World Health Organization

HIV STRATEGIC INFORMATION FOR IMPACT

IMPLEMENTATION TOOL

DATA QUALITY ASSESSMENT OF NATIONAL AND PARTNER HIV TREATMENT AND PATIENT MONITORING SYSTEMS

AUGUST 2018

World Health Organization

HIV STRATEGIC INFORMATION FOR IMPACT

DATA QUALITY ASSESSMENT OF NATIONAL AND PARTNER HIV TREATMENT AND PATIENT MONITORING SYSTEMS

IMPLEMENTATION TOOL

AUGUST 2018

WHO/CDS/HIV/18.43

Suggested citation. Data quality assessment of national and partner HIV treatment and patient monitoring data and systems implementation tool. Geneva: World Health Organization; 2018. (WHO/CDS/HIV/18.43). Licence: CC BYNC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Layout by 400.co.uk

Printed in Switzerland

CONTENTS

ABBREVIATIONS AND ACRONYMS

ART	Antiretroviral therapy
ARV	Antiretroviral
DATIM	Data for Accountability, Transparency and Impact Monitoring
DHIS2	District Health Information Software
DQA	Data quality assessment
EMR	Electronic Medical Record
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
PEPFAR	United States President's Emergency Plan for AIDS Relief
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
US-CDC	United States Centre for Disease Control and Prevention
WHO	World Health Organization

KEY DEFINITIONS

Key operational definitions used in this tool are presented below.

- **Correction factor:** factor used to correct the national antiretroviral therapy (ART) data to adjust for errors from over- or underreporting of the number of people receiving ART. The correction factor is applied as a key objective of this data quality assessment to correct the nationally reported number receiving ART to improve planning based on the results.
- **Data quality assessment:** standardized review of data quality, including verifying and recounting reported data, assessing the system generating the data and using a standardized approach for addressing the data quality issues identified, including adjusting national data on HIV treatment.
- **Lost to follow-up:** people who have not been seen at the health facility for at least 90 days (three months) after the last missed appointment. The 90-day period also applies in contexts with differentiated care service delivery models.
- **Patient monitoring:** also called patient tracking: the routine collection, compilation and analysis of data on patients over time and across service delivery points, using information taken from patient records and registers: either paper-based or entered directly into a computer. The primary purpose of patient monitoring is to enable clinical personnel to record and use individual patient data to guide the clinical management of patients over time and ensure the continuity of care between health facilities.
- **Recreating indicators:** the process undertaken as part of the data quality assessment at the health facility level in which the assessment team calculates and recreates the reported numbers for HIV treatment using standard indicator definitions and using the same data source as health facilities.

ACKNOWLEDGEMENTS

This data quality assessment implementation tool is the result of a collaborative effort between the World Health Organization, The Joint United Nations Programme on HIV/AIDS (UNAIDS), the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund).

We would like to thank the individuals who contributed to this document and provided key inputs into the concepts and materials presented including Irum Zaidi (PEPFAR), John Aberle-Grasse (Unite States Centre for Disease Control and Prevention, CDC), Sadhna Patel (CDC), Ray Shiraishi (CDC), Lindsay Templin (CDC), Peter Ghys (UNAIDS), Mary Mahy (UNAIDS), Kim Marsh (UNAIDS), Kristine Clark (PEPFAR), Ebonnie Weathers (PEPFAR), Jinkou Zhao (Global Fund), Annette Reinisch (Global Fund), Dalila Zachary (Global Fund), Jesus M Garcia-Calleja (WHO), Karin Gichuhi (US Agency for International Development, USAID) and Ana Djapovic Scholl (USAID).

Daniel Low Beer, Françoise Renaud and Hiwot Haile-Selassie (WHO) coordinated the overall process of the development of this tool.

We thank David Breuer for technical editing and 400 Communications for layout and design.

Financial acknowledgment

Funding to support this work came from the United States President's Emergency Plan for AIDS Relief (PEPFAR).

In addition, WHO is thankful to the institutions that contributed staff time and other contributions to the guidance development process.

1. INTRODUCTION

In the past decade, national programmes and donor-funded projects have made great progress in reaching people living with HIV with life-saving treatment in countries across the globe. Measuring success of these initiatives requires strong monitoring and evaluation systems that produce high-quality data. Efforts to ensure data quality, therefore, are not singular events occurring randomly. Rather, these processes need to become institutionalized as part of all routine data management processes. Once achieved, data quality helps to ensure that limited resources are used effectively, progress toward established targets is accurately monitored, measured and reported and decisions are based on strong evidence.

As many countries are quickly approaching the UNAIDS 90–90–90 targets, it is more important than ever to understand exactly how many people living with HIV are receiving treatment. Further, it is imperative that countries understand the treatment gaps remaining by location and population to ensure that all people living with HIV have equitable access to treatment and have suppressed viral loads and that limited resources are allocated appropriately to the areas with the greatest unmet need. As such, the HIV response is at a very important moment in which the accuracy of the data is essential in ensuring that programmatic decisions are made effectively.

The aim of this tool is to help countries that are planning to undertake rapid and robust data quality assessment (DQA) of national and partner data quality with a particular emphasis on HIV treatment while improving and supporting patient monitoring systems to improve data quality and use. However, the intent is not that countries simply perform an assessment but also correct HIV treatment numbers and strengthen the HIV patient monitoring system based on the findings. A key objective of the assessment should be to calculate a nationally representative correction factor to correct the nationally reported number of people receiving antiretroviral therapy (ART). Corrected numbers should be submitted through the Global AIDS Monitoring tool, and the national HIV epidemiological estimates should be updated to reflect the corrected ART numbers to improve planning based on the results.

These DQAs should be implemented in the context of health wide DQAs including health facility audits *(1)* and should be undertaken on an annual or periodic basis *(2)*.

This DQA guidance builds on previous work by specific partners:

- the United States Centers for Disease Control and Prevention on validating indicators;
- the WHO Department of HIV on assessing HIV patient monitoring reporting systems *(3)*; and
- WHO, GAVI, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States Agency for International Development/MEASURE Evaluation data quality review toolkit *(4)*.

This tool aims to harmonize the approaches taken to review, assess and validate treatment data as well as the system generating the data so the results can be used nationally and for specific partners. Data quality has been a focus of global HIV monitoring and reporting efforts. Specifically, all countries supported by the United States President's Emergency Plan for AIDS Relief (PEPFAR) or the Global Fund are expected to have a data quality strategy in place. This document addresses these requirements, providing guidance to be adapted by countries to conduct DQA in a two-stage phased approach (see Section 3 on implementation for further details) and data validation activities at the site level.

The DQA includes three key components:

1. **Rapidly assessing the HIV patient monitoring system.** The first step involves rapidly assessing the patient monitoring system to identify gaps and areas for improvement to strengthen data quality and use. A structured checklist (see Annex A) has been developed to assess whether the patient monitoring system is functional, to determine the quality and completeness of information generated by the system, to assess the capacity and training needs at the facility level and to inform the formulation of an action plan to address the identified gaps.

2. **Recreating select indicators and validating reports.** The second step involves verifying and recreating key indicators (this should include the number of people currently receiving and newly initiating ART) designated by the Ministry of Health (by comparing reported and recreated indicators) and validating the data quality of the HIV patient monitoring tools, comparing site source documents (such as HIV patient cards) with other reporting tools (ART registers, pharmacy records or electronic medical record (EMR) systems).

3. **Assessing the quality and completeness of reports.** This activity will compare monthly reports of numbers on treatment reported by facilities to the aggregate numbers of people receiving treatment at the national level. This desk review can also examine all facilities to quantify the level of missing or delayed reports.

In addition, where feasible a comparison of EMRs to detect duplicates across facilities can be carried out. In countries with high rates of loss to follow-up, this step will use electronic records from facilities to identify potential duplicates indicating silent transfers (as opposed to deaths).

Ministries of Health should implement this DQA in collaboration with partners, including UNAIDS, PEPFAR, the Global Fund and WHO. Each of these stakeholders will play a key role in the roll-out, implementation and follow-up action required to make the DQA and subsequent potential adjustment of data successful. The results will be shared among all stakeholders. Section 3 provides more information on the specific roles and responsibilities of each group.

2. GOALS AND OBJECTIVES

2.1. Goals

The overarching goal is to increase the impact of national HIV treatment programmes by assuring the quality of the reported data and patient monitoring systems through standardized annual monitoring of data quality at sites that deliver HIV services. Improved data will allow programme managers to more accurately pinpoint where additional resources are needed to improve ART provision and clinical health outcomes.

Emphasis is placed on ensuring the quality of data reporting for the indicators below, but countries may choose to assess the data quality of other priority indicators in accordance with the country needs and context:

- people living with HIV currently receiving HIV treatment (by age and sex); and
- people living with HIV newly initiating HIV treatment (by age and sex)

2.2. Objectives

The objectives of DQA are:

(1) to assess the quality of reported data by using standard indicator definitions to recreate the reported numbers for selected indicators and compare with the numbers reported by the national data collection system, such as DHIS2 (District Health Information Software), and by partners;

(2) to verify the quality of and to improve the reported HIV patient monitoring data and systems at the facility level;

(3) to cross-validate a sample of patient records and manually count patient records and describe any systematic data quality challenges with applied indicator definitions and data recording and to recommend actions to improve data quality;

(4) to determine the percentage of people receiving ART nationally over- or undercounted (and subnationally when feasible or the country needs this) and use this to reset the numbers at both the site level and within the national data collection system in addition to ensuring accurate reporting in any reporting systems moving forward; and

(5) to update national reporting data and national epidemiological estimates for improved planning.

3. IMPLEMENTATION

The DQA requires six steps:

1. Setting up a country-based implementation team of stakeholders to agree on the scope and methods and to support the implementation and dissemination of the results of the DQA;
2. To agree on the sampling required and the indicators to include in the assessment and to finalize the site-level instruments;
3. Assessing at the site level to collect data, including assessing the HIV patient monitoring system and recreating the numbers of people receiving and initiating ART;
4. Conducting a desk review to identify challenges in national reporting (can take place simultaneously with step 3);
5. Analysing the results and resetting the site-level and national numbers of people receiving and initiating ART; and
6. Developing a communication strategy and disseminating the updated values.

A two-stage phased approach for implementing a DQA is recommended to assist countries in giving priority to scaling up DQA activities over time and to prepare countries to implement larger-scale DQA when significant data quality issues are identified or when the country needs or wants to review and adjust treatment data at the subnational level. The scope of the two phases is as follows.

Phase 1: in the initial phase, the DQA will be implemented within a nationally representative number of ART sites in which the six steps indicated above will be implemented with a view to validate the number of people on ART and if necessary reset the national ART number as needed, as well as strengthen the overall HIV patient monitoring system.

Phase 2: implementation of the second phase DQA is in response to identified DQA challenges in the phase 1 DQA which warrant further investigation and review of HIV treatment data in a larger number of ART sites or within the context of implementing a DQA strategy in which DQA activities are scaled up over time. Countries completing the first phase of DQA and finding a verification factor (recreated/reported times 100) of less than 90% or greater than 110% within the sample should transition to the second phase in which the exercise is expanded to additional ART sites for an overall representation of 80% of the people currently receiving ART for the reporting period being reviewed. This should be done for a more in-depth review of data quality and to reset ART numbers at these sites and the site-level systems as needed following the same steps identified above. This second phase can be conducted by the Ministry of Health and implementing partners with site staff.

In addition, with larger site sample sizes, countries can also consider analysing and adjusting subnational ART data based on country need and interest in this phase.

3.1. Step 1: Set up a multistakeholder implementation team

Institutionalizing routine assessment and monitoring of the quality of reported data is an integral part of an effective HIV programme. Data quality is especially important given the use of this data to plan for program implementation, the use of global resources and to affirm progress towards epidemic control. As such it is critical there is full ownership and support for DQA from Ministries of Health and partners. Within this context, the specific roles and responsibilities of country stakeholders are detailed below.

Before starting any data collection or review processes, the Ministry of Health and the country team will inform other national and local authorities, such as the district health office, of this assessment and engage them, seeking their involvement in the data validation activities and other subsequent activities to improve data quality.

Roles and responsibilities

3.1.1. Ministries of Health

Ministries of Health are responsible for leading the implementation and overall coordination of the DQA in collaboration with partners, including PEPFAR, the Global Fund, WHO and UNAIDS.

3.1.2. WHO

WHO will coordinate changes to the guidance on DQA to ensure consistency in implementation across all partners. In addition, WHO will provide technical support to Ministries of Health for implementation and convene stakeholders to support the Ministry of Health on using the results and data and improving the system as necessary.

