national level to a provincial store, which supplies HUs directly. Denominators may be set by national level or calculated at provincial or district level, based on local demographic data, or, as experienced in some countries, based on a "household health register" updated annually.

Table B.3: Quality questions, health unit level

No.	Formulation	Comments/clarifications
1	Are there tally sheets for infant vaccinations on the desk (or easily available) and do they have entries for the last immunization day?	<p>Main concern is evidence of use of tally sheet.</p> <p>If tally sheets completed by month and not each immunization session, ensure that tally sheet has month/year clearly marked.</p> <p>Check the numbers given during the last immunization session.</p>
2	Are registers (or pre-printed forms) used for recording individual information about child immunizations?	Check the child registers. These may be child health cards, if cards are kept in HU.
3	Can a child's vaccination history be easily and rapidly retrieved in the registers?	A new dose should not be entered as a complete new entry but entered in the location where previous doses have been entered. Score 0 if register is used as a new entry for any immunization.
4	Are there tally sheets for woman TT vaccinations on the desk (or easily available) and do they have entries for the last immunization day?	<p>Main concern is evidence of use of tally sheet.</p> <p>If tally sheets are completed by month and not each immunization session, ensure that tally sheet has month/year clearly marked.</p>
5	Are registers (or pre-printed forms) used for recording individual information about woman TT immunizations?	Check the woman register. May be health card if cards kept in HU.
6	Does the HU use /maintain a ledger /stock control for vaccines?	
7	Is the ledger up to date in entries for DTP vaccine?	<p>Up to date = all receipts and issues recorded immediately.</p> <p>If no ledger in health unit, score 0. Check against stock (in the fridge). <i>Compare the date of last entry and the date of the last immunization session.</i></p>
8	Is the ledger up to date in entries for TT vaccine?	<p>Up to date = all receipts and issues recorded immediately.</p> <p>If no ledger book in health unit score 0. Check against stock (in the fridge), <i>Compare the date of last entry and the date of the last immunization session.</i></p>

No.	Formulation	Comments/clarifications
9	Is the receipt of vaccine DTP in the ledger complete for the entire audit year?	Complete = entries for each month (normally). If book seems incomplete discuss reasons why (e.g. fridge may have broken down). If no ledger book score 0.
10	Is there a log of the (ledger book/stock card) receipt/issuing of syringes supplied (AD and/or non-AD disposable syringes)?	Monitoring system should be appropriate to the immunization policy. (If needed perform a stock check.)
11	Does the HU record vaccine batch number and expiry date?	OBSERVE minimum of five (among infants or mothers) and check the child/mother's card. If no observation score "na". If you can observe five immunizations, then skip child health card exercise (QQ. 16/17/18).
12	Was the correct vaccination given for every vaccination observed?	
13	Was the correct Individual record completed for every vaccination observed?	
14	Was the correct date to return given for every vaccination observed?	
15	Are the individual recording forms available for the entire audit year?	Individual recording form = tally sheets or register. Note that vaccination dates are not always known. Record in the logbook all the periods that are missing.
16	Did every person taking the child health card exercise get a perfect score for DTP1<1?	Note – if observations conducted (QQ. 15/16/17), can skip child health card exercise.
17	Did every person taking the child health card exercise get a perfect score for DTP3<1?	Select two or three people – one of whom is the primary recorder.
18	Did every person taking the child health card exercise get a perfect score for measles<1?	
19	Does the health unit have a (target) number of infants that they strive to vaccinate against DTP during a calendar year or reporting period or vaccination session?	Obtain the target value and previous year's annual total. Discuss how realistic the value is and record (even if the target is unrealistically high/low, as long as they have set a target they score a 1).
20	Does the health unit have a (target) number of pregnant women that they strive to vaccinate against tetanus during a calendar year, reporting period or vaccination session?	Obtain the target value and previous year's annual total. Discuss how realistic the value is and record (even if the target is unrealistically high/low, as long as they have set a target they score a 1).
21	Is the health unit aware of new births in the target area (from TBAs, local chiefs, birth register, etc.) and attempts to follow up to ensure all newborn children are immunized (house visit, bringing the child to the HU, etc)?	

No.	Formulation	Comments/clarifications
22	Does the HU monitor vaccine wastage?	If the health worker can say how much the DTP wastage is and how it can be calculated, score 1.
23	Is there a map showing the catchment area including the outreach villages?	Ideally shows strategy type.
24	Is there interaction with the community regarding immunization?	Ask for information on what and when. It aims at motivating the parents to immunize children. This is not only social mobilization. There should be, based on data use, interaction directed to areas with problems.
25	Is there a mechanism in place to track vaccine doses that are due or track defaulters?	Can be an appropriate use of a correctly filled register, tickler file, etc.
26	Does the health unit have an up-to-date chart or table on display showing the number (or in %) of child vaccinations by report period for the current year?	If in a file score a 0, but encourage staff to put chart/table on display. (Only one antigen is sufficient to score 1, but encourage them to have all.)
27	Does the health unit monitor dropout rate?	Preferably on display with the same monitoring chart as the coverage one, but score 1 if the health worker can tell you the DO rate for his HU.
28	Are all the health unit reports available for the entire audit year?	Monthly or quarterly depending on country. <i>Record in the logbook all the dates that are missing.</i>
29	Is there one location where the previous reports and recording forms concerning immunization data are stored?	Previous = before 2002 (i.e. not current reports but closed reports). Score 1 as long as the reports are stored and can be retrieved (can be at the house of the nurse, etc.).
30	Are the reports of the health unit organized in a file by date?	If they do not have a file but reports are clearly stored in date order, in booklet form then the answer scores a 1. The main concern is that the reports are easily retrievable. <i>The actual report forms may not be saved but if the aggregated values are kept routinely and precisely in a separate book for this purpose, the question can be answered with a yes.</i>
31	Are health staff aware of standard operating procedure and the forms to complete if there is a report of AEFI?	Case by case, not aggregate reporting.

Notes

1. *Denominator child immunization*

The official WHO definition of denominator for child immunization coverage is the estimated number of surviving children (or infants) at age one in a target area. It is not the *target* number of surviving children. The denominator for child immunization (number of live births less infant deaths) up to one year should not be adjusted (down) for children with contraindications or for the “target” figure.

2. *Denominator for TT2+ immunization coverage*

The official WHO definition of denominator for tetanus immunization coverage (TT2+ = 2 doses or more) is the estimated number of pregnant women in a target area. The number of live births can be used to estimate the number of pregnant women. This figure should not be adjusted (down) for any reason.

3. *Terminology*

- Crude birth rate (CBR): Live birth per 1000 population in a year.
- Infant mortality rate (IMR): Infant deaths (children<1) per 1000 live births in a year.
- Target “surviving children” as percentage of “total population”: Some countries use a “fixed” percentage (e.g. 5%) of the target area’s total population as “denominator for surviving children” for health units. This “formula” is based on a combination of CBR and IMR.

4. *Changing demographics*

It is important that countries use the latest census figures. If the last census is several years old, the country will (normally) use a projection based on the census and an official growth rate. However, figures/findings from recent national or district surveys (e.g. a “head count”, a “mini-census” etc.) and/or research (for example of leading causes of fatal diseases, trends in fertility, mortality, migration etc.) may be used to adjust the population figure (nationwide or at provincial/district level). If some form of adjustment has been made record this in the logbook with reference to the e.g. survey, mini-census and include “figures” (national and district level).

5. *Immunization safety monitoring*

- Supply of syringes: the data should be used to monitor the quantity of supplies received vis-à-vis the number of immunizations given. What is the ratio of :
 - number of AD syringes/number of immunizations given in each “defined period”, or
 - number of non-AD disposable syringes/number of immunizations given in each defined period.
- Note: do not count oral polio vaccine (OPV) as it does not require injection equipment.

Annex C:

The logbook

1. Information for the logbook

National office

- Persons met with titles
- Organizational structure
- Flow of information/data
- Copies of collection and reporting forms
- Notes from all discussions
- Listing of all districts/reporting units
- Copy of WHO/UNICEF JRF and the district tabulations that were used to obtain the totals
- Copy of national tabulations (used in analysis) with documentation of sources
- Answers and clarifications to quality of the system questions
- Further information about denominators
- Vaccine store information
- Notes from discussion at final presentation

District office

- Persons met with titles
- Organizational structure
- Flow of information within district office
- Copies of collection and reporting forms (if different)
- Listing of all health units
- Copies of district tabulations (used in analysis) with documentation of sources
- Answers and clarifications to Quality of the System questions
- Further information about denominators
- Vaccine store information
- Notes from all interviews

Health unit

- Persons met with titles
- Answers and clarifications to quality of the system questions
- Vaccine store information
- Completed forms and results of child health card exercise
- Recounts of vaccinations (all calculations, sums, and notes)
- Calculation of all statistics and indicators
- Notes from all discussions

Summary section

- Listing of possible improvements by district and health unit

2. Use of pre-printed format for the logbook

One major purpose of the logbook is to ensure the exact recording of the data collected and used in the DQA. Pre-printed “data boxes” may be put in the logbook to help with “when, where and what” data to collect, but then use a separate page to record exactly what is found. The data can come in different forms and groupings, and it is important to ensure that whatever format they come in is reproduced. One should be able, at a later date, to go back to the data sources and find exactly what is in the logbook.