3.1.3. PEPFAR

PEPFAR headquarters staff will provide technical assistance to interagency country teams for the development of their specific DQA protocols. In addition, some in-person technical support will be provided from PEPFAR headquarters staff.

PEPFAR field staff from each of the PEPFAR-supported agencies (such as the United States Centers for Disease Control and Prevention, United States Agency for International Development and Department of Defense) are required to participate in planning and implementation of the DQA. PEPFAR field teams should work within the interagency country team to select sites from all ART sites in the county and draft the DQA schedule, draft notification letters to relevant stakeholders and notify implementing

partners and site staff before DQA visits. PEPFAR field staff should also participate in developing the final DQA report and remediation plan and should ensure that implementing partners and sites receive additional technical assistance and remediation, as necessary. Lastly, PEPFAR field staff should coordinate with Ministries of Health to ensure that divergent numbers identified in PEPFAR-supported sites are corrected in the health ministry reporting system and are reported correctly at the next PEPFAR quarterly reporting cycle.

3.1.4. Global Fund

The Technical Advice and Partnerships Department of the Global Fund Secretariat will work closely with the country teams for respective countries to support the implementation of DQA and the use of the findings for programmes.

The Global Fund will also provide funding and technical assistance for implementing DQA by mobilizing technical resources in the monitoring and evaluation technical assistance pool, local Global Fund agents and quality assurance providers for health facility assessments and data quality reviews.

The Global Fund country teams will coordinate with national AIDS programmes and in-country partners to ensure that the correct national numbers are used for quantifying ARV drugs, laboratory reagents and key performance indicators.

3.1.5. UNAIDS

UNAIDS will support its national counterparts responsible for ART reporting to ensure partner buy-in and alignment with the adjustments. In addition, UNAIDS will support country estimates teams to adjust their current and historical numbers of people receiving ART used in their Spectrum models to reflect the DQA results and produce accurate epidemiological estimates.

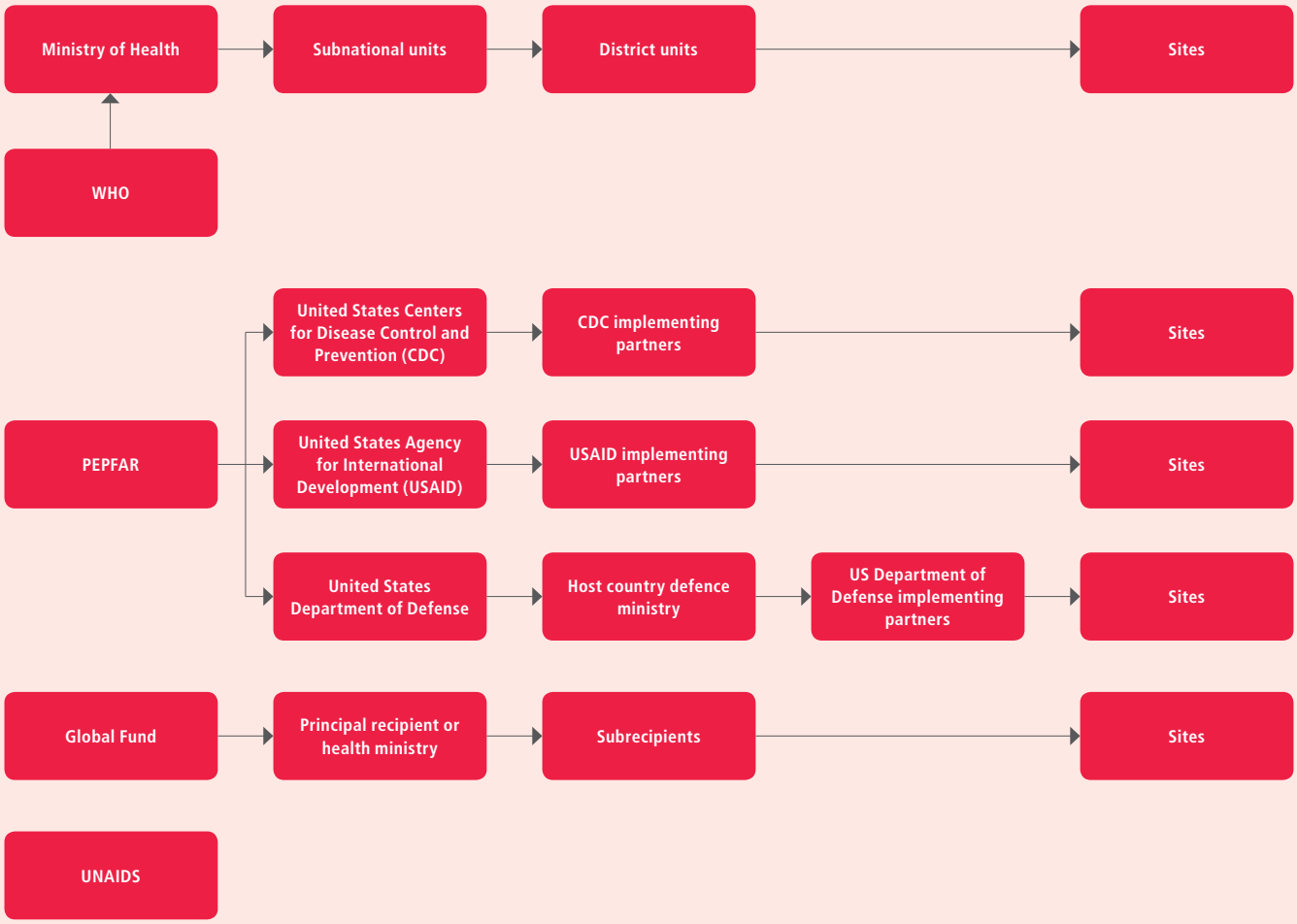
3.1.6. Interorganizational country team

The interagency country team includes the Ministry of Health, UNAIDS, WHO, PEPFAR, the Global Fund and other representatives or stakeholders based in the country that will work collaboratively to carry out the DQA. Within this group, one or more individuals should be chosen as the team leads to oversee the assessment teams and take a leadership role in the site selection, assessment and remediation.

3.1.7. Providers of ART (referred to as implementing partners by the United States Government)

Implementing partners will work alongside the country team to support implementation of the DQA at sites they are supporting, including facilitating communication regarding the assessment and DQA activities at the site level (Fig. 1).

FIG. 1. STAKEHOLDERS INVOLVED IN DQA AT THE GLOBAL AND COUNTRY LEVELS



3.2. Step 2: Decide on the sampling frame and indicators and finalize the instruments

A key aim is to implement a sampling frame that is practical and implements objectives 1 and 2 and provides results for objectives 4 and 5 of DQA (see subsection 2.2), to provide coordinated national and partner-specific assessment.

The primary sampling framework will therefore implement initial stratification by three domains:

- National representation: to validate and correct as required the national numbers of people receiving and initiating ART
- PEPFAR-supported sites: to validate PEPFAR-supported sites, including specific implementers as required; and
- Potentially Global Fund–supported districts if relevant: to assess districts supported by the Global Fund (if these are not distinct, the national strata can be used).

Within these domains, and given the needs of the government and the availability of funds and timing, additional strata can be sampled if required, including:

- By facility type or facilities with paper versus electronic patient monitoring records;
- Of particular programmatic importance: for example, two or three districts might be oversampled to meet the particular needs of a partner or meets the concerns of the Ministry of Health; and
- To measure the reporting adjustments at the subnational level (recommended for the second phase of DQA).

This should be balanced against the sample size implications of increasing the number of strata. In implementing the sampling approach, the following steps are followed.

1. **Create a sampling frame:** a list of all ART sites nationally. In the second phase of DQA, countries may consider disaggregating this list by subnational unit (such as region or district). The sample frame should include the following information:

   a. Site name and location, such as province, district, etc.;

   b. The number of people currently receiving ART in the past calendar year – to validate the primary indicator of currently receiving ART;

   c. The number of new ART initiators in the most recent reporting time frame (such as quarter or year) – to validate the indicator of new ART initiators;

   d. Domains (such as PEPFAR support, Global Fund support, etc.); and

   e. Any additional strata of interest (such as facility type, paper versus electronic, etc.).

2. Decide on the number of ART sites to be sampled nationally and by strata in phase 1. This is a country decision usually based on the objectives of the DQA, feasibility, cost and whether the objective is to develop a correction factor, achieving an acceptable relative margin of error at the national and subnational levels and within specific strata of interest. The interorganizational country team should determine the appropriate sample size based on country priorities for the specific objectives of the DQA and precision of the desired estimates, available resources, feasibility and time considerations. Countries may assess data quality in a limited sample of sites to obtain understanding of data quality issues to determine whether a correction factor is needed or sites with 80% of the people receiving ART should have their numbers of people receiving ART reset. However, a relative margin of error of 10% for a 90% confidence interval is recommended as a minimum level of acceptable precision for the national correction factor for the number of people receiving ART (see subsection 3.8).

TABLE 1. EXAMPLE OF THE STRUCTURE OF THE ART SITE LIST FOR DQA

Site selected?	Province	District	Site name	PEPFAR site	Site implementing partner	Currently receiving treatment (31 March 2018)	Newly initiating treatment (1 Jan–31 Mar 2018)
	Province North	District Alpha	Site 1	Yes	Partner Heart	1093	16
	Province North	District Alpha	Site 2	Yes	Partner Heart	100	8

The following example describes what is recommended for a nationally representative sample to obtain a national correction factor. Table 2 provides examples of sample-size requirements for a ratio of 0.8 for the number of verified people receiving treatment to the number of people facilities reported to be receiving treatment. The examples of numbers of facilities and average numbers of people receiving treatment correspond to the ranges of values observed from existing PEPFAR records. For example, a large country with 1200 facilities, an average of 1000 people receiving ART per facility and a variance component (see Annex B for details on how this is calculated) of 500 000 would require a sample size of 180 facilities to achieve a 10% relative margin of error for a 90% confidence interval. For a small country or stratum with 25 facilities, an average of 1000 people receiving ART per facility and a variance component of 500 000, a sample size of 22 facilities would be required to achieve a 10% relative margin of error for a 90% confidence interval. The sample sizes provided in Table 2 are for perspective only. Sample sizes should be estimated based on country data using the Excel sample-size estimation tool provided in Annex C.

Annex B provides details of the sample-size requirements. Estimating the sample size requires specifying the hypothesized ratio, the total number of health facilities, the average numbers of people receiving ART across all health facilities and a variance component, which is typically large (400 000–1 000 000). The health facility counts and the average numbers of people receiving ART should be obtained from existing records. The variance component and hypothesized ratio can be calculated, as described in Annex B, if an adequate number (>30) of verified facility counts of the number of people receiving ART exist. Otherwise, a variance component value of at least 500 000 and ratio of 0.80 should be assumed.

TABLE 2. EXAMPLES OF SAMPLE-SIZE REQUIREMENTS TO ESTIMATE A RATIO OF 0.80 WITH THE DESIRED RELATIVE MARGIN OF ERROR IN 90% AND 95% CONFIDENCE INTERVAL (CI)

				Sample size	
Number of facilities	Average number of people receiving treatment	Variance component	Desired relative margin of error	90% CI	95% CI
25	300	500 000	10%	25	25
25	300	500 000	15%	24	25
25	300	500 000	20%	24	24
25	300	500 000	30%	23	23
25	300	1 000 000	10%	25	25
25	300	1 000 000	15%	25	25
25	300	1 000 000	20%	24	25
25	300	1 000 000	30%	24	24
25	1 000	500 000	10%	22	23
25	1 000	500 000	15%	20	21
25	1 000	500 000	20%	17	19
25	1 000	500 000	30%	12	14
25	1 000	1 000 000	10%	24	24
25	1 000	1 000 000	15%	22	23
25	1 000	1 000 000	20%	20	21
25	1 000	1 000 000	30%	16	18
150	300	500 000	10%	141	144
150	300	500 000	15%	131	136
150	300	500 000	20%	119	127
150	300	500 000	30%	95	107

				Sample size	
Number of facilities	Average number of people receiving treatment	Variance component	Desired relative margin of error	90% CI	95% CI
150	300	1 000 000	10%	145	147
150	1 000	500 000	15%	58	71
150	1 000	500 000	20%	39	50
150	1 000	500 000	30%	20	27
150	300	1 000 000	15%	140	143
150	300	1 000 000	20%	133	138
150	300	1 000 000	30%	117	125
150	1 000	500 000	10%	88	100
150	1 000	1 000 000	10%	111	120
150	1 000	1 000 000	15%	83	96
150	1 000	1 000 000	20%	62	75
150	1 000	1 000 000	30%	36	46
1 200	300	500 000	10%	794	882
1 200	300	500 000	15%	558	663
1 200	300	500 000	20%	394	492
1 200	300	500 000	30%	214	283
1 200	300	1 000 000	10%	956	1 017
1 200	300	1 000 000	15%	762	854
1 200	300	1 000 000	20%	594	698
1 200	300	1 000 000	30%	364	458
1 200	1 000	500 000	10%	180	240
1 200	1 000	500 000	15%	87	120
1 200	300	1 000 000	30%	364	458
1 200	1 000	500 000	10%	180	240
1 200	1 000	500 000	15%	87	120
1 200	1 000	500 000	20%	51	71
1 200	1 000	500 000	30%	23	32
1 200	1 000	1 000 000	10%	313	400
1 200	1 000	1 000 000	15%	162	218
1 200	1 000	1 000 000	20%	97	133
1 200	1 000	1 000 000	30%	45	63

These examples of values are provided for perspective, and sample sizes should be estimated based on country data using the sample-size estimation tool in Annex C. The numbers of facilities are typical values for small, medium and large countries. The average number of people receiving treatment and the variance component are examples of typical values.

3. ART sites should be selected for the assessment by probability sampling, such as simple random sampling, stratified random sampling, systematic random sampling or probability proportional to size sampling, in which size would be based on the number of people facilities reported to be receiving treatment. To obtain a national correction factor, a qualified statistician should perform the sampling of sites and the country team should archive all the programmes and/or tools used to select the sites, specifically the sampling frame, site selection probabilities and relevant design information, since certain designs require the use of sampling weights during the analysis phase.

4. Some countries may have sites that are very small (such as fewer than 100 people receiving ART) or may be difficult to access because of geographical remoteness or political instability. In these cases, the interorganizational country team may consider excluding some or all of these sites from the evaluation because of logistical considerations. In general, if these sites represent less than 10% of the population receiving ART in the country, countries may choose to exclude these clinics from the sampling frame. In this case, the exclusion from the sampling frame needs to occur before site selection. The final report should include a list of all excluded facilities and reasons for their exclusion. The reported number of people receiving ART from these sites should not be adjusted using the ratio method, since these sites would not be part of the sampling frame and target population. These sites can be included in the second phase of DQA.

In addition to the probability sampling described above, if the interorganizational technical team also chooses to sample certain sites with certainty (probability = 1.0) based on known data quality issues for other key indicators, to promote improvements of data systems, the DQA report should document the criteria and rationale well. Further, these sites should be removed from the sampling frame before sampling and treated as certainty strata and weighted appropriately during analysis.

3.3. Step 3. Site-level assessment

3.3.1. Site-assessment

For this activity in both phases 1 and 2, the interorganizational country team uses standardized processes to review existing information on people receiving ART that is routinely collected through facility- or community-based patient monitoring systems and site assessment tools. DQA activities use a set of standardized tools and data collection instruments (see the annexes) developed specifically for the treatment indicators, although these may be adapted to fit local contexts or to accommodate additional indicators. Data quality should be assessed at the sites for both treatment indicators (number of people currently receiving ART and number of people initiating ART) disaggregated by age and sex.

Selected facilities will be contacted to identify a date and time for the DQA visit. Countries may use their own template for notifying the sites of the visit and should include the following information: the purpose of the visit, proposed visit dates and a request for key staff to be present for the visit.

The site-level assessment visit will consist, at minimum, of the following activities:

- Introductory discussions with key staff of the site and implementing partners;
- Review and completion of informed consent (Annex D);
- Review and completion of the patient monitoring system checklist (Annex A);
- Site walk-through and assessment of record systems to determine patient and data flow (Annex E) from the point of initial data capture (patient files) to data aggregation and reporting (registers and monthly aggregate tools) and to identify gaps and opportunities to improve data quality;
- Recount of reported numbers for selected indicators disaggregated by age and sex and comparison against the numbers reported to the Ministry of Health routinely as well as PEPFAR, for example in DHIS2 and DATIM (Data for Accountability, Transparency and Impact Monitoring), which may include reviewing paper charts, registers, EMR systems, pharmacy records or other record systems;
- Cross-validation of a sample of paper charts, registers, EMR systems, pharmacy records or other record systems (see Annex F); depending on the result, a physical count using patient charts should be conducted if needed; and
- Outbrief with key site and implementing partner staff to summarize key findings from the visit.

Past experience with implementing DQA in countries indicates that one site per day on average is feasible for completing these activities. In terms of human resource, cost and time requirements, this varies significantly according to the number of facilities sampled and patient files reviewed as well as the geographical distribution of facilities and country context. As broad guidance, however, a recent exercise implemented in 84 facilities required a team of 31 data collectors and supervisors over 25 days and 24 data entry clerks over 20 days.

3.3.2. Data collection and analysis

To assure the quality of collected data for review, interorganizational country teams are expected to apply standard data quality assurance practices during data collection. This includes double data entry when possible or having two teams enter a sample of the data to check the quality. At the least, data capture will be conducted in pairs with one partner monitoring the data entry of the other. This will ensure that the data collection team is not introducing any error during the review process. The process for each activity is outlined below.

Primary activity (required):

(1) Recreating selected indicators and validating the report (Annexes A and G):

a. Site staff members first describe the site's data systems, reporting process (Annex A) and methods for calculating each indicator during the discussions (Annex G).

b. The assessment team calculates the selected indicators according to the current definitions, attempting to replicate the procedures used by each site to aggregate and report quarterly totals. If sites report the indicator using a definition that differs from the standard definition, this alternative definition will be known as the site definition and will be documented using the site questionnaire. The reporting and site method for the indicator should be used when recreating the reported number. However, if time and other constraints are present, recreating the standard definition is the priority activity.

c. The recreation of the selected indicators should use the same data source the sites use to report the indicator. For instance, if the sites use the ART register to report the number of people currently receiving ART, the recreation should also use the ART register. Some sites may use the patient charts or other data sources, such as ARV drug pick-up records to report on the number of people currently receiving ART. If this is the case, the recreation should be based on the tools used by the site for reporting.

d. This recreation may include computing patient tallies and confirming results from facility registers, patient databases, pharmacy logs and laboratory records and should review the most recently reported data.

   i. When recreating indicators in facilities with an electronic database, and where indicators were calculated by the site using that electronic system, ask the site staff or database manager for the software report or query used to run the calculations, and validate the consistency of that query with partner and/or Ministry of Health definitions for the respective indicator, when possible. Reports are often routine and so definitions and queries used at sites will often be the same across sites using the same electronic systems.

   ii. A random sample of inactive patient charts (such as 10 charts) should be selected and reviewed to assess misclassification and determine how many may actually still be active. If this review identifies issues with the classification of inactive patient charts, physically counting patient charts should be considered (as described in the section on other data validation activities).

e. The assessment team then compares the calculated results from the reported and site (if this exists) method recreation with the reported value and discuss differences (if any). The measure for comparison will be the verification factor (recreated/reported times 100) and confidence interval, which explains how much of the reported data can be verified. Annex B describes the formulas for estimating the ratio of interest in detail (the ratio of the number of verified people receiving treatment to the number of people facilities reported to be receiving treatment). Certain designs may require using sampling weights. Consult a qualified statistician before analysis. A verification factor within 90% to 110% is within acceptable levels but should still be recorded, reported and reviewed by the Ministry of Health and country team to adjust national ART data *(5)*.

f. Discrepancies between the reported and recreated values (percentage difference) are computed, described and discussed with each site. To the extent possible, the reasons for possible differences between the values computed during the site visit and the values reported by that site are further investigated and described (see other data validation activities for the details of methods that can be used). If immediate remediation is needed, action plans should be developed with the sites and options for correcting the data should be discussed.

To support the primary data validation activity and implement the final step of assessing the discrepancies between reported and recalculated ART numbers, at least one of the data validation activities below should be conducted alongside the DQA. These activities will inform the DQA by providing additional information on the completeness and accuracy of the data sources and reporting tools.

Other data validation activities:

(1) Site-level cross-validation (Annex F): the process of checking the completeness and accuracy of site-level source documents by cross-referencing identified data elements in routine reporting source documents (typically patient charts) with other reporting documents, such as the ART register, pharmacy records or EMR system.

a. The assessment team randomly samples a number of patient charts from the ART register beginning with the start of the time period being reviewed. Assessment teams should define the number of charts to be selected and the specific sampling method (such as every fifth person) during the planning stages of the assessment.

b. The following are options for selecting the number of charts.

i. Select 10% of the charts from active patients receiving treatment. If at least 10% of the charts reviewed are inconsistent with the register, an additional 10% of patient charts are reviewed to better understand the consistency. For example, if 1000 people are active, then 10% (100/1000) of the charts should be reviewed. If 10 or more charts are inconsistent with the register, then the number of charts reviewed is increased by 100.

ii. A random sample of charts may be selected to estimate the completeness and accuracy with a high degree of statistical precision (narrow confidence interval). This often requires a larger sample size and can be calculated using a sample size calculator. For instance, the HIVQUAL sampling method could be used *(5)*.

c. Selected data elements such as the last ARV drug pick-up date and last clinic visit will be compared between data sources (such as ART register, EMRs, pharmacy records etc.) using a data verification tool (Annex F), which will be adapted to the country data systems. The number and types of data elements to be reviewed will be determined by the country team.

d. The data collected will be used to calculate the percentage of discordance between the source document (patient charts) and other data from reporting tools such as the pharmacy system, EMRs and/or ART register.

e. For this activity, teams have access to patient records and charts or personally identifying health information, and the teams therefore apply a standardized practice to data extraction, making sure to cover the name, age, address and phone number of each patient. The patient identifiers such as name, date of birth and sex are used to identify the records for this activity, confirming the same patient across different data sources. These identifiers are not removed from the facility and are not part of the data collected. The identifiers are destroyed before leaving the health facility. Only aggregated data are captured. All data abstraction occurs in a private area, away from patients, and covered (such as closing the folder) if patients are present.

f. This activity seeks to determine agreement (and the percentage difference) among reporting tools at the same site, to describe reasons for the discrepancies observed and to make recommendations, if possible, for improvement.

(2) Physical count using patient charts: in instances where the validity of the indicators produced from site-level reporting tools or from cross-validation are of significant concern, the patient files can be checked and physically counted to confirm the "actual" total of people actively receiving ART. Examples of when a physical count might be beneficial include: when source documents used for reporting appear to be significantly incomplete or when there are larger data quality concerns, such as issues with appropriately accounting for people lost to follow-up and/or deaths.

g. The assessment team should identify patient charts that fall into the following categories and review the charts to confirm the patient status and count the patients whose charts or medical records fall into each category (the definition of these categories may vary from country to country).

i. Active: people actively receiving ART: currently have enough medication that will last until their next scheduled visit.

ii. Missed appointment: missed their last appointment but are within seven days of their missed appointment.

iii. Defaulters: missed their appointments but do not qualify as lost to follow-up: within the three-month window following their missed appointment.

iv. Lost to follow-up: missed appointments and are outside the three-month window following their missed appointment.

v. Transfer out: initiated care and treatment services at another health facility.

vi. Deceased: died.

vii. Transfer in: initiated care and treatment at the current facility.

h. People who are deceased, transferred out or are lost to follow-up are not considered actively receiving ART. All other people are considered active.

i. People may also be actively visiting the facility during the physical recount, so their charts may not be in the file room or charts may be kept in other locations within the health facility such as tuberculosis, maternal and child health clinics etc. The assessment team should ensure that a comprehensive chart count and review is performed.

j. The count of people actively receiving ART should be compared with the number reported by the clinic.

i. The number of people actively receiving ART reported may differ from the physical recount. However, this number should be within acceptable error bounds because of flow in and out of the facility.

(3) **Lost to follow-up assessment:** in facilities that utilize electronic systems for patient monitoring and tracking, queries on recent loss to follow-up can generate a list of patients meeting the lost to follow-up criteria. Verification of lost to follow-up status in the patient chart can provide an additional opportunity for validating the accuracy of the electronic system.

k. The assessment team works with site staff to query the electronic system to generate a list of people in the past 90 days after the last missed appointment (depending on the size of the facility and within the context of differentiated care models in which people may not be required to attend ART sites as frequently) that have been marked as lost to follow-up based on standard definitions.

l. The assessment team pulls each person's chart from the list generated and confirms whether the person is still actively receiving treatment based on chart documentation. In some cases, the pharmacy system might need to be queried as well, since people might bypass clinical visits but still pick up medication from the pharmacy.

m. People misidentified as lost to follow-up will be totalled and used to calculate a percentage of variance.