The raw data collected include the vaccine receipts from the ledger books, vaccinations reported and recounts of vaccinations recorded.

- Ledger book. Each and every receipt found in the ledger book should be written down (date and amount). If some are not applicable for the wastage calculation (for example perhaps just a temporary store for another health unit) then this is also recorded clearly. Sometimes there may be more than one entry a month, sometimes only one a quarter. The number of entries is not fixed. From the complete listing in the logbook, monthly totals can be summarized and entered into the worksheet.
- DTP3 <1. The reporting categories for DTP3 <1 are also not fixed. Sometimes, other DTP3 <1 for health days, outreach, etc. can be found. (e.g. categories for static/fixed clinics, outreach and sometimes mobile). It is important to write down all the categories that make up the DTP3 <1 with the reported values and, if they report it, the total – in the logbook. From this, one then makes the totals to be entered on the worksheet.
- Recounts. When recounting, all subtotals made during the recount should also be entered in the logbook. Subtotals may be made by immunization session, or page, or clinic/outreach, or by vaccinator, or whatever grouping the auditor feels makes sense given the situation of the records at the health unit. Whatever is done, the sub-totals should be recorded in the logbook. No possible fixed format could cater for the possibilities.

See also Annex B: Quality questions with comments/clarification.

See also Annex D: Data entry guidelines with “Source of data” and “Comments on logbook entry”.

For discussion and calculation about “vaccine wastage” see Annex G for details.

Annex D:

Data entry and DQA workbook guidelines

This annex gives a few guidelines to help auditors, external and national, with the DQA workbook in the field.

- Points 1–5: general guidelines: description of the tool structure
 - Points 6–17: workbook instructions (codes used)
 - Points 18–22: security precautions
 - Points 23–28: particular procedures
 - Point 29: troubleshooting
1. The DQA Workbook is based on Excel 2000. Earlier Excel versions, for example Excel 97, may work, but due to the very large size and complexity of the workbook, it cannot be guaranteed that the workbook will work as well as with Excel 2000. Preferably it should be used with Windows 98, 2nd Edition or Windows ME.
 2. The workbook is designed with three “sets” of worksheets:
 - i) A national level with four worksheets: Nat-Samp, Nat-Inp, Nat-Dist-Rep and Nat-Anal.
 - ii) A district level with four identical “sets” each with four worksheets: Dist-Data, Dist-HU-Samp, Dist-HU-Rep and Dist-Anal.
 - iii) A health unit level with one worksheet per health unit (HU-Anal) – a total of six worksheets per district.
 3. The first two worksheets at national level (Nat-Samp and Nat-Inp) and district level (Dist-Data and Dist-HU-Samp) are used for selection of districts (four) or health units (six plus one “reserve”) plus national or district level general information. The third worksheet is used for selected district or health unit information found at national level (Nat-Dist-Rep) or district level (Dist-HU-Rep). The fourth worksheet (in Nat-Anal and Dist-Anal) is used for information about vaccinations, denominators, vaccine store data and quality questions for the system index, and at the top of the worksheet an analysis of: performance indicators, reporting availability, quality of the system index and annual reported DTP3<1 by source. The HU-Anal worksheet is the only worksheet used at health unit level.

-
4. Calculation of the national verification factor with confidence interval is automatically done in the last worksheet “Verification Factor” (VF). The auditors must enter HU data (HU name, HU report and recounted) in yellow cells (C18–E26 etc) from the blue cells on the VF worksheets (cells C9–F14 etc). These data have been transferred onto the VF worksheet from the Dist-HU-Samp worksheet. All other values in the VF worksheet have been automatically transferred into relevant cells.
 5. The four “sets” of district worksheets including the six health units’ worksheet are all labelled “(X)”, where X is 1, 2, 3 or 4. The six health unit worksheets (HU-Anal) are labelled with a number (1 to 6) identifying the health unit’s worksheet in the order the auditors decided to use in the workbook. For example: worksheet “Dist-HU-Samp (2)” is the second worksheet of district no.2 (used for sampling health unit in the district). Worksheet “HU3 Anal (4)” is the worksheet for the third health unit in the fourth district. Once the auditors have decided and entered the sequence for the four districts and six health units within each district, this should not be changed.
 6. All worksheets are “protected” only allowing for data entry in cells with yellow fill colour (cells are not locked). Should a situation occur which demands data entry or other changes to protected cells, see below for guidelines, but it is not possible to un-protect the worksheet once the workbook is “shared”.
 7. Data in cells with light turquoise fill colour are automatically generated/ calculated using information from the same worksheet.
 8. Data in cells with pale blue fill colour are automatically generated/calculated using information from another worksheet and possibly from the same worksheet.
 9. Text in red font or bold font highlights for the auditor’s attention, e.g. compare different values/cells, discuss with national officials, record in logbook etc.
 10. All date cells are formatted as “dd/mm/yy”. The workbook was created with (main) regional settings: English (UK), currency=£, time=hh:mm:ss (AM/PM) and date=Gregorian calendar – dd/mm/yy (short).
 11. All number cells are formatted with “1,000” comma separator (no decimals).
 12. All percentage cells are formatted with one decimal.
 13. Zero values must be entered if a monthly/quarterly report, for example, has 0 for DTP3<1, as this information indicates presence of a valid report.
 14. The value “na” is used to indicate no information available (e.g. on the date the report was received at national level), or not relevant (e.g. for quality questions). Where instructed, “na” must therefore be entered where instructed, or left unchanged if no other valid value is applicable, as the workbook uses the “na” in formulas.
 15. The value “missing” is used to indicate that the information could not be generated or calculated in light turquoise or pale blue cells, e.g. a cell’s value used in a formula as denominator is 0, or “district tabulation” of DTP3<1 not possible (not a complete year’s data entered). Please do not change this value as the workbooks in some cases use it in formulas.
 16. “All other DTP” = DTP1>1 + DTP3>1 + all DTP2 (for use in HU-Anal worksheets). It may include booster doses.

-
17. TT2+ (PW) = TT doses of two and more given to pregnant women (usually either TT2 or boosters, or TT2, TT3, TT4 and TT5 – for use in HU-Anal worksheets).
 18. Virus check/scanning. It is advisable to perform a virus scan/check before opening and/or copying any file (using diskette) to your computer.
 19. Copy DQA workbook to computer's hard drive. Each external auditor will receive a blank copy of the DQA workbook as a zipped file on a diskette. The workbook is approximately 1500 kB without country data. The external auditor can copy the workbook from the diskette by opening the zipped file and save it as "*Countryname 2003*" on the computer's main drive. It is advisable to keep the file on the floppy diskette as a backup workbook.
 20. Data entry: Please be careful when entering data. This Excel workbook does not have logical checks inbuilt and will therefore not test for valid values for different cells like a database application (e.g. 0 or 1 may be valid values but not 11). For example value 11 will be accepted as a "Quality Question", but result in a wrong component value as the formula is using the sum function.
 21. Save and make a backup copy as often as possible.
 22. Copy data. Whenever copying data from one worksheet to another, between different workbooks or between cells in the same worksheet use the "copy", "paste special", "values" functions.
 23. Sampling districts in country with provincial aggregated data (district aggregated data are not available at national level and cannot be submitted to the auditors two weeks before the audit):
 - i) The auditors select two provinces based on the provincial aggregated DTP3<1 for the audit year before arrival in the country. The worksheet Nat-Samp is used with provincial data entered in rows 33 to 182 (instead of district data – province name and audit year DTP3<1). "Sampling interval" (normally automatically calculated in cell H31) is manually calculated as ½ of the total cumulative DTP3<1 (Cum DTP3<1). Using random number tables, choose a random number as for "selection of districts" (see Annex E). Select the first province as the first entry in the list with Cum DTP3<1 larger than the random number and the second province as the next province in the list with "Cum DTP3<1" larger than the sum of random number plus sampling interval. Enter "SEL" (selected) for the two selected provinces in column B. Enter national figures/data in cells C5/6/7/8/9 and 13. (It is very unlikely any province will not be eligible.)
 - ii) In-country, the auditors enter national figures/data in worksheet Nat-Inp cells D15, D17/18, E17/18, F17/18 and B21.
 - iii) From most recent national tabulations by provinces (instead of districts) enter cell D29 and rows 44 to 193 for audit year and year before. (District reports are not available at national level, but provincial reports are. Therefore data for national level analysis, "Nat-Anal", will be based on provincial data.)
 - iv) Worksheet Nat-Anal: enter cells L7–8, all figures for "Step 1" from national vaccine store and all answers to "Quality of the System Chart" in "Step 2".