Assessing and correcting errors in the reported data that result in incorrect counts of people receiving treatment at sites because of loss to follow-up, transfer out and death using one of the latter two data validation activities above is a critical step for adjusting the national ART data as outlined in subsection 3.5.2.

The assessment teams use standardized data collection sheets (Annexes A and H) to collect qualitative and quantitative data from each site. All quantitative information is consolidated using tables (spreadsheets) and shared among participating staff. Implementing partners are asked to maintain the results of all DQAs in a centralized database to demonstrate routine monitoring of data quality and quality improvement over time.

The assessment team works with site-level staff to summarize the results and identify the potential root causes of poor data quality at that site. The results will be used to develop site-specific action plans for improving the quality of data and correcting the problems discovered in the activity. The lessons learned will be summarized across all sites and shared during quarterly meetings with the Ministry of Health and partners.

3.4. Step 4: Desk review of ART data submitted to the national level

A desk review of the quality of existing ART data reported to the national level should be undertaken to evaluate the dimension of data quality. At a minimum, aggregated ART data at the national level should be checked for the completeness and timeliness of ART reports, and this should be quantified. Monthly or quarterly reports on the number of people receiving ART reported by ART sites to the national level should be reviewed in addition to the number of submitted reports and the number of ART sites expected to report for the reporting period covered. Reports from previous years can also be reviewed for a longer-term view of reporting trends.

The desk review is intended to assess errors in reporting and aggregation caused by missing or delayed reports and, when feasible, duplicate reports. For the latter, if possible, EMRs should be used to estimate the number of duplicate reports because of silent patient transfer across ART sites and assess loss to follow-up at the national level.

3.5. Step 5: Analyse the results and reset the numbers of people receiving ART for the site and nationally

3.5.1. Data management

The data collected and analysed as part of this assessment will be shared by all partners and the Ministry of Health. These data may be collected using a combination of paper and electronic forms. Data that are collected on paper forms will be kept in the possession of the field team leads throughout the field exercise. Upon completion of fieldwork, team leads will be responsible for destroying all personal identifying data forms and transporting all aggregated data back to the main office. All aggregated data will be entered into an electronic format such as Microsoft Access, Excel or similar software. The database used will be password protected and will be available on computers that are only accessible to the project team.

The data taken from the site will not include any patient identifiers. Patient identifiers may be used at the sites to identify charts. However, this information will be destroyed before leaving the site.

The data collected will be backed up on password-protected and, where available, encrypted computers at the country office or the Ministry of Health. The results of the DQA will be shared with partners for activity monitoring purposes. However, the raw data files will not be distributed beyond the country team. The data collected on paper forms may be kept for up to five years and then destroyed.

3.5.2. Correction factor to apply to the national numbers of people receiving ART

A key output from the DQA is a quantitative understanding of the likely level of under- or overreporting of the number of people receiving treatment nationally during the assessment period. Misreporting of this number can arise from the following.

Incorrect reporting from the facility and aggregation at the national level. Aggregation of facility level reports to count the number of people receiving treatment at any given time can be subject to error if facility reports are delayed or missing and not adjusted for or if reports for the facility are entered in duplicate.

This type of error can result in either over- or undercounting the actual number of people receiving treatment. The numbers of people receiving treatment should be corrected to account for missing facility reports or reports that have been mistakenly entered in duplicate. The desk review in step 4 assesses this.

Incorrect counting of people receiving treatment at the facility level. In addition to simple errors in aggregation of data between patient records and reporting forms, incorrect counts of the number of people receiving treatment may arise from a failure to properly define "currently receiving ART", from failure to remove people who have died or disengaged from care or who have transferred facilities or from incomplete or backlogged patient records, registers, charts or files. Errors of this type can result in either over- or undercounting the actual number of people receiving treatment at a facility. The correct number can be determined by recreating the reported number using patient records and registries (see subsection 3.3, Step 3: site-level assessment for details).

People who simultaneously seek care at more than one facility. The number of people receiving treatment can be incorrectly counted if people are simultaneously registered at and considered to be receiving treatment by two facilities.

This error will always result in overcounting the number of people receiving treatment. The correct number can be determined by comparing electronic records, where available, across facilities, reviewing possible matches to determine whether they are the same person and then assigning a single location for counting purposes. When this comparison can be done with only a subset of the people receiving treatment, a correction factor could be calculated and applied in addition to the correction factor from step i below, if there is agreement that the same level of duplication is occurring in facilities not included in the comparison. If insufficient information is available to determine the unique identity of individuals, this correction factor should not be used.

To the extent possible, all sources of errors should be considered when reporting on the number of people receiving treatment for the current and historical reporting periods. The Excel spreadsheet (Annex J) shows examples of how to correct the data.

The following steps are used to calculate that national reset value in the year in which the DQA was done.

Step i. Estimate the ratio of the number of people verified to be receiving treatment from the DQA to the number of people facilities reported to be receiving treatment and confidence interval using the method.

Step ii. Multiply the total number of people reported to be receiving treatment from the sites included in the sampling frame by the above ratio and by the upper and lower bound ratio estimates. This will yield adjusted national estimates along with an upper and lower bound estimate.

Step iii. Correct for duplication across facilities if possible (where comparison across facilities has been done using EMRs) by applying the cross-facility duplication adjustment to all sites. If duplicates are resolved at the time of the validation, the cross-facility duplication correction should only be applied to the numbers of people receiving treatment in sites without EMRs.

Step iv. If applicable, apply additional correction factors to the adjusted estimate (for example, correcting for duplication across facilities).

The following steps are used to calculate the historical value in years before the DQA.

One approach to adjusting the previous year's data (assuming that errors in reporting are directly linked to patient load) is to identify the year since 2010 with the largest percentage increase in the numbers of people reported to be receiving treatment and then calculate an interpolated adjustment factor (either linear or exponential) for each year until the year before the DQA was done.

Other approaches could be considered based on whether the country believes that miscounting is likely to be associated with different partner-level support in clinics, the type of reporting system (paper versus electronic) or patient load at the clinic. This approach would require historical understanding of how these facilities attribute changes over time.

3.6. Step 6: Disseminating, notifying and reporting results

A primary aim of the work will be to adjust the number of people receiving ART at the facility level and further correct any strategic information used for planning and reporting. Clear documentation of the assessment, the results and the decision about the correction factor will be critical for explaining changes to ministry officials and development partners. The country report will therefore inform the process of updating estimates rapidly after the report is provided.

Once a nationally representative adjustment factor has been calculated, it needs to be reviewed and agreed by stakeholders. Clear and transparent messaging about the change in the values should be agreed by the interorganizational team and disseminated widely. The corrected treatment values for the year in which the review was done should be submitted through the UNAIDS Global AIDS Monitoring online tool for the year of the assessment.

The adjusted ART data also need to be corrected in the national (or subnational) Spectrum estimates file. This will require correcting the historical years as well as the current year. See the section above on national correction factors to determine how this is done.

Based on the findings from the above methods, the interorganizational country team will produce a brief report (using the template in Annex I) summarizing any systematic problems with defining indicators and data recording, reporting and aggregation from the facility to the national level (where relevant), data quality challenges and recommendations (including those identified in Annex A) to improve the quality of aggregate data reporting and the system that generates the data in the future. This report should be shared with all stakeholders in the interorganizational country team, including implementing partners and Ministries of Health.

Data ownership will be under the Ministry of Health. The Ministry of Health will maintain the results to monitor data quality issues and to track any follow-up action necessary as a result of the assessments. The data collected as part of this assessment will not be publicly available, since they will comprise tallies and counts of data consistency. The value of the dataset to the public is limited, and the cost of making the datasets accessible is prohibitive. However, reports of the assessment will be shared with all global and implementing partners (WHO, PEPFAR, UNAIDS and the Global Fund) and other relevant stakeholders.

4. ETHICAL CONSIDERATIONS

Before collecting data at the site level, teams will discuss the consent process with clinical staff and will provide a copy of the informed consent form (Annex D), which requests permission to conduct the assessment and conveys the following information.

- Participation is voluntary and participants have the right to refuse.
- No incentives will be given.
- No staff personal identification will be collected or recorded. The interviewer will sign the consent form, and the interviewee may retain a copy.

Country teams may take notes on discussions with the site staff, but these discussions will not be recorded. To tally the indicators listed in this protocol, members of the review teams will be viewing registers and databases with patient-level identifiers. The review team may need to use individual identifiers at the time of calculation for some of the indicators to ensure that double-counting does not occur. Data containing individual identifiers will not be removed from any site. Patient confidentiality will be protected by ensuring that patient names, phone numbers and addresses remain covered at all times. Laptops with electronic tools (such as spreadsheets) will be password protected, and laptops will not be left unattended while at the site. No records with individual identifiers will be removed from the site. Although no identifying data will be collected, all data reviewers will sign a statement of intent to maintain confidentiality (Annex G). This is intended as an extra measure to protect patient confidentiality during the review.

Data abstractors may include global and in-country staff and implementing partner staff. All data abstractors will receive training on the confidentiality of patient information before conducting the DQA and will be escorted by designated facility staff through the following areas and other areas as appropriate:

- Patient check-in;
- The waiting area;
- The records area
- The HIV testing and counselling area;
- The patient examination rooms;
- The laboratory and/or phlebotomy areas; and
- The pharmacy.

The interorganizational country team requests a waiver of authorization or consent for review of medical records during site visits. The waiver is appropriate because: (1) the analysis will involve no more than minimal risk to human subjects; (2) the assessment will not adversely affect the rights and welfare of the subjects; (3) the assessment could not practicably be carried out without the waiver because consent cannot be obtained from all service recipients without infringing on the ability to carry out the programme in an efficient manner; and (4) the specific elements of health information requested are not more than the minimum necessary to accomplish the goal.

5. REFERENCES

1. Service Availability and Readiness Assessment (SARA): an annual monitoring system for service delivery. Geneva: World Health Organization; 2015 (http://www.who.int/healthinfo/systems/sara_implementation_guide/en, accessed 25 June 2018).

2. Consolidated guidelines on person-centred HIV patient monitoring and case surveillance. Geneva: World Health Organization; 2017 (http://apps.who.int/iris/bitstream/handle/10665/255702/9789241512633-eng.pdf;jsessionid=45D9CD690D25D8292BFCEC519220B199?sequence=1 accessed 25 June 2018).

3. Annex 2.6.2: Patient monitoring systems assessment checklist. In: Consolidated guidelines on person-centred HIV patient monitoring and case surveillance. Geneva: World Health Organization; 2017 (http://www.who.int/hiv/pub/guidelines/WHO_Consolidated_Guidelines_Annexes_2.6.2.pdf?ua=1, accessed 25 June 2018).

4. World Health Organization, Gavi, Global Fund to Fight AIDS; Tuberculosis and Malaria, United States Agency for International Development/MEASURE Evaluation. Data quality review tool kit. Geneva: World Health Organization; 2017 (http://www.who.int/healthinfo/tools_data_analysis/dqr_modules/en, accessed 25 June 2018).

5. Routine data quality assessment tool (RDQA). Chapel Hill (NC): MEASURE Evaluation; 2015 (https://www.measureevaluation.org/resources/tools/health-information-systems/data-quality-assurance-tools/rdqa-guidelines-2015, accessed 25 June 2018).

6. New York State Department of Health AIDS Institute and National HIVQUAL Project. HIVQUAL workbook. Albany (NY): New York State Department of Health AIDS Institute: 2006 (http://nationalqualitycenter.org/files/hivqual-workbook, accessed 25 June 2018).

Annex A. Checklist for assessing site-level patient monitoring systems

This simple assessment should be adapted to the setting and carried out at the beginning of the data quality assessment. The tool has been developed for the Ministry of Health to be used at the health facility level to implement data quality assessment. The tool provides a quick review of the presence and quality of: integrated systems and national tools; human resource capacity; efficient patient and data flow; and accurate and complete data collection, transfer and reporting. Each sub-checklist is followed by a list of recommended actions that the review team should carry out immediately. The review team should then outline the follow-up plan, including the action needed at the national level or on subsequent site visits.

Instructions for the review team (parts A and B)

This is the first tool the team should use once arriving at the site after the team has done introductions and are settling in. Most questions are appropriate for the site data clerk, but if the questions would be better answered by the facility management this is indicated. Questions focus on the period of interest: month X to month Y.

Part A: ART-specific questions

1. General information (for facility management)

1.1 In what month and year did the facility begin providing antiretroviral therapy (ART)? _____

2. Patient-level paper or electronic data collection systems and confidentiality

2.1. What data collection systems or patient monitoring systems is this facility using (check all that apply)?

☐ Electronic systems

☐ Paper-based registers (skip to question 3)

☐ Other? _____

Electronic register or electronic medical records

2.2. Does the facility have an electronic register or electronic medical records for ART for collecting ART programme data or reporting ART programme data?

☐ Yes. If yes, please list the name of the system or systems: _____

☐ No

2.3. Is the facility currently using the electronic register or electronic medical records?

☐ Yes

☐ No

2.4. How often are data entered into the system?

☐ Daily

☐ Weekly

☐ Monthly

☐ Other: _____2.5. Is there a backlog of data entry?

☐ Yes. If yes, explain: _____

☐ No

2.6. Is the computer that has the electronic register or electronic medical records password-protected?

☐ Yes

☐ No

2.7. Does the facility keep a paper backup other than patient charts?

☐ Yes. If yes, is it a ☐ register? ☐ other tool? Please explain: _____

☐ No

3. Reporting to partners (for the management of the facility)

3.1. How does the facility submit monthly reports on ART to the Ministry of Health?

☐ Electronic report

☐ Paper form

Form name or number: _____

3.2. How does the facility submit reports for PEPFAR or other implementing partners?
(Skip to question 4 if the facility is not supported by an implementing partner)

☐ Electronic report

☐ Paper form

Form name or number: _____

4. Personnel (for the management of the facility)

4.1. Who is responsible for calculating ART indicators and completing monthly reports for the Ministry of Health implementing partner? (please mark all that apply)

ART:

☐ A dedicated facility-based monitoring and evaluation specialist hired by the Ministry of Health or implementing partner

☐ A monitoring and evaluation specialist hired by the Ministry of Health who visits the facility on a routine basis

☐ Data entry clerk

☐ Nurse or other clinical staff member

☐ Other: _____

4.2. Are processes in place to ensure that ART data are compiled and reported if the designated personnel are not available?

☐ Yes

☐ No

4.3. Have personnel been trained on how to use and complete paper-based registers and electronic medical record systems and reporting forms?

☐ Yes

☐ No

5. Data quality (for the management of the facility)

5.1. Does the facility follow quality control procedures for data entry into an electronic register, electronic medical records or a paper-based register?

☐ Yes

☐ No

5.2. Does the facility have standard operating procedures on data quality for monthly ART reporting processes?

☐ Yes

☐ No

5.3. Does the facility have a tool that can be used for conducting internal data quality checks?

☐ Yes

☐ No

5.4. Does the facility receive feedback from the implementing partner on the quality of its ART reports?

☐ Yes

☐ No

If so, how often? _____

5.5. Does this facility receive visits from the Ministry of Health, district hospital or partner staff (such as PEPFAR or the Global Fund primary recipient or subrecipient) to check the quality of the ART programme data?

☐ Yes

☐ No

If so, how often? _____

Part B: Assessment of the HIV patient monitoring system to be administered at the health facility

For Part B:

Do you have the necessary patient monitoring elements in place? Tick (✓) the yes box if the statement describes your health centre. If not, tick no. Items with "no" need to be implemented or improved. If not applicable, tick N/A.

1. Organization and use of HIV patient monitoring tools

1.	Yes	No	N/A	Use of patient monitoring tools
A	☐	☐	☐	The facility is using the national patient monitoring tools.
B	☐	☐	☐	The facility is using additional or other tools than the national patient monitoring tools.

List the tools and state the reasons for using them.

Comments

Recommended action. If the health centre is using something other than the national tools, the district management team should ensure that the correct tools and accompanying training are provided. If facilities are using these tools because of a lack in the national system, the district team should note this and report it to the Ministry of Health for follow-up. Institutions other than the Ministry of Health or donors supporting the facility may implement additional tools and forms. The district team should ensure that the Ministry of Health has authorized these and that there is no duplication with the national tools. The use of additional tools should be minimized if possible.

Follow-up plan

2.	Yes	No	N/A	The following national patient monitoring tools are available in adequate supply (may insert relevant TB and maternal, newborn and child health tools as relevant):
A	☐	☐	☐	Patient-held card
B	☐	☐	☐	HIV patient card
C	☐	☐	☐	Community ART monitoring tool
D	☐	☐	☐	ART register
E	☐	☐	☐	Cross-sectional report
F	☐	☐	☐	ART cohort analysis report
G	☐	☐	☐	Appointment book
H	☐	☐	☐	Transfer or referral form

Comments

Recommended action. If one or more of the tools is absent or in short supply, the district team should ensure adequate supply by copying or providing new forms to the facility. Ensure that the facility team has recently received the necessary training in patient monitoring.

Follow-up plan

3.	Yes	No	N/A	Organization and storage of patient monitoring tools
A	☐	☐	☐	HIV patient cards and ART registers are well organized and stored in a secure location
B	☐	☐	☐	A unique patient ID is generated systematically according to national standards and provided to each patient enrolled in HIV care

Comments

Recommended action. If the records are not well organized, identify the reason, such as lack of space, lack of storage structure or not organized by patient ID or other efficient means. Ensure adequate space, shelving or filing cabinets and orderly organization of records. If records are not secure, ensure that there is a locked cabinet or office where they can be stored, with limited access to this storage.

Follow-up plan

4.	Yes	No	N/A	The patient and data flows are well defined and efficient
A	☐	☐	☐	HIV patient cards are pulled from storage for all patients to be seen at the start of day
B	☐	☐	☐	HIV patient cards follow patients and are completed as they go through care
C	☐	☐	☐	HIV patient cards are returned to registration after each visit and stored

Comments

Recommended action. If data flow does not correspond to patient flow (laboratory tests, clinical care, counselling points or drug pick-up are not updated in patient record) or if cards do not follow patients, discuss with the facility team to understand the patient and data flows. Together, outline recommendations and detail steps to be taken on how to improve the process and ensure that patient information is complete (such as ensuring that drug pick-up and not just drug prescription is recorded on the patient card). Use flow diagrams if necessary.

Follow-up plan

5.	Yes	No	N/A	Appointment system
A	☐	☐	☐	An appointment book or system is used to log the patients' next visit, prepare the clinic day for the expected patients, identify missed appointments and follow up with patients missing appointments
B	☐	☐	☐	The contact information for the patient and treatment supporters are updated and complete
C	☐	☐	☐	The dates for lost to follow-up are recorded on summary forms

Comments

Recommended action. Health workers need to know when patients miss appointments and to follow up as necessary. The health facility must therefore have a simple yet functioning appointment and follow-up system. If none exists, see the examples provided. A simple appointment book, one page for each day, can be used or a tickler file system.

Follow-up plan

6.	Yes	No	N/A	Transfer or referral system
A	☐	☐	☐	Standard transfer forms are used to receive and transfer out patients
B	☐	☐	☐	Health centres follow the national transfer protocol when transferring and receiving transfer patients

Comments

Recommended action. Every health facility should follow the national, standardized transfer or referral system in place. This includes transferring key information, such as that given on the front of the patient card to the receiving facility to ensure that the patient receives continuous care and treatment. If no transfer protocol exists, a minimum of key information should be transferred with the patient, including sociodemographic characteristics and a summary of treatment (as on the front page of the HIV patient card).

Follow-up plan

7.	Yes	No	N/A	ARV drug consumption (for pharmacy personnel)
A	☐	☐	☐	Do you currently have expired ARV drugs within the stocks at your facility?
B	☐	☐	☐	Have you ever had expired ARV drugs within the stocks at your facility in the past year?
C	☐	☐	☐	Do you have a standard report or log you use for reporting stocks of expired ARV drugs? If so, to whom do you report this information? (indicate in comments)

Comments

Recommended action. Pharmacy records need to be well maintained to track the levels of ARV drug stocks and reports need to be sent regularly to indicate loss in stocks to district level or the appropriate level under which ARV drug supply is managed to prevent drug stock-outs.

Follow-up plan

8.	Yes	No	N/A	Are the patient monitoring systems for HIV, maternal, newborn and child health and HIV and TB and HIV integrated at this facility?[1]
				Antenatal care and services to prevent the mother-to-child transmission of HIV
A	☐	☐	☐	Are some or all of the HIV patient monitoring tools used in the maternal, newborn and child health setting? **List all.** _____ _____ _____
B	☐	☐	☐	Are some or all of the TB patient monitoring tools used in the maternal, newborn and child health setting? **List all.** _____ _____ _____
				Do the following maternal, newborn and child health patient monitoring tools include HIV elements?
C	☐	☐	☐	Antenatal care and maternal health card
D	☐	☐	☐	Antenatal care register
E	☐	☐	☐	Labour record
F	☐	☐	☐	Labour and delivery register
G	☐	☐	☐	Child health card
H	☐	☐	☐	Other (specify)_____
I	☐	☐	☐	Is there a separate or different patient record for HIV-exposed infants?
J	☐	☐	☐	Is there a register for HIV-exposed infants or HIV-exposed mother-infant pairs?
K	☐	☐	☐	Is the register for HIV-exposed infants or HIV-exposed mother-infant pairs linked to the antenatal care register or ART register entries for the mother?
				TB and HIV
L	☐	☐	☐	Are some or all of the HIV patient monitoring tools used in the TB clinic? **List all.** _____ _____ _____
M	☐	☐	☐	Are some or all of the TB patient monitoring tools used in the HIV setting? **List all.** _____ _____ _____
N	☐	☐	☐	Do the TB patient monitoring tools include HIV elements (TB treatment card and registers)? **List all.** _____ _____

[1] Integration may also include other programmes, including hepatitis, noncommunicable diseases such as hypertension, diabetes and others. Adapt as appropriate.

Comments

Recommended action. If one or more relevant staff members are not trained on one or more of the components of the patient monitoring system, the district team should schedule and provide appropriate training or retraining to these staff members followed by hands-on support within 2–4 weeks.

Follow-up plan

2. Use of patient monitoring tools: completeness and accuracy

9. Take a sample of five HIV patient cards and check for the following:

	Yes	No	N/A	The HIV patient card is complete and accurately filled out
A	☐	☐	☐	The HIV patient card has been started for all patients enrolled in HIV care and/or receiving ART
	Yes	**No**	**N/A**	**Summary page**
B	☐	☐	☐	The sociodemographic information is complete
C	☐	☐	☐	The box on family status is complete as relevant
D	☐	☐	☐	The box on HIV care summary is complete
E	☐	☐	☐	The box on prior ARV drugs is complete
F	☐	☐	☐	The box on ART care is complete as relevant
G	☐	☐	☐	The box on ART treatment interruptions is complete as relevant
H	☐	☐	☐	The box on follow-up status is complete
	Yes	**No**	**N/A**	**Encounter page**
I	☐	☐	☐	One row is completed for each visit
J	☐	☐	☐	The TB status is filled in at each visit
K	☐	☐	☐	The weight is filled in at each visit
L	☐	☐	☐	The pregnancy status is filled at each visit if the woman is of childbearing age
M	☐	☐	☐	If the infant is younger than 59 months, the age in months, weight gain with or without oedema, mid-upper-arm circumference and nutritional problems are recorded
	Yes	**No**	**N/A**	**Education and support page**
N	☐	☐	☐	Regular comments and dates are filled in as appropriate by a health worker
	Yes	**No**	**N/A**	**Considerations for preventing the mother-to-child transmission of HIV**
O	☐	☐	☐	The box on HIV-exposed infant follow-up is updated on the mother's HIV patient card
P	☐	☐	☐	HIV-exposed infants who have been confirmed as HIV-positive have their own HIV patient card and line in the ART register

Comments

Recommended action. In general, if information is incomplete or inaccurate, go directly to the source from which that information should have come. For example, the registration clerk or nurse generally fills out the sociodemographic information, whereas the doctor or clinician fills out most of the encounter page. Talk to the responsible health worker about the gap or error and discuss the reasons why. If the health worker did not receive the appropriate training or was inadequately trained, follow the recommended action in Part B, Section 1 (on organization and use of HIV patient monitoring tools). If the health worker knows how to fill in the information but was too busy or simply forgot, explain the importance of complete information for patient care and for data transfer to the registers later. Flag the health worker for subsequent visits to ensure that he or she is filling in the information correctly.