-
- v) **Save the workbook** (“*Countrysname2003*”) and “**share**” (worksheet Nat-Dist-Rep cannot be finalized at this stage, but will be done when the two teams meet again at national level). Create a copy of the shared workbook for “team 2”. Agree to the order of the workbook: e.g. team 1 uses the worksheets for districts no.1 and 2 and team 2 uses the worksheet for districts no.3 and 4.
 - vi) **Travel to the selected provincial HQ.** Each team selects two districts within the selected province, based on district totals/reports at provincial level. Use a copy of Nat-Samp (e.g. open a new blank workbook and copy the Nat-Samp worksheet into this workbook. NB: copy, then choose “paste” – do not choose “paste special” and “values”). Agree on districts that are not eligible. Calculate the sampling interval as $\frac{1}{2}$ of total Cum DTP3<1 for all eligible districts in the province; use random number tables (NB: a new set); select random number following instructions in Annex E for selection of districts. First selected district is the first district in the list with Cum DTP3<1 larger than the random number and the second district as the next district in the list with Cum DTP3<1 larger than the sum of sampling interval plus random number. Enter “SEL” for the two selected districts.
 - vii) In worksheet Nat-Dist-Rep (each team in their respective copy of the shared DQA workbook): Enter D8–9, E8–9, F8–9, district 1 and district 2 for team 1. Team 2 uses D10–11, E10–11, F10–11, district 3 and district 4.
 - viii) Visit the two selected districts: Each team visits the two selected districts in the province entering data as per manual and instructions in annexes using the team’s copy of the shared DQA workbook (Dist-Data, Dist-HU-Samp, Dist-HU-Rep, Dist-Anal and (6) HU-Anal for each district – team 1 for districts no.1 and 2 and team 2 for districts no.3 and 4).
 - ix) **Merge workbooks at national level:** The two teams merge the workbook as per the guidelines in Annex ..on page ... The two copies of Nat-Samp for selection of districts will not be used, but should be kept as documentation for selection of districts (also documented in the logbook). Finalize Verification Factor worksheet.
 - x) **Final discussion/presentation at national level and report:** The national verification factor is (correctly) calculated based on the four selected districts’ findings. “Performance Indicators”, “Preliminary accuracy estimate of DTP3<1 for the audit year” and “quality of the system index by component” are based on national level data (as normal) but “Completeness” and “Reported DTP3<1” are based on national level totals for province aggregated data and reports to national level (no district totals at national level).
24. Insert rows if the number of districts is >150 or the number of health units in one district is >125. This can only be done before the workbook is shared. It is therefore important to clarify this before finalizing the national level.

-
- i) *Nat-Samp worksheet*: **Un-protect** worksheet: click “Tools”, “Protection”, and “Unprotect sheet”. **Insert rows**: Click any row after row 86, click “Insert”, “Rows” (as many times as new rows needed). The formula in column G is not copied, therefore copy the last cell in column G before creating new rows: click “Copy”, drag over *all* the cells in G below the cell you copy from and paste. **Protect worksheet**: click “Tools”, “Protection”, and “Protect sheet”; then click “OK”.
 - ii) *Nat-Inp worksheet*: **Un-protect** worksheet. **Insert rows** as many times as needed before last yellow row 193. Formulas for columns R, S, T, U, W, X, Y and Z are not copied therefore copy these cells (copy and paste) into new inserted cells. **Protect worksheet**.
 - iii) *Dist-Data worksheet* (more than 125 health units): **Un-protect** worksheet. **Insert rows** as many times as needed before last yellow row 143. Copy formula in row E cells into new inserted cells in E. **Protect worksheet**.
 - iv) *Dist-HU-Samp worksheet* (more than 125 health units): **Un-protect** worksheet. **Insert rows** as many times as needed before last yellow row 176 but after yellow row 51. Copy formulas in columns G, I and J into inserted cells in G, I and J. **Protect worksheet**.
25. Reporting periods Nat-Inp (cell B21) are normally monthly (=12). In a few countries they are quarterly (=4). If a country’s reporting periods for the audit year are different from 12 or 4 (e.g. half-yearly, bi-monthly) enter this in cell B21 (e.g. 2 or 6). In worksheets with “reporting periods” data enter values in the first columns from left to right (e.g. enter in “Jan/Qtr1” and “Feb/Qtr2” for two reports in the audit year).
 26. Sort health units (DTP3<1 values) for health unit sampling – Dist-HU-Samp, Step 2, a. **This cannot be done on a protected and shared workbook/worksheet. The auditor must therefore copy the data from Dist-HU-Samp onto a blank worksheet, do the sorting and copy back onto the Dist-HU-Samp worksheet. It is important to do the sorting before labelling HU “NE”, as HUs with NE will otherwise be listed at the bottom of the list. Select all cells below the labels “Enter NE”, “HU code”, “HU Name”, “Annual DTP3<1” (in the columns C, D, E and F). Copy to interim worksheet (copy, paste special, values). Sort (all cells still highlighted): click “Data”, “Sort”; click “Annual DTP3<1” in “Sort by”, click “Descending”, click “OK”. Copy all data back to the Dist-HU-Samp worksheet. Carry on with “Step 2” in worksheet.**
 27. Using the reserve health unit – Dist-HU-Samp and Dist-HU-Rep. **Copy cells D66–O66 to the similar area above for the health unit which could not be visited (copy, paste special, values). Also copy cell I62 to the respective cell “I” above. In worksheet Dist-HU-Samp, copy cells D43, E43 and F43 to the similar cells for the health unit which could not be visited. Change audit date if needed.**
 28. **No access to health unit (not responding/refusal). Just leave the worksheet (HU-Anal) blank. In the VF worksheet remember to enter this HU’s data from blue cells (e.g. C9–F14) to yellow cells. The “recounted” value will be 0, but must be entered in a yellow cell.**

-
29. **Verification Factor:** The HU's "reported" DTP3<1 value for HU is calculated, based on the district's annual tabulation for the HU, the HU's monthly/quarterly reports found at district level and monthly/quarterly reports found at the HU. The recounted DTP3<1 value is based on the auditor's recounted value and the availability of the HU's monthly reports at district and HU level. If the HU sampling at district level was based on an annual district tabulation for each HU in the district (i.e. cell C6 in the Dist-Data worksheet) the reported DTP3<1 will be the larger value of the district's annual tabulation for the HU and the sum of monthly/quarterly reports found at district and/or HU level. The recounted value will be the auditor's recounted DTP3<1.

If the district sampling of HU was based on monthly/quarterly reports/values at district level, the reported DTP3<1 for the HU will be the sum of monthly/quarterly reports found at district and/or HU level. The recounted value for each month/quarter will be the auditor's recounted value if a monthly/quarterly report for the HU is available at district or HU level. If not, the recounted value, even with a positive figure from individual recording forms, will be set to "na". It is important to keep this formula in mind when discussing the DQA results, including VF for the national level and each individual district (data consistency, report availability and correct storing and filing of forms/reports).

30. **Troubleshooting:**

- i) **Pale blue/light turquoise cells not updated:** This may be due to problems with sufficient system resources. It can be rectified cell by cell by pressing "F2" and "enter".
- ii) **Not enough system resources (or similar Excel prompts):** close as many programs/applications running in background (and using RAM) as possible/feasible and/or install more RAM.