Follow-up plan

10.	Yes	No	N/A	ART register – find register entries for a sample of HIV patient cards
A	☐	☐	☐	ART registers are filled in after ART starts and updated with each patient visit. The columns are complete using standardized coding
B	☐	☐	☐	The contact information is complete with a unique ID
C	☐	☐	☐	TB treatment, co-trimoxazole prophylaxis, TB preventive therapy and hepatitis B and C screening have been completed as relevant
D	☐	☐	☐	The pregnancy columns have been updated if relevant
E	☐	☐	☐	The patients are organized by the date ART started, and months do not overlap on the page
F	☐	☐	☐	Patients transferring in are recorded below the line under those starting in the original clinic by the date ART started
G	☐	☐	☐	Baseline status when ART started and changes in regimen with reasons and dates are recorded. Make sure the changes match the right side
H	☐	☐	☐	Standard codes in each column are used for the current drug regimen or patient status in the top row
I	☐	☐	☐	Current breastfeeding or pregnancy codes have been filled in as relevant in the bottom row
J	☐	☐	☐	The months are labelled at the top of the columns
K	☐	☐	☐	The CD4 count, if available, has been recorded at 6, 12, 18 and 24 months and yearly thereafter
L	☐	☐	☐	The viral load, if available, has been recorded at 6 and 12 months and yearly thereafter

Comments

Recommended action. If information is missing or incorrectly filled in, talk to the responsible health worker about the gap or error and discuss the reasons. If the health worker did not receive the appropriate training or was inadequately trained, follow the recommended action in Part B, Section 1 (on organization and use of HIV patient monitoring tools). If the health worker knows how to fill in the information but was too busy or simply forgot, explain the importance of complete information for patient care and for tallying data from the registers for the cross-sectional and ART cohort reports later. Flag the health worker for subsequent visits to ensure that he or she is filling in the information correctly.

Follow-up plan

11.	Yes	No	N/A	Cross-sectional report
A	☐	☐	☐	Cross-sectional reporting forms have been completed and sent up or collected on a timely basis
B	☐	☐	☐	All cells have been filled in
C	☐	☐	☐	Tallies add up
D	☐	☐	☐	Table 1 on new and cumulative people who started receiving ART by sex and age has been completed
E	☐	☐	☐	The subsets of the people who have started receiving ART have been completed: pregnant and breastfeeding women, baseline CD4/CD4 ≤200 cells/m3, active TB disease, started on TB preventive therapy or screened for hepatitis B or C
F	☐	☐	☐	Table 2 on people currently receiving ART by first-, second- and third-line ARV drugs and by sex and age has been completed
G	☐	☐	☐	The subsets of those currently receiving ART has been completed (TB treatment started, viral load results recorded and viral load suppressed)
H	☐	☐	☐	Table 3 on antenatal care information has been completed
I	☐	☐	☐	Table 4 on labour and delivery information has been completed
J	☐	☐	☐	Table 5 on information on HIV-exposed infants has been completed

Comments

Recommended action. If cells are not complete or inaccurately tallied, go to the source, work with the health worker to review and reinforce understanding. If the health worker did not receive the appropriate training or was inadequately trained, follow the recommended action in Part B, Section 1 (on organization and use of HIV patient monitoring tools). If reports are consistently late, consider the reasons why and problem solve with health workers to ensure timely reporting.

Follow-up plan

12.	Yes	No	N/A	Validate the ART cohort report by using the ART registers and re-tallying the columns
A	☐	☐	☐	ART registers are tallied to complete ART cohort reports and sent up or collected regularly with the supervision of district management team
B	☐	☐	☐	All the columns are filled for cohorts completing the baseline and 6, 12 and 24 months until the present
C	☐	☐	☐	Fractions are recorded where relevant
D	☐	☐	☐	The tallies add up
E	☐	☐	☐	Viral load used to track the status of adults

Comments

Recommended action. The ART cohort report requires validation by the district team during facility visits even if the facility fills it out. This can be coupled with the annual patient monitoring review. If the facility is unable to fill out the ART cohort report, the district team must do this. This can be done every 6–12 months during site visits. A copy of the report should remain at the site for the health workers to review the progress of their patients receiving ART. If cells are not complete or inaccurately tallied, go to the source, work with the health worker to review and obtain understanding. If the health worker did not receive the appropriate training or was inadequately trained, follow the recommended action in Part B, Section 1 (on organization and use of HIV patient monitoring tools). If the reports are consistently late, consider the reasons why and problem solve with health workers to ensure timely reporting.

Follow-up plan

13.	Yes	No	N/A	Data use
A	☐	☐	☐	Health workers have regular meetings to review patients' charts or to review case management
B	☐	☐	☐	Health workers understand how to use information on the patient card to manage patient care and treatment
C	☐	☐	☐	Health workers understand how to use registers to help to follow up the status of patients' care and treatment
D	☐	☐	☐	Health workers understand how to use cross-sectional reports for planning purposes as relevant
E	☐	☐	☐	Health workers understand how to use ART cohort analysis reports to identify patient outcomes and follow up accordingly

Comments

Recommended action. In addition to being able to accurately complete all patient monitoring tools, health workers should be able to use the information collected and reported to inform both patient management and programme monitoring regularly and should be a routine part of high-quality care and treatment. Quality assurance activities may also be carried out by reviewing some of the data collected. Regular site visits by the district management team and clinical mentors can support data use among health workers. Health workers should understand that using data is as important as filling, entering and reporting it.

Follow-up plan

Annex B. Estimating a ratio

Estimation from simple random sampling

The objective is to estimate the ratio of the number of verified people receiving treatment to the number of people facilities reported to be receiving treatment. Health facilities are the primary and only sampling unit, and suppose there are some number N health facilities that report results. Health facility $j,j=1,\cdots,N$, reports some number x_j of people who received care during some reporting period. These counts are to be verified from a random sample of n of those same health facilities, selected without replacement. The verified counts are denoted by $y_i,i=1,\cdots,n$, and the corresponding unverified reported counts are denoted by $x_i,i=1,\cdots,n$. If the sample is completely random, then the estimate of the true but unknown ratio $R=\sum_{j=1}^{N} y_j \Big/ \sum_{j=1}^{N} x_j$ is given by

$$\hat{R}=\frac{\sum_{i=1}^{n} y_i}{\sum_{i=1}^{n} x_i}=\frac{\bar{y}}{\bar{x}} \tag{1}$$

where $\bar{x}$ and $\bar{y}$are the means of the unverified and verified patient counts, respectively (1). The sampling standard error of $\hat{R}$ is given by

$$s(\hat{R})=\frac{\sqrt{1-\frac{n}{N}}}{\sqrt{n}\bar{x}}\sqrt{\frac{\sum_{i=1}^{n}(y_i-\hat{R}x_i)^2}{n-1}}. \tag{2}$$

Therefore an approximate large-sample $(1-\alpha)100\%$ confidence interval for R is given by $\hat{R}\pm t_{n-1,\alpha/2}\, s(\hat{R})$, where $t_{n-1,\alpha/2}$ is the $a/2$ tail quantile of the t distribution having $n-1$ degrees of freedom.

Extension to stratified random sampling

Suppose the population of N sampling units (health facilities) can be segmented into L independent sampling strata in which there are N_h sampling units in stratum $h,h=1,\cdots,L$ so that $N=\sum_{h=1}^{L} N_h$. Then the population ratio is given by

$$R_{st}=\frac{\sum_{h=1}^{L} N_h R_h}{N}.$$

Suppose samples of size n_h are selected randomly and independently without replacement from each of the L strata. Then the sample estimate of R_{st} is given by

$$\hat{R}_{st}=\frac{\sum_{h=1}^{L} N_h \hat{R}_h}{N} \tag{3}$$

where

$$\hat{R}_h=\frac{\sum_{i=1}^{n_h} y_i}{\sum_{i=1}^{n_h} x_i}=\frac{\bar{y}_h}{\bar{x}_h}.$$

It follows then that the sampling standard error of $\hat{R}_{st}$ is given by

$$s(\hat{R}_{st}) = \frac{\sum_{h=1}^{L} N_h s(\hat{R}_h)}{N}$$

where the $s(\hat{R}_h)$ are obtained from

$$s(\hat{R}_h) = \frac{\sqrt{1-\frac{n_h}{N_h}}}{\sqrt{n_h}\bar{x}} \sqrt{\frac{\sum_{i=1}^{n}(y_i - \hat{R}_h x_i)^2}{n-1}}.$$

Therefore an approximate large-sample $(1-\alpha)$ 100% confidence interval for R_{st} is given by $\hat{R} \pm t_{n-1,\alpha/2}\, s(\hat{R}_{st})$, where $t_{n-1,\alpha/2}$ is the $a/2$ tail quantile of the t distribution having n-1 degrees of freedom.

Sample size requirements for estimating a ratio

Given two random variables x_i and y_i to be observed from a simple random sample of n elements from a finite population of size N, the sampling variance of the estimated ratio $\hat{R} = \sum_{i=1}^{n} y_i \Big/ \sum_{i=1}^{n} x_i$ is given by[1]

$$s^2(\hat{R}) = \frac{1-\frac{n}{N}}{n\bar{x}^2} \frac{\sum_{i=1}^{n}(y_i - \hat{R}x_i)^2}{n-1} \qquad (1)$$

where $\bar{x} = \sum_{i=1}^{n} x_i / n$. Let B denote the desired margin of error (confidence interval half-width) for estimation of R so that $\left(B/z_{\alpha/2}\right)^2 = s^2(\hat{R})$, where $z_{\alpha/2}$ is the quantile for the $a/2$ tail area of the normal distribution needed to obtain a $(1-\alpha)$ 100% confidence interval. Substituting $\left(B/z_{\alpha/2}\right)^2$ for $s^2(\hat{R})$ in equation (1) and solving for n yields the sample-size formula given by

$$n = \frac{\hat{\sigma}^2}{\frac{B^2\bar{x}^2}{z_{\alpha/2}^2} + \frac{\hat{\sigma}^2}{N}} \qquad (2)$$

where

$$\hat{\sigma}^2 = \frac{\sum_{i=1}^{n}(y_i - \hat{R}x_i)^2}{n-1}.$$

Here, R is the ratio of verified TX_CURR to reported TX_CURR, so that y and x in the formulas above are verified and reported TX_CURR, respectively. The variance term $\hat{\sigma}^2$ is unknown before the sample of n elements (facilities) is observed. However, given pre-existing similar observations x_j and y_j for $j=1,\cdots,m$, $\hat{\sigma}^2$ can be estimated as

$$\hat{\sigma}_m^2 = \frac{\sum_{i=1}^{m}\left(y_i - \hat{R}x_i\right)^2}{m-1}.$$

Of course, the desired margin of error will only be achieved if it turns out that $\hat{\sigma}^2 = \hat{\sigma}_m^2$, so it is important that $\hat{\sigma}_m^2$ is likely to be at least as large as the unknown $\hat{\sigma}^2$. One solution is to inflate $\hat{\sigma}_m^2$ by a factor greater than 1 (such as 1.10–1.50). The accuracy of the sample size estimate also depends on the accuracy of preliminary estimates of the ratio R and the mean number receiving treatment reported (but not verified) $\bar{x}$ as well as the total number of facilities in the country N.

In the absence of pre-existing observations, one must use tabled values. Table 1 in Annex I shows the previously observed values of R and $\hat{\sigma}^2$.

Reference

1. Cochran WG. Sampling techniques. 3rd edition. New York: John Wiley & Sons; 1977.

Annex C. DQA sample size calculator

See the separate Excel file with the DQA sample size calculator.

Annex D. Informed consent

Project title: Data quality assessment for standard indicators

You are a staff member of a health-care facility providing HIV treatment and care services. This form contains information seeking your consent for participating in validating data at this facility. This activity will help the Ministry of Health and partners in describing the data collection procedures for reporting programme indicators. It will also identify data quality challenges and make recommendations on improving the quality of data reporting in the future. These data will assist the Ministry of Health and partners in continuing to provide high-quality patient care.

We will be interviewing one or more staff members at each health care facility. Each interview will take about two hours. The questions we will ask have no right or wrong answers. We do not believe that we are asking any sensitive questions, but you are free to not answer any question you want or to stop the interview at any time. Refusing to participate will not have any effect on your job at the health-care facility or with the implementing partner.

Your participation in this assessment is voluntary; however, your input is very valuable to us. We will not be recording your name or any other personal information about you. If you agree to participate, we want you to share your perceptions and opinions about the quality and processes of the data and services. If you decide to participate, the information that you provide should not harm you in any way. Similarly, participating provides you no direct benefit other than helping to improve data reporting and clinical services at your health-care facility or at facilities the implementing partner supports.

You will not be given any money for your time in participating in this assessment.

All data collected and information generated will be secure, and the confidentiality of those participating will be protected. Only the interorganizational country team or Ministry of Health staff will have access to the interview data. Feedback on our findings will be provided to the health-care facility and partner staff after each assessment. As stated above, your name and any other personal information about you will not be recorded. Your responses to the interviews will only be identified by an identification code, which will identify the health-care facility or the implementing partner. The results will be combined before reporting to others.

If you have any questions about participating in these interviews or about the assessments, please ask them now. Your participating in the interviews will indicate that you agree to participate in this part of the assessments. It will also indicate that you have had the opportunity to ask any questions about this and that these have been answered to your satisfaction. If you have any further questions, please contact [local contact name and phone number]. You will be offered a copy of this consent document, if you wish. You will not need to sign it since your participation in this assessment will remain anonymous.

Interviewer:

I have read this informed consent form aloud to the interviewee and confirm that he or she agrees to participate in this interview.

Name of the interviewer: ……..

Signature of the interviewer: ……

Date: ……..

Facility code: ……

Annex E. Tool for mapping data flow

Date .....

Partner .....

Clinic name .....

Location .....

Observer .....

Time started .....

Time stopped .....

Introductory script for data mapping

Thank you for having us at your facility today. We are here as part of an interagency effort to ensure the quality of the data collected and reported from this facility. The focus of this data quality improvement project is to identify how we can better support ongoing quality improvement efforts at your facility. We are interested in shifting the orientation of data quality activities from data quality assessment only to include activities that range from routine daily checks (that can address deficiencies immediately) to less frequent activities such as monthly or quarterly data quality assessment. We would like to locate and fix any data defects or bottlenecks within the data workflow to improve the quality of information gathered in real time and moving forward. We would like to help to strengthen and streamline the process for validating patient health information.

Today, we are interested in learning about the data quality challenges and successes at your site. This guiding questions and site visit will be an opportunity to delve deep into the challenges, successes, best practices and innovation in the health information systems here at your facility. To begin, we would like you to walk us through the care and treatment cascade at your facility. Please describe the process that a patient goes through from HIV testing and counselling to pre-ART initiation, ART initiation and ART retention and how this process may differ for various populations, such as pregnant women and HIV-exposed infants. We are interested in learning how services are recorded and patient data tracked throughout the cascade. Finally, we would like to hear how ART information is recorded in the pharmacy and how data are aggregated and verified before monthly and quarterly reporting.

Additional notes can be reported here

ANTIRETROVIRAL THERAPY

Guiding questions	Sketch the data flow: note differences for new or returning patients
When a patient is confirmed as being HIV positive, describe what happens between confirmation and ART initiation. How are the services recorded, and what tools and registers are used? **Consider the following probes.** • How is ART initiation documented? • How is ART retention documented? • At what point in the patient flow are facility or implementing partner unique IDs assigned? Where is this recorded? • Does this process differ between ward and HIV clinic patients? Pregnant women? • Who do patients see before the doctor or health-care provider (triage nurse, medical assistant etc.)? • When are the patient files pulled? • When are the files moved to the doctor's office? • Who is responsible for filing patient files after the appointment concludes? • What is the process of updating registers after patient visits? • Who enters the data into the registers? • How is the patient checked out, including scheduling for the next visit? • When are viral load tests performed? What tools are used to document that blood has been drawn for viral load tests? • What is the process of obtaining results, and where are the viral load results documented?	

PHARMACY

Guiding questions	Sketch the data flow: note differences for new or returning patients
From the first prescription received at a pharmacy to refills, what happens with a patient's health information? How are pharmacy pick-ups recorded and where? Consider the following probes. • How is the patient ID confirmed before they receive their prescription? • How are files transferred between the clinical service and pharmacy? • What files are transferred? • When does the database get updated (if applicable)? • Can patients go directly to the pharmacy for pick-up? • How often do patients pick up ARV drugs? Does this differ for new and established patients? • What documentation do they bring? • How does this differ between the first prescription and refills? • Are there opportunities for quality checks?	

Annex F. Site-level validation

Steps for performing the site-level validation

With assistance from the data associate

1. Identify the main data source used for national reporting (such as electronic medical records, ART register, patient charts etc.) at the facility.
2. If the ART register is the primary national reporting tool:
    a. Systematically select the desired number of patients to be reviewed. Start by opening the register to the last page of the previous month (for example, if conducting a data check on 15 March, open the register to 28 February). Randomly select one patient from the page. Moving backward, select every 20th patient until all the patients are selected. For low-volume clinics, select every fifth patient moving backward.
    b. Using the ART register form (or electronic medical records or pharmacy), abstract the identified data fields for each patient selected, using a dash to note when information is missing.
3. Use the patient chart form to abstract the same data fields for the same patients from the patient charts.
4. Pull the paper patient charts (or other primary source) for all the selected patients.
5. Using information contained in the charts or other primary source, complete the relevant data fields, using a dash to note when information is missing. Make sure that the order of patients is the same across all forms used to abstract patient information so that patients can be compared.

Cross-check the treatment data

Compare the information in each form. For each comparison (ART register versus patient charts or patient charts versus pharmacy), calculate the total discordance across all data elements and patient charts by dividing the total number of column discrepancies by the total number of records compared. Additional calculations should review the percentage discordance within each data element to better understand where information is not being updated routinely. The calculations table below should be filled in before completing the site visit. Any materials with patient information will be destroyed before leaving the facility. If personally identifiable information is collected electronically, the files should be deleted or the paper forms with personally identifiable information should be shredded.

Data management and personally identifiable information

Data from patient charts, ART registers (or electronic medical records) and pharmacy records will be abstracted using the tools provided. Data abstractors will cover the patient's personal identifying information as they review the records, ensuring patient privacy. When data abstraction from all sources has been completed, the discrepancies for each data element in each source comparison will be totalled and noted in the table calculations provided. No patient information will be removed from the facility. All documentation used to calculate the discordance between data sources will be destroyed before leaving the facility.

CALCULATIONS TABLE

	Last ART pick-up date	Last clinic visit (DD-MM-YY)	ART regimen	Last viral load result	% discordance
Total number of records (number of patients reviewed)					
Patient charts versus ART register Total number of discrepancies					
% discordance (variance) Number of discrepancies/number of records reviewed					
Patient charts versus pharmacy records Total number of discrepancies					
% discordance (variance) Number of discrepancies/number of records reviewed					

Team number _____ Site name _____ Date of visit _____

Review a certain number (*n*, determined by the review team) of randomly selected charts (only patients with a recorded visit in the past three months) and compare with the ART register and patient charts. Records can be randomly selected from the electronic system, the ART register or the filing cabinet. Ensure that the records have a visit recorded in the past three months. Record the information from the chart collecting the age or date of birth, sex, date of last recorded clinical visit and the last date the patient picked up their ART medication. These same data points will be collected from the ART register and the pharmacy record if available. The personal identifiers collected on these worksheets will be destroyed before leaving the facility. Use the calculations table to aggregate the totals.

Please record the following variables during site visit: current age and clinical visit during the time period				Pharmacy records					
Patient clinic number	**First name**	**Last name**	**Date of birth (DD-MM-YY)**	**Number**	**Sex (M/F)**	**Last clinic visit (DD-MM-YY)**	**ART regimen**	**Last viral load result**	**Comments**
				1					
				2					
				3					
				4					
				5					
				6					
				7					
				8					
				9					
				10					
				11					
				12					
				13					
				14					
				15					
				16					
				17					
				18					

Patient clinic number	First name	Last name	Date of birth (DD-MM-YY)	Number	Sex (M/F)	Last clinic visit (DD-MM-YY)	ART regimen	Last viral load result	Comments
				19					
				20					
				21					
				22					
				23					
				24					
				25					
				26					
				27					
				28					
				29					
				30					
				31					
				32					
				33					
				34					
				35					
				36					
				37					
				38					
				39					
				40					

Team number _____ Site name _____ Date of visit _____

Review a certain number (*n*, determined by the review team) of randomly selected charts (only patients with a recorded visit in the past three months) and compare with the ART register and patient charts. Records can be randomly selected from the electronic system, the ART register or the filing cabinet. Ensure that the records have a visit recorded in the past three months. Record the information from the chart collecting the age or date of birth, sex, date of last recorded clinical visit and the last date the patient picked up their ART medication. These same data points will be collected from the ART register and the pharmacy record if available. The personal identifiers collected on these worksheets will be destroyed before leaving the facility. Use the calculations table to aggregate the totals.

Please record the following variables during site visit: current age and clinical visit during the time period

ART register

Patient clinic number	First name	Last name	Date of birth (DD-MM-YY)	Number	Sex (M/F)	Last clinic visit (DD-MM-YY)	ART regimen	Last viral load result	Comments
				1					
				2					
				3					
				4					
				5					
				6					
				7					
				8					
				9					
				10					
				11					
				12					
				13					
				14					
				15					
				16					
				17					
				18					

Patient clinic number	First name	Last name	Date of birth (DD-MM-YY)	Number	Sex (M/F)	Last clinic visit (DD-MM-YY)	ART regimen	Last viral load result	Comments
				19					
				20					
				21					
				22					
				23					
				24					
				25					
				26					
				27					
				28					
				29					
				30					
				31					
				32					
				33					
				34					
				35					
				36					
				37					
				38					
				39					
				40					

Team number _____ Site name _____ Date of visit _____

Review a certain number (*n*, determined by the review team) of randomly selected charts (only patients with a recorded visit in the past three months) and compare with the ART register and patient charts. Records can be randomly selected from the electronic system, the ART register or the filing cabinet. Ensure that the records have a visit recorded in the past three months. Record the information from the chart collecting the age or date of birth, sex, date of last recorded clinical visit and the last date the patient picked up their ART medication. These same data points will be collected from the ART register and the pharmacy record if available. The personal identifiers collected on these worksheets will be destroyed before leaving the facility. Use the calculations table to aggregate the totals.

Please record the following variables during site visit: current age and clinical visit during the time period				Patient charts					
Patient clinic number	**First name**	**Last name**	**Date of birth (DD-MM-YY)**	**Number**	**Sex (M/F)**	**Last clinic visit (DD-MM-YY)**	**ART regimen**	**Last viral load result**	**Comments**
				1					
				2					
				3					
				4					
				5					
				6					
				7					
				8					
				9					
				10					
				11					
				12					
				13					
				14					
				15					
				16					
				17					
				18					

Patient clinic number	First name	Last name	Date of birth (DD-MM-YY)	Number	Sex (M/F)	Last clinic visit (DD-MM-YY)	ART regimen	Last viral load result	Comments
				19					
				20					
				21					
				22					
				23					
				24					
				25					
				26					
				27					
				28					
				29					
				30					
				31					
				32					
				33					
				34					
				35					
				36					
				37					
				38					
				39					
				40					

Annex G. Confidentiality agreement

Statement of intent to maintain confidentiality

Project title: Data quality assessment for ART indicators

Interorganizational team lead for data quality assessment:

As a member of this project team, I understand that I may have access to confidential information about study sites and participants. By signing this statement, I am indicating that I understand my responsibilities to maintain confidentiality and agree to the following.

- I understand that names and any other identifying information about study sites and participants are completely confidential.
- I agree not to divulge, publish or otherwise make known to unauthorized people or to the public any information obtained in the course of this research project that could identify the people who participated in the study.
- I understand that all information about study sites or participants obtained or accessed by me in the course of my work is confidential. I agree not to divulge or otherwise make known to unauthorized people any of this information, unless specifically authorized to do so by approved protocol or by the local principal investigator acting in response to applicable law or a court order or public health or clinical need.
- I understand that I am not to read information about study sites or participants, or any other confidential documents, nor ask questions of study participants for my own personal information but only to the extent and for the purpose of performing my assigned duties on this research project.
- I agree to notify the local principal investigator immediately should I become aware of an actual breach of confidentiality or a situation that could potentially result in a breach, whether it involves me or another person.

Signature	Date	Printed name
Signature of the principal investigator	Date	Printed name

Method for validating data on ART

Instructions for the data quality assessment team: please describe in detail the method your team used to validate each indicator.

1. People newly receiving ART

1a. Definition of site method (how does the site collect and report this indicator?): is this different to the method used by the Ministry of Health? If so, how?