Table D.1: Data obtained from the country before audit and at the national office when in the country

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
Basic facts, and WHO/UNICEF JRF for the audit year	Include photocopy of WHO/UNICEF JRF, GAVI annual report	Step 1: Sampling of districts (auditing company) <ul style="list-style-type: none"> country name, start date of audit audit year, year previous reported DTP3 <1 (WHO/UNICEF JRF) 	Nat-Samp
Data sent by country before start of DQA	Include printout of data sent Keep computer file of data sent Include random number table used	Step 2: Sampling of districts (auditing company) <ul style="list-style-type: none"> national total DTP3 <1 (national tabulation) district names, DTP3 <1 for audit year, and eligibility Step 3: <ul style="list-style-type: none"> Enter SEL by each district selected Auditors check and finalize worksheet in-country 	
National tables (or use totals of a district tabulation)	Include photocopy of tabulation (if available)	Step 1: no entry	Nat-Inp
		Step 2: no entry (but save country's computer file if available)	
		Step 3: national values for year previous to audit year DTP1 <1, DTP3 <1, surviving infants denominator	
		Step 3: National values for audit year <ul style="list-style-type: none"> DTP1 <1, DTP3 <1, surviving infants denominator date of tabulation 	

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
National tabulations of district values	<p>Keep computer file</p> <p>If no computer file, include photocopy of tabulation</p>	<p>Step 4/5: District values for audit year and year previous</p> <ul style="list-style-type: none"> number of reporting periods (12 or 4) date of tabulation (for national district tabulation) for each district: province/region code, name, DTP1<1, DTP3<1, denominator, number district reports received, whether eligible for DQA (EL or NE) check whether national totals consistent between data for audit year entered in steps 3 and 4 	
District reports for each selected district for the audit year	<p>If a total value for DTP3<1 is not reported, then all categories reported are recorded (for example, if districts report DTP3 <1 given in static clinics and given in outreach but not the total DTP3 <1). What is important is the "total" reported value for the district at national level</p>	<p>Step 1: no entry</p> <p>Step 2:</p> <ul style="list-style-type: none"> District name, start date of audit in district and district's tabulated DTP3 <1 value for audit year (from Nat Inp) in the order that the four districts should appear in the workbook <p>Step 3: District values for four selected districts for the audit year</p> <ul style="list-style-type: none"> DTP3 <1 value for each reporting period (12 or 4) 	Nat-Dist-Rep
WHO/UNICEF JRF		<p>Top section B</p> <ul style="list-style-type: none"> Dates on WHO/UNICEF JRF for audit year and year previous 	Nat-Anal

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
Ledger book for Vaccines (audit year)	Include: <ul style="list-style-type: none"> • Date of each receipt of DTP vaccine and amount received • Whether recorded in vials or doses • Whether any part of year missing in ledger book • Date, amount and reasons for "damaged" DTP vaccine discarded/write off • If different vial sizes received during audit year calculate either in doses or in only one vial size 	Item 1: Vaccine ledger book data for national level <ul style="list-style-type: none"> • if recording DTP vaccine in vials: doses per vial (cell B45) • DTP stock balance at beginning of audit year (01/01) • DTP stock balance of end of audit year (31/12) • monthly totals DTP vaccine received • whether data is considered complete for the year (cell B54) • monthly totals of DTP vaccine (in doses) damaged and discarded 	
Answers to Quality of System questions	Include: <ul style="list-style-type: none"> • All clarifications • All supporting evidence • Sometimes specific values 	Item 2: <ul style="list-style-type: none"> • Actual answers to the Quality of the System questions as "0", "1" or "na" 	

The DQA workbook is now "shared" and used by the two audit teams for visits to the four districts including the 24 HUs.

Note: The worksheets are numbered with "(1)", "(2)", "(3)", or "(4)", e.g. "Dist-Data (1)" is for the first of the four selected districts.

Table D.2: Data obtained at the district office

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
Health unit reports for the audit year – ONLY IF annual values (district tabulation) are unavailable	If a total value for DTP3<1 is not reported, then record each category reported (for example, if HU reports DTP3 <1 given in static clinics and outreach but not the total DTP3<1) and enter the reporting period's total in the worksheet	<p>Step 1: Enter "1", "2" or "3"</p> <ul style="list-style-type: none"> • If annual DTP3<1 data for the audit year are available for all HUs (district tabulation) enter "1" • If no district tabulation and number of HUs<50 enter "3" (sample for all months for all HUs) • If no district tabulation and number of HUs>50 and monthly reporting enter "2" (sample three months and enter all HUs) • If no district tabulation and number of HUs>50 and quarterly reporting enter "3" (sample all HUs for all four quarters) <p>Step 2: Only if annual DTP3 <1 by health unit unavailable (no district tabulation) ("2" or "3" in Step 1), enter (as instructed on the worksheet)</p> <ul style="list-style-type: none"> • Number of months /quarters of data entered • HU name, HU code (if applicable or relevant), and DTP3 <1 by health unit by reporting period for the audit year (see above step 1: 12 months, four quarters or three months sampled) 	Dist-Data
Annual totals of DTP3 <1 for each health unit for audit year (from district tabulation or created in Dist-Data from HU reports or other tabulations)	Photocopy of table (if available)	<p>Step 1: Annual DTP3<1 data for audit year are not available (no district tabulation and step 2 in Dist-Data completed)</p> <ul style="list-style-type: none"> • Transfer (copy) HU code, HU name and DTP3<1 from Dist-Data row 18 to 143 to rows 49 to 176 • If annual DTP3<1 is available for HU (district tabulation and only step 1 completed in Dist-Data) enter HU code, HU name and DTP3<1 from district tabulation in row 49 to 176 	Dist HU Samp

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
Verbal discussion	<p>Enter results of sample selection</p> <p>Include random number table used in selection</p>	<p>Step 2: Select health units</p> <ul style="list-style-type: none"> Enter "NE" for each HU not eligible for selection, sort, stratify, give numbering within strata, select six "regular" HUs and one "reserve" HU Create sum of DTP3 <1 for each stratum (for all HUs, EL and NE) and enter in cells E27–28–29 (check total strata sum DTP3<1 with HU sum, cell G30, and correct if any difference) <p>Step 3: For each selected health unit (six plus one), in order to be entered into the workbook and decide order of HU worksheet (HU-Anal), enter</p> <ul style="list-style-type: none"> strata number health unit name DTP3 <1 value (from worksheet's column F) expected audit date (not for reserve HU) 	
Health unit reports for audit year (selected health units) as found at district	If a total value for DTP3<1 is not reported, then record each category reported (for example, if HU reports DTP3 <1 given in static clinics and outreach but not the total DTP3<1)	<p>Step 1: For each selected health unit (six plus one),</p> <ul style="list-style-type: none"> annual DTP3<1 tabulation at district office for each selected HU (7) DTP3 <1 value from HU reports for each reporting period 	Dist-HU-Rep
Annual table or tabulation for year previous to audit year and audit year	Copy of tabulations or table	<p>Item 1: enter</p> <ul style="list-style-type: none"> annual district totals for year previous to audit year (DTP1 <1, DTP3 <1 and surviving infants denominator) annual district totals for audit year (DTP1 <1, DTP3 <1 and surviving infants denominator). NB: District's annual DTP3<1 for audit year is MUST 	Dist-Anal

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
Ledger book for vaccines (audit year)	<ul style="list-style-type: none"> • Date of each receipt of DTP vaccine and amount received with monthly totals • Whether recorded in vials or doses (see comments for national level) • Whether any part of year missing in ledger book • Date, amount and reasons for "damaged" DTP vaccine discarded/write off 	<p>Item 2: enter</p> <ul style="list-style-type: none"> • if recording DTP vaccine in vials: doses per vial (cell B50) • DTP stock balance at beginning of audit year (01/01) • monthly totals DTP vaccine received • DTP stock balance at end of audit year (31/12) • whether data is considered complete for the year: enter "1" if complete (cell B59) • monthly totals of DTP vaccine damaged and discarded in doses 	
Answers to quality of system questions	<ul style="list-style-type: none"> • All clarifications • All supporting evidence • Sometimes specific values 	<p>Item 3: enter</p> <ul style="list-style-type: none"> • Actual answers to the Quality of the System questions as "0", "1" or "na" 	
District monthly reports for the audit year (Number of health units reporting may be on separate chart/table)	If a total value for DTP3<1 is not reported, then all categories reported are recorded (for example, if HU reports DTP3 <1 given in static clinics and given in outreach but not the total DTP3 <1)	<p>Item 4: enter</p> <ul style="list-style-type: none"> • data from the district's reports from audit year: reported DTP3 <1 and number of health units reporting for each reporting period 	

Note: The worksheets are numbered with "(1)", "(2)", "(3)", "(4)", "(5)" or "(6)": e.g. "HU3 Anal (4)" is the third health unit in the fourth district

Table D.3: Data obtained at each health unit

Source of data	Comments on logbook entry	Comments on worksheet entry	
		Data to be entered	Worksheet name
Annual chart or table or Monthly reports (year previous to audit year)	If a total value for DTP3<1 is not reported, then all categories reported are recorded (for example, if HU reports DTP3<1 given in static clinics and given in outreach but not the total DTP3<1)	<p>Item 1: enter</p> <ul style="list-style-type: none"> DTP3 <1 for year previous to audit year (either annual value OR reported monthly /quarterly values) 	<p>HU1 Anal</p> <p>HU2 Anal</p> <p>HU3 Anal</p>
Ledger book for Vaccines (audit year)	<ul style="list-style-type: none"> Date of each receipt of DTP vaccine and amount received Whether recorded in vials or doses (see comments for national level) Whether any part of year missing in ledger book Record any quantities which have been returned to the district store, have been held in store for another HU etc and subtract from monthly totals (but not damaged vaccine/write off due to e.g. expired vials) 	<p>Item 2: Data from HU vaccine stock ledger; enter</p> <ul style="list-style-type: none"> if recording DTP vaccine in vials: enter doses per vial DTP stock balance at beginning of audit year (01/01) monthly totals DTP vaccine received DTP stock balance at end of audit year (31/12) whether data is considered complete for the year: enter "1" 	<p>HU4 Anal</p> <p>HU5 Anal</p> <p>HU6 Anal</p>
Answers to Quality of System questions	<ul style="list-style-type: none"> All clarifications All supporting evidence Sometimes specific values 	<p>Item 3: enter</p> <ul style="list-style-type: none"> actual answers to the Quality of the System questions as "0", "1" or "na" 	
Health unit reports for the audit year	Record of each DTP dose /category, measles<1, and each TT2+ dose from each report	<p>Item 4: enter data from HU reports for audit year</p> <ul style="list-style-type: none"> DTP1 <1, DTP3 <1, "All other DTP", measles <1, TT2+ (PW) ("all other DTP"=DTP1>1 plus DTP3>1 plus all DTP2) 	
Individual recording forms for the audit year (usually either tally sheets or register books)	<p>Record of each sub-total made (could be by page, date, or whatever is done)</p> <p>For TT2+, sub-total record of each dose</p>	<p>Item 5: Enter recounts of the monthly/ quarterly values for the audit year</p> <ul style="list-style-type: none"> Must be done: DTP3 <1 As time permits, do in this order: DTP1 <1, Measles <1, and TT2+ (PW) 	

On return to national level, the two audit teams merge the two copies of the DQA workbook to the “final” DQA workbook.

Verification Factor worksheet

For the four districts enter in correct strata (yellow cells C18 to E26, C41 to E49, C66 to E74 and C91 to E99) from blue cells (C9 to F14, C32 to F37, C56 to F61 and C81 to F86) HU name, HU report (final reported DTP3<1 for the HU for the audit year) and HU recount (final recounted DTP3<1 for the HU for the audit year). The VF and CI will then be calculated automatically. For “non-responding” HU enter HU name, HU report and HU recount, where HU recount = 0.

Use of reserve health unit

In the rare situation a regular selected health unit cannot be visited due to weather, road conditions or any other conditions that justify not visiting the HU (NB: must be documented in the logbook) the audit team will use the selected reserve HU. Before the visit, it is necessary to adjust the workbook:

Dist-HU-Samp worksheet: relevant cell E37–42, F37–42 and G37–42.

If the reserve HU is in a different stratum to the regular selected HU that cannot be visited: Dist-HU-Samp worksheet relevant cell D37–42.

Dist-HU-Rep worksheet: insert values from the reserve HU row 66 in relevant row 12, 21, 30, 39, 48 or 57 (by using the functions copy, paste special, values) and value from cell I62 into relevant cell I9/18/27/36/45 or 54.1. If reporting is monthly (see Table D.4)

Formats for data entry of health unit data

Each antigen/dose combination has its own table. Data on line one “Reported (district)” are entered at the district office from the reports found at the district office. The second line “Reported (HU)” data are entered at the health unit from the reports found at the health unit.

Recounted values are entered on the third line at the health unit. The entire year for DTP3<1 must be done. DTP1<1 and measles<1 vaccinations given to children under one and TT doses 2+ given to pregnant women are recounted as there is time. If a time period is not done for these other antigen/dose combinations, then a clear, neat X is placed through the month label. It will be important when summing the reported values to only include those reporting periods that were recounted. The examples below are for DTP3<1.

1. *If reporting is monthly (see Table D.4)*

Table D.4: DTP3<1 vaccinations

Reporting period	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Yr total
Reported (district)													
Reported (HU)													
Recounted													

2. *If reporting is quarterly (see Table D.5)*

Table D.5: DTP3<1 vaccinations

Reporting period	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Yr total
Reported (district)					
Reported (HU)					
Recounted					

The row “Reported (district)” is only required for DTP3<1. The other antigen/dose combinations do not require this data.

Sharing and merging DQA files

At beginning of audit:

1. Create country DQA file by saving as "*Countryname2003*".
2. Enter all data obtained at national level in the file *Countryname2003* (Nat-Samp, Nat-Inp, Nat-Dist-Rep and Nat-Anal).¹
3. Make the file *Countryname2003* a shared workbook by doing the following:
 - a) Click "Tools", "Share Workbook".
 - b) On "Editing" tab, click "Allow changes by more than one user at the same time".
 - c) On "Advanced" tab, click "Keep change history for" under "Track changes", and enter 100 days.
 - d) Click "OK" at bottom of dialogue box.
 - e) In response to prompt to allow the file to be saved, click "OK".
 - f) The file *Countryname2003* is now a shared workbook for 100 days (shown with "[Shared]" after the name). This file is used by one team in the field.
4. Make a second shared workbook as a copy using "File", "Save as", and name the file "*Countryname2003 team 2*" (which will also have "[Shared]" written after the name). The second team in the field uses this file.
5. Files are transferred from computer to computer using a diskette. It is advisable to check the files for virus before transferring between computers. It is necessary to zip the file because of the workbook's size, before transferring to a diskette, and to unzip it from the diskette. When entering data in the field the files should be on the hard drive.
6. Some workbook features will not be allowed when "shared", but all normal data entry can be done. Each team will only enter data for the two district set worksheets the team will be auditing.

Merging files at end of audit:

1. Copy both files (*Countryname2003* and *Countryname2003 team 2*) to one hard drive folder.
2. Open *Countryname2003*.
3. Click "Tools", **Compare and Merge Workbook**.
4. If/when prompted to save file, click "OK".
5. Dialogue box "Select files to merge into current workbook" appears. Select *Countryname2003 team 2*, and click "OK".
6. There should be no prompts for conflicts of data because each team should be entering only data from the districts they visit. If there are any conflicts, the auditors will have to determine which was entered incorrectly and select the correct data.

¹ In case of provincial level aggregated data see instructions above, Annex D point 23.

-
7. *Countryname2003* now contains all the data entered by team 2 (from *Countryname2003* team 2). Use *Countryname2003* for the analysis and report writing.
 8. Save the now merged file, “Countryname 2003 [Shared]”.
 9. Undo the shared feature:
 - a) click “Tools”; click “Share Workbook”
 - b) In “Editing”, click to remove the tickmark beside “Allow changes by more than one user at the same time” (this removes the shared feature)
 - c) Click “OK”
 - d) In response to prompt “This action will remove the workbook from shared use etc.” click “yes”.
 10. The workbook is now un-shared. Save the file *Countryname2003*.
 11. Enter remaining data in worksheet Verification Factor.
 12. Save again when all entries are complete *Countryname2003*.
 13. The workbook is now final and can be used for de-briefing at national level, report writing etc.

Annex E:

Sampling guidelines

Selection of districts

1. Starting with the first eligible district, the cumulative sum of DTP3<1 vaccinations for the audit year is automatically calculated on the worksheet Nat-Samp. The value for the last eligible district equals the total number of DTP3<1 vaccinations.
2. Determine the sampling interval, defined as the total number of DTP3<1 vaccinations divided by 4. This is automatically done in “Nat-Samp” cell H31.
3. Choose one random number between 1 and the sampling interval. This is only done when at least two auditors are present. See the example in Annex E.
 - a) The auditors have a set of four pages of random numbers. One auditor chooses a page without looking.
 - b) The other auditor selects a spot on the chosen page without looking by pointing with a pencil.
 - c) Using the selected spot, lines across the page are drawn above the row and to the left of the nearest number.
 - d) Count right from the column line over a number of adjacent columns equal to the number of digits in the sampling interval and draw another column line (in the example, the number of digits would be 6).
 - e) Circle the first number within the column line and below the row line that are less than the sampling interval (and ignoring zero).
 - f) If such a number has not been found and the bottom of the page is reached, then draw a third column line down the page, the same number of digits away from the second column line. Start at the top of this column and continue search for the number that is less than the sampling interval.
 - g) The time, date and country are written on the page and it will be included in the logbook for reference.
4. Identify the first district: it is selected as the first district in the list (from top down) of eligible districts with a cumulative value of DTP3<1 larger than the random number when the district before in the list has a cumulative value of DTP3<1 smaller than the random number.
5. The second district is selected as the next district in the list of eligible districts, which has a cumulative value of DTP3<1 larger than the sum of random number plus sampling interval and the district before in the list has a cumulative value of DTP3<1 smaller than the sum of random number plus sampling interval.

-
6. The third district is selected as the next district in the list of eligible districts, which has a cumulative value of DTP3<1 larger than the sum of random number plus two times the sampling interval and the district before in the list has a cumulative value of DTP3<1 smaller than the sum of random number plus two times the sampling interval.
 7. The fourth and final district is selected as the next district in the list of eligible districts, which has a cumulative value of DTP3<1 larger than the sum of random number plus three times the sampling interval and the district before in the list has a cumulative value of DTP3<1 smaller than the sum of random number plus three times the sampling interval.

A district can be selected more than once, in this case, 12 health units (4 by stratum) will be selected. Two sets of district worksheets will be created by naming the first set “*Districtname no.1*” and the second set “*Districtname no.2*”. The audit team will visit the district office once, collecting necessary data. The information will be entered in both sets of district worksheets.

Selection of health units

1. Calculate the total DTP3<1 for audit year for all health units. Sort the list of *all* health units in descending order by the number of DTP3s.² This cannot be done in the shared, protected worksheet Dist-HU-Samp, why it is necessary to copy all the HUs with DTP3<1 numbers on to a “working” worksheet, do the sorting on this worksheet and copy back to Dist-HU-Samp. This should be done before labelling the HUs “NE”; otherwise all HUs with NE will appear at the “bottom” of the list. *NB: it is a must to enter NE for non-eligible HUs in Dist-HU-Samp column C, cells C49 etc. before the sampling starts as selection of HUs is done for eligible HUs only.*

If the number of health units in the district is > 50 AND reporting period is monthly AND the annual DTP3<1 totals for the audit year are not directly available (so that the amount of time necessary to compile the full sample frame would limit the ability to complete the data collection activities), a modified sample frame can be constructed. To construct the modified sample frame, randomly select three months. Number the months 01-January, 02-February, 03-March, 04-April, etc. and select three two-digit numbers between 01 and 12 from the random number table. These three numbers will represent the months of DTP3<1 reports to be entered into the Dist-Data worksheet for ALL health units. Sort the list of all health units in descending order by the annual DTP3<1 contribution (see comments above about sorting the list). If the reporting period is “quarterly”, all four quarter’s reports from ALL health units must be entered

2. Divide the eligible health units into three strata based upon the cumulative percentage of total DTP3<1. The first stratum should include all health units where the cumulative DTP3<1 is between 1% and 33.33%, the second stratum between 33.34% and 66.66%, and the third stratum above 66.67%. If the split between two strata does not correspond exactly to e.g. 33.33 – 33.34, make the split taking the upper value, i.e. above 33.33% (e.g. 36%) instead of below (e.g. 32%).

² See Annex D for “sort” instructions

-
11. Select two eligible health units randomly from each stratum. If any stratum has only one health unit, then three are selected from the following stratum. Count the number of eligible health units in the stratum, and then count the number of digits in the number (example, if 12 eligible health units then two digits).
 - a) The district officer selects, without looking, one of the four pages of random numbers, and then again without looking selects a spot on the selected page.
 - b) Two lines are drawn on the page relative to the spot selected. One line is above the nearest row of numbers and the other is to the left of the nearest number.
 - c) Count from the column line over the number of digits in the count of health units in the stratum and draw another column line.
 - d) Circle the first two *different* numbers within the column lines and below the row line that are less than the count of health units (and ignoring zero). A health unit can thus not be selected twice.
 - e) If two *different* numbers have not been found and the bottom of the page is reached, then draw a third column line down the page the same number of digits away from the second column line. Start at the top of this column and search for the remaining numbers that are less than the count of health units.
 - f) Continue in the same column for the next two strata, changing the width of the column to match the number of digits in the count of health units for the stratum.

 4. One reserve health unit is selected using another random number, chosen between one and the total number of health units in the district, using the same procedure as described above. Thus the reserve health unit might fall into any stratum, but must be different from the regular selected health units.

If a district is selected twice, 12 health units will be selected with 4 from each stratum. The first and second health unit selected in each stratum will be visited as health units for "*Districtname* no.1" and the third and fourth health unit selected in each stratum as health units for "*Districtname* no.2". One reserve health unit will be selected for each district. If e.g. stratum no.1 has less than four eligible health units, the auditors must select the "missing" health unit(s) from the next stratum. If there are 12 or less than 12 eligible health units in the district, all health units will be selected.

5. A health unit cannot be selected twice.

Additional information on district and HU sampling

1. If a district is randomly selected twice, the selection of health units within each stratum should be doubled (i.e. select four regular health units within each stratum and two reserve health units). Name the worksheets District 1 and District 2 and enter identical district data for the two sets of worksheets (both in “Nat” worksheets and “Dist” worksheets) with the two HUs first selected from each stratum as District 1 HU and the two HUs selected last in each stratum as District 2 HU.
2. If a health unit is selected, but during travel time an unforeseen disaster occurs (e.g. armed conflict breaks out or flooding occurs and the roads are not passable), the health unit is replaced by the reserve health unit and the worksheets updated accordingly.
3. Make every attempt to collect data. A district or health unit with inaccessible records (i.e. the staff is not in or refuses entry, the door to the district or health unit is locked, etc.) will be treated as a respondent with zero information.³ The auditor should discuss with the national counterpart whether, e.g., the team should return to the health unit in another attempt to collect information. Whatever outcome, remember to record it in the logbook.
4. If the country’s immunization data is aggregated at national level based on provincial aggregated district data, two provinces will be randomly selected by the auditors following the sampling guidelines for district sampling.

The case of subdistricts

In some countries, health unit information (name of all vaccinating HUs and HU reports) for the audit year may be unavailable at district level because the information is located in subdistricts. In that case:

1. Get a table/file/chart/list etc. from the district with all subdistricts including reported DTP3<1 for the audit year.
2. Decide eligibility for subdistricts (EL or NE). A subdistrict with less than three HU reporting immunizations (at least once) in the audit year is “NE”. (If no information about subdistricts reporting HUs assume they have at least three “EL” HUs. If this later turns out not to be the case audit the one or two eligible HUs in the subdistrict and record it in the logbook).
3. Prepare a copy of worksheet Nat-Samp. Enter all EL subdistricts with the tabulated (from a district table etc.) or calculated total DTP3<1 for the audit year in columns E and F, cells 33 etc. and all NE subdistricts in columns L and M, cells 33 etc. Change cell H31 to =IF(G182<>0,+G182/2, “missing”) (which gives a sampling interval of ½).
4. Using the same sampling strategy as for sampling of four districts, with a sampling interval of 50% sample two EL subdistricts. Enter “SEL” in column B. The selected subdistrict with the larger DTP3<1 value for the audit year becomes stratum 1 and the other stratum 2. Enter this (DTP3<1) in Dist-HU-Samp cells E27 and E28.

³ See Annex D for “HU non-respondent with zero information”.

-
5. Enter or copy from copy worksheet Nat-Samp all districts in Dist-HU-Samp in columns C, E and F cells 49 etc. This gives us annual totals DTP3<1 (cell D12 and M51) which can be used for comparison with district figures in the discussion about data consistency and also used in Dist-Anal “Annual DTP3<1 by source” (value for “In health units eligible for audit”). It will also give us the district figures for the two selected subdistricts, which again can be used for comparison of data (district and subdistrict level) and discussion about data consistency. NB: The two figures in Dist-HU-Samp cells E30 and G30 will not match, as only two subdistricts data were used for cell E30.
 6. Enter in the logbook the monthly/quarterly reported DTP3<1 for audit year for the two selected subdistricts and keep the (copy) worksheet as documentation.
 7. Enter value “1” in Dist-Data cell C6.
 8. If district has list/table/chart/file with all HUs, which reported immunization at least once in the audit year, select three HUs from each of the two selected subdistricts:
 - a) Decide HU eligibility (EL/NE).
 - b) Using random number table (new) and numbering all EL HUs from 1 to “n” sample and select three EL HUs from each subdistrict. If only three EL HUs elect all three. Sample a reserve EL HU from remaining EL HUs in the two subdistricts.
 - c) IF the district also has information about all HUs reported DTP3<1 for the audit year:
 - d) enter strata, HU name , DTP3<1 and audit date for selected HUs (six plus reserve) in Dist-HU-Samp cells D37 – G42. If the information is not available, the information will be collected at the 2 subdistricts.
 - e) visit the two selected subdistricts and for the selected 3+3+1 HUs enter monthly/quarterly figures in Dist-HU-Rep.
 - f) It may be useful to record in the logbook the subdistrict’s annual tabulated DTP3<1 for the audit year and monthly/quarterly figures for comparison later on (data consistency).
 - g) Continue the audit (quality questions etc). The Dist-Anal “Report Availability” figures for the number of HUs reporting in audit year and “%HU reports found at district” are incorrect, because we do not have figures for this as the calculations are based on subdistrict data in various worksheets. Make a note in the logbook and report.
 9. If district does not have a list/table/chart/file with all HUs which reported immunization at least once in the audit year, the auditors must select HUs from each of the two selected subdistricts. Visit the two selected subdistricts.
 - a) Decide HU eligibility (EL/NE).
 - b) Using random number table (new) and numbering all EL HUs from 1 to “n”, sample and select three EL HUs from each subdistrict. If only three EL HUs, select all three. Sample a reserve EL HU from remaining EL HUs in the two subdistricts, which will be done at the second subdistrict.

If less than three HUs in the subdistrict (with which information the district could not provide the auditors) select the HUs, which reported immunizations in the audit year and make a note in the logbook and final report (as this has some consequence for the VF/CI).

- c) Enter strata, HU name, DTP3<1 and audit date for selected HUs (six plus reserve) in Dist-HU-Samp cells D37–G42.
- d) For the selected 3+3+1 HU enter monthly/quarterly figures in Dist-HU-Rep.
- e) It may be useful to record in the logbook the subdistrict’s annual tabulated DTP3<1 for the audit year and monthly/quarterly figures for comparison later on (data consistency).
- f) Continue the audit (quality questions etc). The Dist-Anal “Report Availability” figures for the number of HUs reporting in audit year and “%HU reports found at district” are incorrect, because we do not have figures for this as the calculations are based on subdistrict data in various worksheets. Make a note in the logbook and report.

When finalizing the audit and the final worksheet verification factor, the auditors must be careful only to enter data for strata 1 and 2 for districts with subdistricts.

The auditors must be prepared to adapt the workbook, logbook and audit to a situation with a mixture of the reporting systems mentioned so far. For example, a country may have both a regional/provincial level and subdistricts or subdistricts reporting directly to a province without copy to the district.

Example of using the Random Number Table for selection of districts

Sampling interval = cum DTP3/4 = 584 524 / 4 = 146 131 (six digits). The spot selected fell on the six digit grouping 966575 (see Figure E.1). Note that the actual 5 digit grouping is extended on the right to get a sixth digit. The vertical and horizontal lines were therefore drawn to the left and top of this row.

Figure E.1: Random number table example

20	57430	82270	10421	00540	43648	75888	66049	21511	47676	33444
21	73528	39559	34434	88596	54086	71693	43132	14414	79979	85193
22	25991	65959	70769	64721	86413	33475	42740	06175	82758	66248
23	78388	16638	09134	59980	63806	48472	39318	35434	24057	74739
24	12477	09965	96657	57994	59439	76330	24596	77515	09577	91871
25	83266	32883	42451	15579	38155	29793	40914	65990	16255	17777
26	76970	80876	10237	39515	79152	74798	39357	09054	73579	92359
27	37074	65198	44785	68624	98336	84481	97610	78735	46703	98265
28	83712	06514	30101	78295	54656	85417	43189	60048	72781	72606
29	20287	56862	69727	94443	64936	08366	27227	05158	50326	59566
30	74261	32592	86538	27041	65172	85532	07571	80609	39285	65340

The four numbers to be used for selection of four districts are **102 373**; **248 504** (=102 373 + 146 131); **394 635** (=102 373 + (2 x 146 131)) and **540 766** (=102 373 + (3 x 146 131)). The districts selected are those that have these numbers within their cumulative counts for DTP3<1, in this example, Dundee, Nyeri, Rossem and Waverly (see Table E.1). A district can be selected more than once.

Table E.1: District's cumulative counts for DTP3<1

District name	DTP3	Cum DTP3
Bennet	85 245	85 245
Dundee	45 124	130 369
Jamestown	36 875	167 244
Nyeri	96 185	263 429
Pokot	76 359	339 788
Rossem	77 125	416 913
Travert	22 654	439 567
Unison	57 692	497 259
Waverly	87 265	584 524
Country Total	584 524	

Annex F:

Information for the sample of child health cards

- Note 1: DTP may still be abbreviated as DPT – use abbreviation in use in the country
- Note 2: In addition to recording the vaccinations given to the following children, the health worker should indicate the date that the child should return for the next vaccination. The date depends upon the Health Unit’s timetable of scheduled vaccination sessions. Therefore the health worker should have at hand the Health Unit’s timetable for the next six months.
- Note 3: It is likely that some/many health workers/vaccinators will include “OPV0” -discuss this with the national auditors and fill in the Child Health Cards accordingly.
- Note 4: Many health workers/vaccinators will regard this exercise as a “test” and therefore be a little stressful and nervous. The exercise can be made free and easy by friendly and encouraging discussions/dialogue and by asking the national auditor to conduct the exercise.

Example Child A – due for DTP2, OPV2

BCG, DTP1, OPV1 given,
Child old enough for OPV2/DTP2 vaccination

Example Child B – not due for any vaccination

BCG, DTP1, OPV1, DTP2, OPV2, DTP3, OPV3 given,
Child too young for receiving measles vaccination yet

Child 1 – due for DTP3, OPV3

BCG, DTP1, OPV1, DTP2, OPV2 given,
Child old enough for OPV3/DTP3 vaccination

Child 2 – due for BCG

Child born two days ago

Child 3 – due for DTP2, OPV2

BCG, DTP1, OPV1 given,
Child old enough for OPV2/DTP2 vaccination

-
- Child 4 – not due for any vaccination
BCG, DTP1, OPV1 given on schedule, OPV2/DTP2 given only two weeks ago
Child old enough for OPV3/DTP3
- Child 5 – due for BCG, DTP1, OPV1
No vaccinations given,
Child old enough for OPV1/DTP1 vaccination
- Child 6 – due for Measles
BCG, DTP1, OPV1, DTP2, OPV2, DTP3, OPV3 given
Child old enough for Measles vaccination
- Child 7 – due for BCG, DTP1, OPV1
No vaccinations given,
Child old enough for OPV1/DTP1 vaccination
- Child 8 – due for DTP1, OPV1
BCG given at birth,
Child old enough for OPV1/DTP1 vaccination
- Child 9 – due for measles
BCG, DTP1, OPV1 given on schedule, DTP2/OPV2 given just two weeks ago
Child old enough for measles vaccination
- Child 10 – due for DTP3, OPV3
BCG, DTP1, OPV1, DTP2, OPV2
Child old enough for OPV3/DTP3 vaccination
- Child 11 – due for BCG
No vaccinations
Child born 2 weeks ago
- Child 12 – due for BCG, DTP1, OPV1
No vaccinations,
Child old enough for OPV2/DTP2 vaccination
- Child 13 – due for DTP1, OPV1
BCG at birth,
Child old enough for OPV1/DTP1 vaccination
- Child 14 – due for DTP3, OPV3
BCG, DTP1, OPV1, DTP2, OPV2 given
Child old enough for OPV3/DTP3 vaccination
- Child 15 – due for DTP1, OPV1
BCG given late
Child old enough for OPV1/DTP1 vaccination

Child 16 – due for DTP3, OPV3, measles
BCG late, DTP1, OPV1 late, DTP2, OPV2 late
Child old enough for measles vaccination

Child 17 – due for Measles
BCG, DTP1, OPV1, DTP2, OPV2, DTP3, OPV3 given
Child old enough for measles vaccination

Child 18 – due for DTP3, OPV3, measles
BCG, DTP1, OPV1, DTP2, OPV2 given
Child old enough for measles vaccination

Child 19 – due for DTP2, OPV2
BCG, DTP1, OPV1 given late
Child old enough for OPV3/DTP3 vaccination

Child 20 – due for DTP2, OPV2
BCG, DTP1, OPV1 given
Child old enough for OPV2/DTP2 vaccination

Relevant totals (for Child 1-20) are: BCG 5 - DTP1 – 6; DTP2 –4; DTP3 – 5,
Measles -5

Figure F.1: Two-year calendar

January							April							July							October						
1	2	3	4	5	6		1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	
7	8	9	10	11	12	13	8	9	10	11	12	13	14	8	9	10	11	12	13	14	7	8	9	10	11	12	13
14	15	16	17	18	19	20	15	16	17	18	19	20	21	15	16	17	18	19	20	21	14	15	16	17	18	19	20
21	22	23	24	25	26	27	22	23	24	25	26	27	28	22	23	24	25	26	27	28	21	22	23	24	25	26	27
28	29	30	31				29	30						29	30	31					28	29	30	31			
February							May						August						November								
				1	2	3			1	2	3	4	5				1	2	3	4					1	2	3
4	5	6	7	8	9	10	6	7	8	9	10	11	12	5	6	7	8	9	10	11	4	5	6	7	8	9	10
11	12	13	14	15	16	17	13	14	15	16	17	18	19	12	13	14	15	16	17	18	11	12	13	14	15	16	17
18	19	20	21	22	23	24	20	21	22	23	24	25	26	19	20	21	22	23	24	25	18	19	20	21	22	23	24
25	26	27	28				27	28	29	30	31			26	27	28	29	30	31	25	26	27	28	29	30		
March							June						September						December								
				1	2	3					1	2							1							1	
4	5	6	7	8	9	10	3	4	5	6	7	8	9	2	3	4	5	6	7	8	2	3	4	5	6	7	8
11	12	13	14	15	16	17	10	11	12	13	14	15	16	9	10	11	12	13	14	15	9	10	11	12	13	14	15
18	19	20	21	22	23	24	17	18	19	20	21	22	23	16	17	18	19	20	21	22	16	17	18	19	20	21	22
25	26	27	28	29	30	31	24	25	26	27	28	29	30	23	24	25	26	27	28	29	23	24	25	26	27	28	29
														30							30	31					

January

		1	2	3	4	5			
6	7	8	9	10	11	12			
13	14	15	16	17	18	19			
20	21	22	23	24	25	26			
27	28	29	30	31					

April

		1	2	3	4	5	6		
7	8	9	10	11	12	13			
14	15	16	17	18	19	20			
21	22	23	24	25	26	27			
28	29	30							

July

		1	2	3	4	5	6		
7	8	9	10	11	12	13			
14	15	16	17	18	19	20			
21	22	23	24	25	26	27			
28	29	30	31						

October

			1	2	3	4	5		
6	7	8	9	10	11	12			
13	14	15	16	17	18	19			
20	21	22	23	24	25	26			
27	28	29	30	31					

February

						1	2		
3	4	5	6	7	8	9			
10	11	12	13	14	15	16			
17	18	19	20	21	22	23			
24	25	26	27	28					

May

			1	2	3	4			
5	6	7	8	9	10	11			
12	13	14	15	16	17	18			
19	20	21	22	23	24	25			
26	27	28	29	30	31				

August

					1	2	3		
4	5	6	7	8	9	10			
11	12	13	14	15	16	17			
18	19	20	21	22	23	24			
25	26	27	28	29	30	31			

November

							1	2	
3	4	5	6	7	8	9			
10	11	12	13	14	15	16			
17	18	19	20	21	22	23			
24	25	26	27	28	29	30			

March

						1	2		
3	4	5	6	7	8	9			
10	11	12	13	14	15	16			
17	18	19	20	21	22	23			
24	25	26	27	28	29	30			
31									

June

							1		
2	3	4	5	6	7	8			
9	10	11	12	13	14	15			
16	17	18	19	20	21	22			
23	24	25	26	27	28	29			
30									

September

1	2	3	4	5	6	7			
8	9	10	11	12	13	14			
15	16	17	18	19	20	21			
22	23	24	25	26	27	28			
29	30								

December

1	2	3	4	5	6	7			
8	9	10	11	12	13	14			
15	16	17	18	19	20	21			
22	23	24	25	26	27	28			
29	30	31							

Annex G:

Vaccine wastage

Definitions

At levels above the delivery level (district/provincial/national stores), at one point of time, doses that have been issued (distributed) during a period may be:

- doses used for immunization
- doses still in stock at levels below
- doses wasted.

Therefore, the number of doses issued may not be representative of the number of doses spent (used for immunization and wasted), because the level of stock at the various levels below may vary widely (according to coverage, local policies, local strategies, new vaccine introduction, etc.). At delivery level, all issued doses correspond to doses spent (used for immunization or wasted).

Therefore, the DQA distinguishes between the wastage calculation at delivery level and at above levels (levels that distribute).

- *At national and district level, the wastage of unopened vials (system wastage) will be calculated for the storage facilities. This falls mainly into six categories:*
 - vaccines discarded due to heat exposure
 - vaccines discarded due to VVM indication
 - vaccines frozen
 - breakage
 - vaccines discarded due to expiry dates
 - missing inventory.

The latter corresponds to “unexplained number of doses not matching an inventory count” when one is conducted.

The following might be noted, for example: On 1 August, according to the ledger stock book, the DTP balance is 3000 doses but the fridge physical inventory of that day retrieves 2940 doses, then the balance should be adjusted to 2940 in the book, “missing” 60 doses. The DQA will include 60 doses in the wasted category (“damaged” in the worksheet).

The *system wastage* will be calculated as the proportion of (unopened) doses wasted out of the number of doses handled by the store.

$$\text{Number of doses handled} = \text{Number of doses in stock at the beginning of the period} + \text{Number of doses received during the period}$$

At *health unit level*, the *global wastage* will be calculated, corresponding to the wastage of *opened (administered wastage)* and *unopened vials*.

The global vaccine wastage rate (%) = 100 - vaccine usage rate

where:

$$\text{the vaccine usage rate (\%)} = \frac{\text{number of doses administered}}{\text{number of doses issued}}$$

number of doses administered = number of doses used for immunization (“injected”)⁴

and:

$$\text{Number of doses issued} = \text{Number of doses in stock at the beginning of the period} + \text{Number of doses received during the period} - \text{Number of doses in stock at the end of the period}$$

Interpretation

Whatever the figure found at any level, it is crucial to try to identify and discuss the main causes of wastage. The importance of monitoring wastage should always be stressed. The level of immunization coverage should also be taken into account in the interpretation: classically at higher coverage levels necessitating more difficult to reach children (e.g. outreach sessions), the wastage rate is likely to increase, and a higher wastage figure may be more acceptable.

⁴ In the DQA, the number of doses used for immunization includes doses given for children over one year, although those doses may be considered as wasted doses, or doses given outside the target group.

Causes of wastage

The factors that contribute to vaccine wastage can be categorized as follows:

- Vaccine and syringe related factors
 - more wastage is reported with bigger size vial
 - dead space in syringes
- National policy related factors
 - Poor procurement practices
 - Vaccine Vial Monitor (VVM) policy adoption
 - Policies to avoid missed opportunities
- Logistics related factor
 - Poor stock control (expiry dates...)
 - Poor quality/management of cold chain
 - Poor distribution/transport practices
- Immunization practice related factors
 - Vaccines thrown away at the end of the session
 - Poor reconstitution practices
 - Small session size
 - Wrong target groups
 - Contamination

Annex H:

Core indicators

1. Immunization core indicators audited at national level (refers to the year 2002)

All indicators should be in the WHO / UNICEF Joint Reporting Form. If not completed put “na”. The auditor should ask what is the value at the time of the visit and check it against last tabulations/reports available. Some rows (marked *) just aim to document the country situation for a better interpretation. They are not supposed to be checked. The table below should be put as an annex to the report.

Table H.1: Immunization core indicators audited at national level

Core indicator	JRF	Reported at the time of the audit	Comments
Districts with DTP3 coverage $\geq 80\%$ N (admin, DTP3<1) %			
Districts with measles coverage $\geq 90\%$ N (admin measles<1) %			
Districts with DOR $< 10\%$ N (admin, DOR DPT1 DPT3) % Comments			
Type of syringes used in the country*			

Core indicator	JRF	Reported at the time of the audit	Comments
% of districts that have been supplied with adequate (equal or more) number of AD syringes for all routine immunizations (less OPV) during the year			
Comments			
Core indicator	JRF	Reported at the time of the audit	Comments
Introduction of hepatitis B (Hep B) (yes /no when/ partially/ specify presentation)*			
Introduction of <i>Haemophilus influenzae</i> type b (Hib) (yes /no when/ partially/specify presentation)*			
Country wastage rate of DTP			
Country Wastage rate of Hep B vaccine			
Country Wastage rate of Hib vaccine			
Comments			
Interruption in vaccine supply (any vaccine) during the audit year at national stock			

Core indicator	JRF	Reported at the time of the audit	Comments
How many districts had an interruption in vaccine supply (any vaccine) during the audit year?			
Comments			
% district disease surveillance reports received at national level compared to number of reports expected (routine reporting of VPD)			
% of district coverage reports received at national level compared to number of reports expected			This is not availability
% of district coverage reports received on time at national level compared to number of reports expected			
Comments			
Number of districts which have been supervised at least once by higher level during the audit year			
Number of districts which have supervised all HUs during the audit year			
Comments			

Core indicator	JRF	Reported at the time of the audit	Comments
Number of districts with microplans Including routine immunization			
Comments			
Additional information: Number of districts reported in the country:			

2. Immunization core indicators audited for the district level (refers to the year 2002)
(1 table per district – should be as an annex to the report)

Table H.2: Immunization core indicators audited for the district level

Indicator		Information at the national level	Information at the district level
District DTP3 coverage (last tabulation available)	N %		
District measles coverage (last tabulation available)	N %		
District drop-out (DTP1–3)			
No syringes supplied in 2002 to the district			
Total immunization given in 2002 (less OPV)			
No district coverage reports received / sent		/12	/12
No district coverage reports received on time / sent on time		/12	/12
No district disease reports sent (regular VPD reporting)		/12	/12
No HU coverage reports received/sent			/12
No HU coverage reports received/sent on time			/12
Any district vaccine stock-out in 2002?			
If yes specify which vaccine and duration			
Has the district been supervised by higher level in 2002?			
Has the district been able to supervise all HUs in 2002?			
Did the district have a microplan for 2002?			

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic

diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

Department of Vaccines and Biologicals

Health Technology and Pharmaceuticals

World Health Organization

CH-1211 Geneva 27

Switzerland

Fax: +41 22 791 4227

Email: vaccines@who.int

or visit our web site at: <http://www.who.int/vaccines-documents>