1b. Recreation of the indicator	
Site method	**The method used by the Ministry of Health[a]**
Were you able to calculate the site method? ☐ Yes ☐ No If no, explain:	Were you able to calculate using the method used by the Ministry of Health? ☐ Yes ☐ No If no, explain:
Which data sources did you use to calculate by the site method? ☐ ART register ☐ ART patient card ☐ Pharmacy tools ☐ Electronic register or electronic medical records ☐ Other:	Which data sources did you use to calculate by the Ministry of Health method? ☐ ART register ☐ ART patient card ☐ Pharmacy tools ☐ Electronic register or electronic medical records ☐ Other:
Describe how you calculated using the site method (if it is the same as the site method description above, please note that):	Describe how you calculated using the Ministry of Health method:
1. Is the site method consistent with the Ministry of Health method? ☐ Yes ☐ No 2. Are people transferring in excluded? ☐ Yes ☐ No	*The Ministry of Health[a] method:* *Includes = treatment-naive people receiving ART* *Excludes = transfers in*

[a] This should be the same method used by PEPFAR and other partners.

2. People currently receiving ART

1a. Definition of site method (how does the site collect and report this indicator?): is this different to the Ministry of Health method? If so, how?

2b. Recreation of the indicator using site and the Ministry of Health method	
Site method	**The method used by the Ministry of Health[a]**
Were you able to calculate the site method? ☐ Yes ☐ No If no, explain:	Were you able to calculate using the method used by the Ministry of Health? ☐ Yes ☐ No If no, explain:
Which data sources did you use to calculate by the site method? ☐ ART register ☐ ART patient card ☐ Pharmacy tools ☐ Electronic register or electronic medical records ☐ Other:	Which data sources did you use to calculate by the Ministry of Health method? ☐ ART register ☐ ART patient card ☐ Pharmacy tools ☐ Electronic register or electronic medical records ☐ Other:
Describe how you calculated using the site method (if it is the same as the site method description above, please note that):	Describe how you calculated using the Ministry of Health method:
1. Is the site method consistent with the Ministry of Health method? ☐ Yes ☐ No 2. Are people transferring in included? ☐ Yes ☐ No 3. Are people restarting included? ☐ Yes ☐ No 4. Are people transferring out excluded? ☐ Yes ☐ No 5. Are people stopping ART excluded? ☐ Yes ☐ No 6. Are people who are dead excluded? ☐ Yes ☐ No 7. Are people dropping out (lost to follow-up) excluded? ☐ Yes ☐ No 8. Are lost (missed drug pick-up) included? ☐ Yes ☐ No	*The Ministry of Health method[a]:* *Includes = receiving treatment, transfers in, restart, lost (missed drug pick-up)* *Excludes = transfer out, stopped, dead, dropout (lost to follow-up)*

[a] This should be the same method used by PEPFAR and other partners.

Annex H. Record and tally sheets for data quality assessment

Note: The following data collection guidance and tools are an example, and each country is expected to modify the tools to appropriately fit their reporting processes and procedures. For this example, the number of people currently receiving ART and the number of people newly initiating ART were used to demonstrate how the data collection forms can be formatted to capture the appropriate data elements. Countries may need to further refine the data collection fields, disaggregation or months of capture. Since this is just an example, countries may also need to add in additional reporting months or indicators based on their defined needs or objectives such as tools for HIV testing, preventing the mother-to-child transmission of HIV etc.

In this example below, data are being collected and validated across three main collection points for the second quarter of the 2017 fiscal year. As the guidelines note, choosing the most recent time frame for validating the data is best.

For this example:

- **In section 1: the data obtained from PEPFAR through DATIM are available by facility and are obtained on a quarterly basis. For non-PEPFAR sites, if the facility is supported by another partner, these data should be reported. Ministry of Health facility data are obtained from a facility through monthly aggregated reporting forms.**
- **Data obtained directly from the sites through register counts is completed in section 2.**

Instructions

The **[COUNTRY NAME]** ART tally sheets are divided into three sections:

Section 1 will be completed using the national or PEPFAR site-level reported results (such as from DHIS2 or DATIM) for the specific quarter of interest and using facility-level monthly aggregate results for the months that correspond to the quarter of interest. For sites supported by other partners other than PEPFAR, this should be reported in this section. The results from these months for the ART indicators will be directly transcribed in Tables 1 and 2.

Section 2 will be completed by recreating the ART indicators at the site level. The data quality assessment team should work with the health facility staff to understand what tools and systems are being used to calculate the national or PEPFAR (for PEPFAR sites) ART indicators and to replicate that process. The results from the recreated indicators will then be used to complete Tables 3 and 4.

Data quality assessment Form 1: [COUNTRY NAME] ART data quality assessment RECORDING SHEETS

Site Name: _____ Visit Date: _____ Team #: _____

Section 1: reported site data

Complete Tables D1 and D2 using reported site-level results for the Ministry of Health and for partners for the selected time period. PEPFAR results can be pulled directly from DATIM or via an implementing partner database. Ministry of Health results can be accessed using the Ministry of Health monthly reports found at the health facility or through an alternative health ministry mechanism (a health information system if possible).

TABLE D1. SITE DATA ON THE NUMBER OF PEOPLE NEWLY INITIATING ART

Data source: DATIM results (quarter and year) *Ministry of Health monthly reporting form: months X–Z*

	PEPFAR (DATIM or PEPFAR-specific data system) or other partner data: quarter 2 in fiscal year 2017	Ministry of Health monthly report (January 2017)	Ministry of Health monthly report (February 2017)	Ministry of Health monthly report (March 2017)	Ministry of Health quarterly total for quarter 2 in fiscal year 2017	Comments
Total numerator						
Disaggregates						
Pregnant						
Breastfeeding						
Confirmed TB or TB treated						
Age and sex disaggregation						
0–4 years old (both sexes)						
5–9 years old (both sexes)						
Females						
10–14 years old						
15–19 years old						
20–24 years old						
25–49 years old						
50+ years old						
Unknown						
Males						
10–14 years old						
15–19 years old						
20–24 years old						
25–49 years old						
50+ years old						
Unknown						

Site Name: _____ Visit Date: _____ Team #: _____

TABLE D2. DATA COLLECTION TOOL – REPORTED SITE DATA ON THE NUMBER OF PEOPLE CURRENTLY RECEIVING ART

Use this table to record the reported results for the number of people currently receiving ART across all disaggregates for both PEPFAR and other partners (for sites supported by partners other than PEPFAR) and Ministry of Health reporting. Be sure to verify the correct time frame being reviewed. For the number of people currently receiving treatment reported by the Ministry of Health, use the reported data from the last month in the quarter (for the second quarter: March)

PEPFAR data sources and quarter: _____ Ministry of Health data sources (month reviewed): _____

	PEPFAR (DATIM or PEPFAR-specific data system) or other partner data: quarter 2 in fiscal year 2017	Ministry of Health monthly report (March 2017)	Comments
Total numerator			
Disaggregates			
Age and sex disaggregation			
0–4 years old (both sexes)			
5–9 years old (both sexes)			
Females			
10–14 years old			
15–19 years old			
20–24 years old			
25–49 years old			
50+ years old			
Unknown			
Males			
10–14 years old			
15–19 years old			
20–24 years old			
25–49 years old			
50+ years old			
Unknown			

Data quality assessment Form 1: [COUNTRY NAME] ART data quality assessment RECORDING SHEETS

Site Name: _____ Visit Date: _____ Team #: _____

Section 2: recreating the indicators

Complete Tables D3 and D4 using the same methods the ART site uses for calculating the indicators (site method) when they complete the national or PEPFAR or partner data collection tool. Record the numbers recreated for each indicator in the site method section in each of the tables. If this method differs from the PEPFAR or partner method (as defined in the PEPFAR guidance on monitoring, evaluation and reporting indicators), recreate the numbers using the PEPFAR or partner method and record this in the PEPFAR or partner method section of the tables. The example tally sheets for each indicator are used to keep track of the count as each patient is identified for each indicator.

TABLE D3. RECOUNTED OR VERIFIED NUMBER OF PEOPLE NEWLY INITIATING ART IN THE SECOND QUARTER OF FISCAL YEAR 2017

Use this table to fill in the totals collected from the tally sheets. If the site method differs from the national recommended method of recounting people newly initiating ART, recount using both methods and record this in the appropriate columns. In addition, if there is an electronic medical records system but it is not used to verify people newly initiating ART, the electronic medical records column can be used to include these totals.

	Electronic medical records (optional)	Site method	Ministry of Health[a] method (if applicable)	Comments
Total numerator				
Disaggregates				
Pregnant				
Breastfeeding				
Confirmed TB or TB treated				
Age and sex disaggregation				
0–4 years old (both sexes)				
5–9 years old (both sexes)				
Females				
10–14 years old				
15–19 years old				
20–24 years old				
25–49 years old				
50+ years old				
Unknown				
Males				
10–14 years old				
15–19 years old				
20–24 years old				
25–49 years old				
50+ years old				
Unknown				

[a]This should be the same method used by PEPFAR and other partners.

Site Name: ____________________ Visit Date: ____________________ Team #: ____________________

Tally sheets for recounting the number of people newly initiating ART (the Ministry of Health method)		Total
Pregnant	00000 00000	
Breastfeeding	00000 00000	
Confirmed TB or TB treated	00000 00000	
Age and sex disaggregation	**Total ART clinic registrations**	
0–4 years old (both sexes)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
5–9 years old (both sexes)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
Females		
10–14 years old	00000 00000	
15–19 years old	00000 00000	
20–24 years old	00000 00000	
25–49 years old	00000 00000	
50+ years old	00000 00000	
Unknown	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
Males		
10–14 years old	00000 00000	
15–19 years old	00000 00000	
20–24 years old	00000 00000	
25–49 years old	00000 00000	
50+ years old	00000 00000	
Unknown	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	

Data quality assessment Form 1: [COUNTRY NAME] ART data quality assessment RECORDING SHEETS

Site Name: _____ Visit Date: _____ Team #: _____

TABLE D4. RECOUNTED AND VERIFIED NUMBER OF PEOPLE CURRENTLY RECEIVING ART IN THE SECOND QUARTER OF FISCAL YEAR 2017

Use this table to fill in the totals collected from the tally sheets. If the site method differs from the national or PEPFAR or partner-recommended method of recounting people currently receiving ART, recount using both methods and record it in the appropriate columns. In addition, if there is an electronic medical records system but it is not used to verify the number of people currently receiving ART, the electronic medical records column can be used to include these totals.

	Electronic medical records (optional)	Site method	Ministry of Health[a] method (if applicable)	Comments
Total numerator				
Age and sex disaggregation				
0–4 years old (both sexes)				
5–9 years old (both sexes)				
Females				
10–14 years old				
15–19 years old				
20–24 years old				
25–49 years old				
50+ years old				
Unknown				
Males				
10–14 years old				
15–19 years old				
20–24 years old				
25–49 years old				
50+ years old				
Unknown				

[a]This should be the same method used by PEPFAR and other partners.

Site Name: ____________ Visit Date: ____________ Team #: ____________

Tally sheets for recounting the number of people currently receiving ART (the Ministry of Health method)		Total
Age and sex disaggregation	Total ART clinic registrations	
0–4 years old (both sexes)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
5–9 years old (both sexes)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
Females		
10–14 years old	00000 00000	
15–19 years old	00000 00000	
20–24 years old	00000 00000	
25–49 years old	00000 00000	
50+ years old	00000 00000	
Unknown	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
Males		
10–14 years old	00000 00000	
15–19 years old	00000 00000	
20–24 years old	00000 00000	
25–49 years old	00000 00000	
50+ years old	00000 00000	
Unknown	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	

Annex I. Site summary template for data quality assessment

Introduction

- Objectives of the data quality assessment
- Include the site name, date of the visit and names of the reviewers

Methods

- Verifying the reported data
- Cross-checking data across source documents
- Mapping patient and data flows

Results

- Summary of the quantitative results (Annex J can be used to summarize the results for all sites)

TABLE G1. CROSS-VALIDATION (OR OTHER OPTIONAL ACTIVITY) AT THE SITE LEVEL

		Percentage variance		
Source document 1	Source document 2	Overall concordance	Data element 1, such as the last ARV pick-up date	Data element 2, such as the last viral load result
Example: patient charts	Such as a register (paper or electronic)	90%	90%	80%

Summary of qualitative results (complete if the activity is performed) at the site level

- General insights from the data flow mapping
- General insights from the checklist for assessing the site-level HIV patient monitoring system, which might inform the interpretation of the verification factors

Priority concerns and data quality issues

- Highlight two or three data quality issues or concerns

Plans for remediation and follow-up

- Should be based on dialogue with site-level staff and should be actionable and feasible to immediately address data quality issues and draw on the recommendations of the checklist for assessing the site-level HIV patient monitoring system
- Should include a site-level and above-site-level point person for following up on the progress of remediation plans

Annex J. Example of how to adjust ART data at the national level

See the separate Excel file with an example of how to adjust data at the national level.

For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv