World Health Organization

HIV STRATEGIC INFORMATION FOR IMPACT

IMPLEMENTATION TOOL

MODULE FOR ASSESSING AND STRENGTHENING THE QUALITY OF VIRAL LOAD TESTING DATA WITHIN HIV PROGRAMMES AND PATIENT MONITORING SYSTEMS

SEPTEMBER 2020

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ABBREVIATIONS AND ACRONYMS

ART	antiretroviral therapy
ARV	antiretroviral
DBS	dried blood spot
DHIS2	District Health Information Software
DQ	data quality
DQA	data quality assessment
DQI	data quality improvement
EMR	electronic medical record
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
LIMS	laboratory information management system
LQAS	lot quality assurance sampling
PEPFAR	United States President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VL	viral load
WHO	World Health Organization

GLOSSARY

Cross-validation: Comparison of the consistency of key data elements between different sources, in which patient files are usually used as the main source document or gold standard.

Data quality (DQ) assurance activity: used as an umbrella term to refer to the range of DQ activities recommended in this module, including routine DQ assessment, DQ monitoring via supportive supervision or using lot quality assurance sampling (LQAS) and routine site level data/performance review.

Data quality assessment: one of the DQ assurance activities recommended in this module. Its primary activity involves recounting and verifying indicators to enable comparison with those reported to ministries of health. This module recommends routine data quality assessment. However, nationally representative data quality assessments or audits may be implemented to validate national viral suppression data or based on programmatic needs, including findings of previous routine DQ assurance activities that indicate persistent or substantial DQ challenges or discrepancies between different data systems or partner data.

Data quality improvement: a process designed to strengthen the quality of data and the underlying data management and reporting systems. It encompasses a broad range of activities, including but not limited to training and mentoring, developing standard operating procedures for data entry, cleaning and management, deduplicating data, updating electronic and paper data sources and DQ assurance activities.

Decision rule: a rule used for DQ monitoring using lot quality assurance sampling (see below for definition). The decision rule determines how many records (such as patient files) need to be sampled within the source document (such as an antiretroviral therapy register) for the entire lot to be classified as acceptable.

Lot: a lot is the collection of patient records in a source document: for example, a register.

Lot quality assurance sampling: a DQ assurance activity described in this module that uses a classification method to define acceptable and unacceptable levels of data completeness and consistency.

Person-centred monitoring: refers to monitoring that places the person at the centre of accessing and measuring a sequence of health services (such as from testing to linkage to treatment) and involves people and benefits to them in the monitoring process. In the context of this publication, it refers to a shift from measuring services (such as the number of HIV tests or the number of people receiving treatment) to supporting people receiving HIV and health services by putting them at the centre of monitoring.

Source document: in this module, this describes the main document (usually patient charts or files) used as the gold standard to assess and cross-validate data elements captured in other data sources such as registers, electronic medical records and laboratory information management systems.

1. INTRODUCTION

In recent years, ensuring and improving data quality (DQ) has grown increasingly important within health programmes for strengthening patient monitoring. This has reinvigorated efforts to improve the quality of routine data and use to improve patient management and programmatic impact, enable performance monitoring and increase accountability. Good-quality data not only enhances confidence but also the credibility of data, enabling better evidence-informed programme planning, decision-making, resource allocation and service delivery. Recognizing this, a number of countries and implementing partners have made significant investments and contributions for strategic initiatives to support DQ improvement (DQI) and use within HIV programmes and health information systems more broadly.

Since many countries are now approaching the UNAIDS 90–90–90 targets and moving towards the 95–95–95 targets for HIV treatment and care[1], it is now more important than ever to collect and report accurate data in real time to understand where gaps in service delivery remain and ensure the use of data to improve programme management and quality.

Historically HIV DQI activities were given priority within treatment programmes to support efforts to increase treatment coverage and retention, and to ensure correct quantification, procurement and supply of antiretroviral (ARV) drugs and laboratory commodities. As a result, DQ tools and activities have primarily focused on HIV treatment indicators. Strengthening DQ and use along the entire cascade of HIV services, however, is essential for ensuring the quality and continuity of HIV care *(2,3)*. Moreover, given the importance of viral suppression as a key outcome of HIV treatment, ensuring accurate and timely viral load (VL) data, with the results available for use, is critical for enhancing programmatic impact and improved clinical care and outcomes for people living with HIV (PLHIV).

Recognising that strong DQ is a precursor to strong data use, in 2017 WHO launched the consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(2)*, which included the implementation of periodic DQ assessments (DQA) among its 15 key recommendations. This was followed by the development and publication of the first joint implementation tool for DQA for HIV treatment programmes in 2018 by WHO, UNAIDS, PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) to address concerns around the accuracy of data on antiretroviral therapy (ART) and improve DQ and systems *(4)*. The joint DQA tool was developed to help countries undertake rapid and robust national DQA with a focus on but not limited to HIV treatment while improving and supporting patient monitoring systems to strengthen DQ and improve use.

Following this guidance, a number of countries implemented national DQAs of HIV treatment data between 2018 and 2019. According to the Global AIDS Monitoring, by July 2020, 56 countries reported completing a DQA to determine the accuracy of national-level data on the number of people receiving ART in the previous year and had results. A further 15 countries were conducting a DQA at the time of reporting and expected results the following year *(5)*. This indicates the increasing priority countries are giving to DQA activities and provides an opportunity to integrate and expand these efforts to include other HIV programmatic indicators along the care cascade.

Moving forward, there is greater recognition that efforts to ensure DQ should not be limited to one-off exercises such as national DQAs but rather routine activities that are institutionalized and integrated as part of strengthening health information systems and long-term DQI strategies. DQI should be considered an integral part of programme implementation and a key component of continuous quality improvement of services. This requires implementing people-centred monitoring approaches to HIV data at the service delivery level. This places the person at the centre of accessing and measuring a sequence of health services (such as from testing to linkage to treatment) and involves people and benefits to them in the monitoring process. In the context of this publication, it refers to a shift from measuring services, such as the number of VL tests or people receiving treatment, towards people. This in turn relies heavily on measuring and analysing performance to improve the quality of care, which is underpinned by accurate, valid and complete data.

In addition, DQ assurance activities should target a broader range of indicators of programmatic priority, preferably integrating VL monitoring to enable accurate measurement of programme performance and improved service quality. In accordance with this, in 2019 WHO and the PEPFAR VL working group issued technical guidance on considerations for developing a monitoring and evaluation framework for VL testing *(6)*. The guidance recommended implementing routine quality assessments of VL data and noted that further guidance and protocols for implementing DQAs are needed. The guidance also recommends, when possible, that DQ assurance activities be implemented jointly with service delivery and quality assessments. In accordance with these recommendations and with a view to supporting the institutionalization of DQ within programme management, this module focuses on routine DQ assurance activities that can be implemented more frequently and combined with service delivery and quality assessments.

[1] The targets are that 90/95% of people living with HIV know their HIV status; 90/95% of the people who know their HIV-positive status are accessing treatment; and 90/95% of the people receiving treatment have suppressed viral loads by 2020 (90%) and 2030 (95%) *(1)*.

2. GOAL, OBJECTIVES AND TARGET AUDIENCE

2.1. Goal

The overarching goal is to support the assessment of DQ, strengthen data and patient monitoring systems and support data use for programme improvement. This module aims to support countries in implementing routine DQ assurance activities for assessing and strengthening the quality of VL testing data at sites that deliver HIV services and is a supplement to the 2018 DQA implementation tool for HIV treatment *(4)*. The module enables countries to select DQ assurance activities tailored to their context and aligned with existing DQI strategies.

In addition, it intends to support efforts to institutionalize such activities and integrate them within other ongoing DQ assurance activities focused on other HIV programme indicators, to improve data and its use along the cascade of care in accordance with the WHO 2020 consolidated HIV strategic information guidelines *(3)*, the WHO 2017 consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(2)* and national HIV treatment and care guidelines.

Efforts to enhance the quality and use of data, including accuracy, timeliness, completeness and return to the facility and patient records of VL testing and suppression data are envisaged to improve programme implementation and clinical outcomes and to support the validation of national estimates of viral suppression. VL data are important for patient care and as a key outcome of the care cascade to achieve treatment goals.

2.2. Specific objectives

The objectives of this module are:

- To enable rapid assessment and verification of the quality and coverage of VL testing data, including completeness, reliability and accuracy at select facilities and laboratories on a routine basis;
- To assess bottlenecks to improving DQ, including those linked to the return of test results to facilities and patient records (including electronic medical records and laboratory information management systems) to improve care and feed into the development of strategies to reduce VL result turnaround time.
- Address DQ and service flow for both laboratory or referral testing and point-of-care or facility-based testing and potential differences.
- Support the development and implementation of key remedial actions that can be followed up to address the root causes of identified DQ challenges in VL monitoring and strengthen data systems.
- Support the rapid use of VL testing data to improve patient care and programme management, for example to implement differentiated care for stable patients or support the management of patients with elevated VL and respond to gaps in viral suppression and ensure data use.

2.3. Target audience

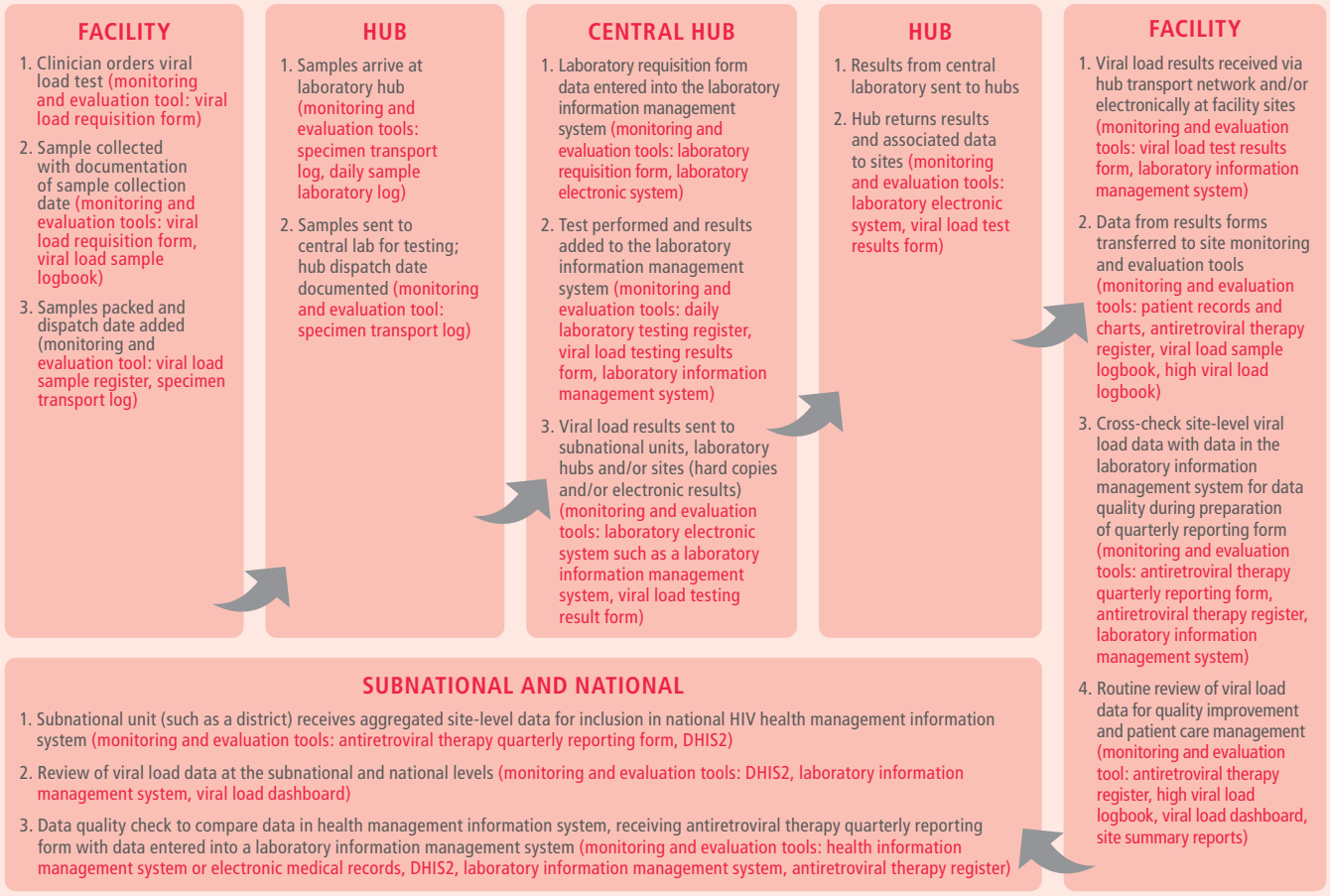
This module is intended primarily to serve the needs of HIV programme staff who supervise facility and laboratory staff engaged in collecting, entering, managing and reporting HIV-related VL strategic information within the health sector. The activities included in this module may be implemented by supervisory teams involved in conducting routine DQ assurance and improvement activities at the facility or laboratory level. Other potential users include stakeholders who supervise, collect, manage and analyse strategic information, including health facility staff, nongovernmental organizations, private-sector care providers, civil society and academic groups involved in teaching and research. These stakeholders can participate in government-led consultative processes for DQI.

3. VL INDICATORS

Measuring and understanding progress towards the viral suppression target among people receiving ART and as a proportion of all PLHIV has proven challenging in many countries, where the coverage and reporting of VL testing has been suboptimal. Several bottlenecks limit the availability and use of VL testing data to enhance patient care and programme improvement. First, routine VL testing may not be offered at all treatment facilities or may target specific populations, which is often less frequently implemented. As a result, the representativeness of estimates of viral suppression based on those accessing testing may be over- or underestimated, and this could introduce bias in interpreting the results. Assessing the completeness of VL monitoring data at the facility and laboratory level and determining the coverage of VL testing in terms of the proportion of eligible PLHIV who receive a test and have their results documented in their patient records and used is therefore important.

Second, at the facility or laboratory level, timely transmission, receipt and use of VL test results is a key issue in many settings affecting both the completeness of data and quality of care. Understanding the flow of results and assessing the average turnaround time from blood draw to the laboratory and from the laboratory to facility and ultimately patient records is essential to identify delays in reporting results. Bottlenecks in reporting or returning VL results need to be identified to support remedial actions, improve data flow and ensure the clinical utility of results for improved patient care and service delivery. Fig. 1 illustrates recommended standard operating procedures for data capture, flow and analysis that can be used to address such bottlenecks.

FIG. 1. EXAMPLE OF DATA FLOW AND STANDARD OPERATING PROCEDURES FOR DATA CAPTURE, FLOW AND ANALYSIS FOR VL TESTING[a]



[a] This is applicable to laboratory networks served by hubs and regional laboratories.
Source: *Technical update. Considerations for developing a monitoring and evaluation framework for viral load testing (6).*

In addition, understanding and verifying the level of concurrence in VL test results between different sources (paper-based patient records, versus electronic medical records (EMR) as well as VL testing databases and laboratory information management systems (LIMS) and laboratory test result forms) is important for establishing the origin of observed DQ issues.

Moreover, the availability of disaggregated data on VL coverage and suppression by age, sex, pregnancy status, key population and TB status is also important for programme monitoring and identifying gaps in service delivery for specific populations and groups and has been lacking in many settings. Assessing whether country data systems can meet the needs for disaggregated information is therefore critical.

Finally, at the district, subnational and national levels, integrating and linking LIMS to HIV patient monitoring systems is a challenge in settings where unique identifiers for health or HIV services are not available. As a result, distinguishing the actual number of people who received a VL test result as opposed to the number of tests performed has been challenging in certain contexts and has affected the accuracy of aggregate reporting and the return of results to patients to improve the quality of care. DQ assurance activities can help to address and support the validation of VL monitoring data collected through aggregate reporting systems. Data visualization tools, including dashboards of key VL testing indicators at the district, subnational and national levels, can also help to identify and address DQ challenges within aggregate systems and contribute towards strengthening programme monitoring efforts.

In summary, all these issues affect the quality of VL testing coverage and suppression data. In this context it is recommended that the following indicators be given priority for routine DQ assurance activities. These indicators below should align with national ministry of health indicators for VL coverage and suppression.

- **Proportion of people on ART (at least 6 months) with VL test results**
- **Proportion of people on ART (for at least 6 months) who have virological suppression** (based on routine VL testing)

In addition, given the importance of timely transmission and receipt of VL results for both data completeness and quality of care, the turnaround time of VL results should also be assessed. Countries may also consider including other indicators that are of programmatic and clinical priority in accordance with their needs and context.[2]

A wider range of indicators are recommended for comprehensive monitoring and evaluation of the VL testing service. Further information on recommended indicators and tools and broader considerations and guidance for countries in establishing monitoring and evaluation frameworks for VL testing are available in the 2019 technical update from the WHO and PEFPAR VL group *(6)*.

Finally, the definition of viral suppression depends on the sensitivity of the test and what level of virus it can detect. For this module, in accordance with the 2016 consolidated WHO ARV guidelines *(7)* and the 2020 WHO consolidated HIV strategic information guidelines *(3)*, it is defined as a VL of less than 1000 copies/mL. However, countries may consider using thresholds that are more appropriate to their context.

[2] Additional VL indicators recommended in the WHO consolidated HIV strategic information guidelines *(3)* include (1) early VL testing (six months): number and proportion of people living with HIV receiving ART who had VL monitoring at six months after initiating ART (indicator reference: AV.7) and (2) appropriate second (follow-up) VL test: proportion of people receiving ART with VL ≥1000 copies/mL who received a follow-up VL test within six months (indicator reference: AV.8).

4. IMPLEMENTATION OF ROUTINE DQ ASSURANCE ACTIVITIES

4.1. Overview

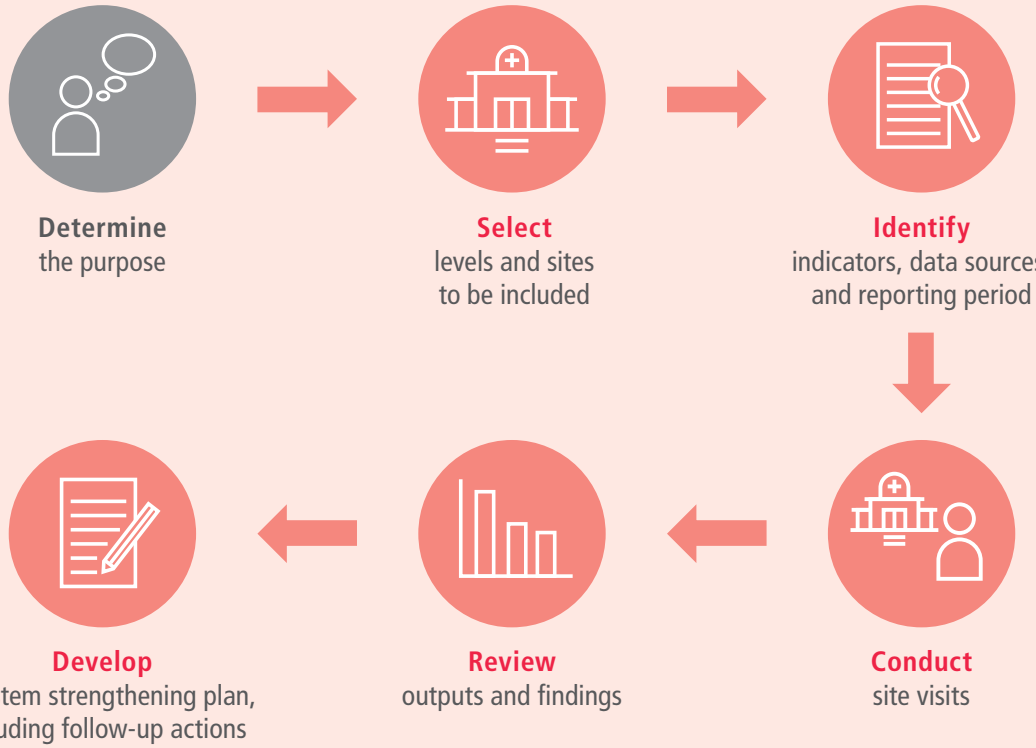
DQ assurance activities determine which types of data need to be improved, the relative strengths and weaknesses of data sources and the reliability and completeness of information and thus support the accurate measurement of programme performance. The steps shown in Fig. 2 are recommended when implementing any routine DQ assurance activity.

Step 1: Determine the purpose of the exercise

The first step is to determine the purpose of the exercise. This will help in selecting the most appropriate routine DQ assurance activity together with considerations of cost, human resource capacity, required time and desired frequency for implementation and the relative strengths and weaknesses of the different approaches. Table 1 describes recommended routine DQ assurance activities along with their relative strengths and weaknesses that countries can use and adapt for their context, building on and linking to existing ongoing DQI initiatives.

Based on the findings of these routine DQ assurance activities, and if there are persistent DQ issues such as repeated negative findings from multiple sites or specific partners etc., a national DQA may be implemented (see subsection 4.2 on routine DQAs, which also includes further details of when a national DQA may be required or appropriate). This may be a comprehensive national DQA or audit if all sites are included.

FIG. 2. STEPS FOR IMPLEMENTING ROUTINE DQ ASSURANCE ACTIVITIES AT HEALTH FACILITIES



Source: *Routine data quality assessment tool – user manual (8).*

TABLE 1. MENU AND ESTIMATED COST OF RECOMMENDED ROUTINE DQ ASSURANCE ACTIVITIES, WITH RELATIVE STRENGTHS AND WEAKNESSES

Recommended routine DQ assurance activity	Description	Strengths	Limitations	Implementation considerations	Indicative costs
1. Routine DQA	External assessment conducted by supervisors focusing on: • Indicator verification: recount of VL indicators at the facility or laboratory level and comparison against the numbers reported to the ministry of health routinely and partners if appropriate • Data completeness checks • Cross-validation of a sample of facility records across different sources (paper versus EMR or laboratory result forms and VL databases or LIMS) to determine the consistency of data across data sources • Mapping of data and service delivery flow (Web Annex B)	• Enables on the spot feedback and mentoring • Cross-validation enables DQ issues to be identified that may only be evident in one data source • Verified recounts from source documents of the number of eligible PLHIV receiving a VL test and verification of the viral suppression indicator enable site-level correction of data • Mapping of data and service delivery flow enables data deficiencies or bottlenecks to be identified and corrected within the data workflow, including returning VL results to facilities and patient records • Site-specific action plans are a key output of DQA exercises and identify key remedial actions to improve DQ	More costly and human resource and time intensive	• Routine DQAs do not need to be national and can be done in a selected number of sites • Quicker to implement than national DQA depending on the number of sites and number of patient files sampled • Can be implemented more frequently than national DQAs or audits • Criteria for selection: desire or need to verify reported VL indicators either externally or coordinated by ministries of health in collaboration with partners • Frequency: semi-annually or annually[a]	$$$$
2. DQ monitoring via supportive supervision	External assessment conducted at the same time as supportive supervision for programme monitoring focusing on assessing: • Data completeness • Cross-validation of a sample of facility records across different sources (paper versus EMR or laboratory result forms and VL databases or LIMS) to determine the consistency of data across data sources (see subsection 4.2 and Web Annexes C and D for sampling methods) • Mapping of data and service delivery flow (Web Annex B) • Assessment of service delivery and quality, including clinical care and laboratory aspects (Web Annexes C and D)	• Enables on-the-spot feedback and mentoring • Cross-validation enables DQ issues to be identified that may only be evident in one data source • DQ monitoring conducted at the same time as supportive supervision provides a convenient and cost-effective method for integration within programme monitoring activities • Can be implemented more frequently than routine DQAs since there is no recount and recreation of indicators and are thus quicker to conduct	Usually includes assessing both service delivery and quality as well as DQ and there may therefore be less time for conducting more comprehensive DQ checks	• Criteria for selection: desire or need to conduct joint assessment of DQ and service delivery and quality or use existing supervision activities for DQI • Frequency: semi-annually[a]	$$

Recommended routine DQ assurance activity	Description	Strengths	Limitations	Implementation considerations	Indicative costs
3. DQ monitoring using lot quality assurance sampling (LQAS)	External or conducted by supervisors. Site-level assessment based on LQAS used to assess the completeness and consistency of records and investigate suspected DQ problems	Selection of sites: enables the identification and targeting of lots (collection of records) not meeting predetermined DQ standards, when more extensive DQ assessment and targeted support for DQI is needed, while acceptable lots can be skipped until the next round of monitoring. Relatively rapid and inexpensive data collection approach that enables small sample sizes and more frequent sampling to categorize and set priorities for areas based on their performance on key indicators.	Sampling and defining the DQ standard for a programme area may be challenging and requires piloting More often applied to ART, since it is "particularly well suited to indicators with extensive recordkeeping from multiple sources" *(9)* and less implementation experience for VL monitoring Assessing concordance can be limited by non-standardized recording of data elements across data sources, which does not reflect real inconsistencies but rather a lack of standardized reporting and recording Focuses on assessing DQ and does not include service delivery and quality	• Criteria for selection: LQAS is useful for identifying sites where a routine DQA could be done with a recount of the indicators and more in-depth completeness and cross-validation checks of a sample or all the active patient files • Frequency: quarterly or semi-annually[a] • Tool: MEASURE Evaluation guide to LQAS for HIV programmes *(10)*	$$$
4. Routine site-level performance review and data review meetings	Clinical team reviews the completeness of data and tallies the results from registers and compares them to the monthly total in the EMR or alternative documenting source, such as laboratory results forms or LIMS The turnaround time for VL test results should also be assessed, given its importance for both data completeness and quality of care	• Enables rapid and frequent review • Low cost • Supports the rapid implementation of site-level correction of data as needed • Enables the facility to develop plans to improve the patient monitoring system • Can be integrated into routine performance review and continuous quality improvement activities to improve service delivery	DQ checks implemented are not as comprehensive as the above activities. Typically, since this is implemented by facility staff, the benefit of support, mentoring and engagement of higher levels, such as district-, subnational- and national-level teams or partners is not leveraged.	• Criteria: ideally implemented in all facilities; however, if it is not feasible in facilities in which previous routine DQAs or DQ monitoring via supportive supervision or using LQAS have identified DQ challenges • Frequency: monthly[a]	$

[a] The frequency of implementation of the DQ assurance activities should align with the VL testing requirements in accordance with national guidelines.
Source: adapted from *A menu of tools for data quality assessment and review (9).*

Step 2: Select sites (for external DQ assurance activities)

Once the purpose or the objective of the exercise has been agreed upon and the type of DQ assurance activity selected, the health facilities and laboratories where it will be implemented should be selected. For DQ activities that are to be implemented in a sample of sites on a routine basis, purposive sampling may be used. This may focus on high-volume sites or those with known DQ issues depending on country needs and context. The number of facilities and laboratories to be sampled should be determined based on available resources and monitoring needs.

In situations in which a facility or laboratory visit may not be feasible, remote DQ assurance activities may be considered. Depending on country data systems, this could include reviewing data extracts or obtaining remote access to data from laboratories and comparing them with either facility or district or subnational aggregate reports from the ministry of health for consistency and completeness.

Step 3: Define the indicators, data sources and reporting period

The indicators to be included in the exercise, such as VL coverage, suppression and test turnaround time, should be selected first. The data sources for the indicator(s) and data elements should then be selected and the time period for assessing the reported data determined.

Step 4: Finalize the assessment tools and prepare for site-level implementation or assessment

Standardized tools and data collection instruments developed specifically for the VL monitoring indicators should be used. The web annexes provide examples of tools that may be adapted to fit local contexts or to accommodate additional indicators. All instruments should be pilot tested and finalized before site assessment begins. In addition, tools should be reviewed periodically and revised as needed between DQ assurance activities to ensure that they are still relevant and useful.

Staff engaged in the DQ assurance exercise and completing on-site assessments should complete training. Training should cover:

- standard operating procedures that outline protocols that teams should follow from pre-departure, on-site and post-departure of site visits (such as preparing site materials, introducing the team to site facility, data abstraction or reviews, site briefing of findings etc.);
- in-depth review of data collection processes and data collection tools to be completed on-site while completing assessments; and
- review of logistics and team assignments.

Step 5: Implement at the site level

Selected facilities and laboratories will be contacted to identify a date and time for the DQ assurance activity. Countries may use their own templates for notifying the sites of the visit, which could 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 visits will vary depending on the specific DQ assurance activity (see subsections 4.2–4.4 for specific details for each activity).

Step 6: Review outputs and findings

Mentoring (if applicable) and feedback of the output and findings of the DQ assurance activities should be provided to relevant facility or laboratory personnel, including management engaged in the exercise as part of the site out-brief. See Section 5 on the outputs of DQ assurance activities for further details.

Step 7: Develop an action plan to address DQ challenges and strengthen the patient and laboratory monitoring system

One of the key outputs should be developing a DQI plan with key site-specific remedial actions based on the findings of the DQ assurance activity to address the observed issues and challenges that are followed up. See Section 5 for further details and Web Annex I for a template DQI plan that can be adapted for use as required.

The following sections provide a more detailed overview of the recommended DQ assurance activities, including describing the methods and implementation considerations.

4.2. Routine DQA

Routine DQAs are exercises led by ministries of health with support from partners that follow similar implementation steps and methods as described in the 2018 WHO, UNAIDS, Global Fund and PEPFAR DQA implementation tool for HIV treatment programmes *(4)*. This includes establishing assessment teams, defining roles and responsibilities and activities to be completed and undertaking site assessments to recalculate specific indicators and compare these with those reported to ministries of health. When possible, VL indicators should be incorporated into existing DQA exercises rather than implemented as standalone activities. Routine DQAs, however, do not necessarily need to be national exercises and will largely depend on the country context, the availability and quality of VL data, findings of previous DQAs or needs based on major discrepancies between, for example, DHIS2 data and LIMS or partner data. In addition, one important use case of national DQAs is to validate country-level data on viral suppression by enabling comparison of the viral suppression coverage verified by a national DQA with viral suppression data reported through the aggregate reporting system at the national level. This will serve to strengthen the data for monitoring the HIV care cascade and the third 95% target for viral suppression. If a country decides to correct or update the national viral suppression coverage following a national DQA, the corrected data should be updated in their Spectrum file and submitted through the Global AIDS Monitoring tool.

Various sampling approaches, such as purposive sampling of high-volume sites, those identified to have DQ challenges in previous assessments or those targeted for programmatic reasons, can be used and a smaller number of sites can be sampled. In addition, the patient monitoring questionnaire included in the 2018 HIV DQA tool *(4)* can be substituted with the clinical facility viral load data and service quality tools included in this module (see Web Annexes C and D), which combine key elements of the patient monitoring questionnaire but are adapted for routine implementation and considerations for VL testing services. These tools rely heavily on-site level data and can be used to assess both VL data and service quality. Web Annex C is an abbreviated assessment tool focusing more on DQ, whereas Web Annex D is a more detailed tool and assesses several aspects of the quality of VL testing services (such as clinical, laboratory etc.) as well as DQ and documentation, tools and reporting of VL data.

The main activities to be implemented during routine DQA include:

- introductory discussions with key staff of the site including facility management and service providers;
- review and completion of informed consent (Web Annex A);
- assessment of service delivery and data flow processes for viral load testing from the facility to the laboratory and from the laboratory to the facility to enable any data deficiencies or bottlenecks within the data workflow to be identified and addressed in real time (Web Annex B);
- checks of the completeness of viral load monitoring data within all or a sample of patient files (see sections 2 and 3 of Web Annex C and part 3 of Web Annex D for examples of tools with data completeness checks);
- cross-validation of data elements of a sample of patient files with laboratory forms, LIMS and/or EMR (see sections 2 and 3 of Web Annex C and Part 3 of Web Annex D for cross-validation activities);
- recount and recreation of viral suppression and coverage indictors (see Web Annex E);
- feeding back findings to the facility and laboratory team and developing a DQI plan for site(s) (Web Annexes F and I); and
- on-the-spot mentoring and feedback as required throughout the exercise.

4.2.1 Recount and recreation of reported numbers for selected VL indicators

The primary activity of a routine DQA is verifying key programmatic indicators reported to ministries of health. In addition to ART indicators, routine DQAs should include VL coverage and suppression indicators, disaggregated by age, sex, key population, pregnancy and TB status if possible. The recounted numbers for these should be compared against the data reported to the ministry of health routinely and partners if desired, following similar steps and implementation arrangements as described for ART indicators in the 2018 WHO, UNAIDS, Global Fund, PEPFAR DQA implementation tool for HIV treatment data *(4)*. It is important to ensure during the recount of indicators that only active clients receiving ART for at least six months are included. Individuals classified as lost to follow-up according to national guidelines and, if relevant and different, partner definitions of lost to follow-up should be excluded. In addition, the percentage of VL tests performed should be calculated and reported per facility along with the number of PLHIV actively receiving ART and eligible for testing who receive a VL test during the selected reporting period.

As noted earlier, these exercises can focus on a smaller number of sites with greater emphasis on implementing more smaller-scale assessments routinely as part of longer term DQI efforts. This contrasts with less frequent, larger nationally representative assessments used to adjust national data on VL coverage and suppression that are more resource intensive and should be implemented when there is a justifiable need because findings from successive routine DQ exercises indicate persistent DQ challenges or to validate national viral suppression data.

Web Annex E provides examples of tools that can be used specifically for recounting and verifying viral coverage and suppression indicators that can be adapted to align with national definitions of these indicators as required. The reasons for possible differences between the values computed during the DQA and the values reported by that site should be further investigated and documented. Remedial activities should be defined and included in the DQI action plan based on site-level findings as described in Section 5.

In addition to recalculating and verifying VL indicators, routine DQA should also incorporate routine checks on VL testing data completeness and cross-validation of data elements. These are described in more detail below.

Completeness checks involve counting in the health facility either how many people had a VL test with results documented in their patient files among all active clients receiving ART for at least six months during the reporting period or from a random sample of these patient files, such as 10% (see Section 2 of Web Annex C or Part 3 of Web Annex D for step-by-step instructions). Understanding the completeness of VL monitoring is important, since data completeness affects both service delivery and DQ. In addition, the consistency of data across sources as described below cannot be assessed if data are missing or incomplete.

Cross-validation of sampled patients across multiple sources is a technique that determines the consistency of data from one source to another. Cross-validation is an important tool for DQ assurance since it can often uncover problems evident in one data source that are less obvious in another and is recommended as a DQ assurance activity in the 2019 technical update on VL testing monitoring and evaluation *(6)*. It involves checking the completeness and accuracy of site-level source documents by cross-referencing identified data elements in routinely reported source documents (typically patient files) with other reporting documents, such as laboratory forms, ART registers, LIMS and the EMR system.

The first step for cross-validation activities is to identify the main data source used for national reporting (such as ART registers or patient files etc.) at the facility. This is followed by systematically selecting the desired number of patient files to be assessed. It is important to ensure when sampling patient files that only the people who meet the national eligibility criteria for VL testing (such as receiving ART for at least six months) and not lost to follow-up or transferred out of the facility are selected. The following options can be used to select the number of patient files to be assessed for completeness and cross-validation.

Option 1: select 10% of the charts from people receiving ART for at least six months with a VL test documented in the last month. Alternatively, if the LIMS is the source data, randomly select 10% of patients from a line list of patients with VL results returned in the past month extracted from the LIMS, which should be taken to the facility. If at least 10% of the charts reviewed are inconsistent with the alternative data source (EMR, LIMS or laboratory forms), this site should be included in the next planned routine DQA to better understand the challenges in consistency and DQ. Similarly, for checks on whether all eligible people (such as those actively receiving ART for at least six months) have a VL test documented, 10% of these patient files can be sampled and checked for completeness. If 10% of the reviewed files do not include a VL test, then the site should be included in the next routine DQA as above for further assessment *(4)*.

Option 1: may be more feasible to implement routinely given the time and resource constraints associated with reviewing a large sample of patient charts.

Option 2: 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 *(4,11)*. This may be preferable in instances such as following up findings of LQAS (see subsection 4.4) of the completeness and consistency of data elements that indicate DQ challenges that would warrant more in-depth review and assessment of a larger sample of patient files.

If cross-validation and completeness checks of a sample of patient files indicate significant issues of concern, these facilities can be targeted for more comprehensive or full review and cross-validation of patient files of those eligible for a VL test within the selected reported period in future follow-up DQI initiatives.

4.2.2 Data elements to be cross-validated

Selected data elements, including the date of the last VL test, the result of the last VL test and the date ART was initiated, are compared between data sources (Sections 2 and 3 of Web Annex C and Part 3 of Web Annex D can be used for this), which will be adapted to country data systems. Country teams will determine the number and types of data elements to be reviewed. The data collected will be used to calculate the percentage of discordance between the source document (usually patient files) and other data from reporting tools such as the LIMS, EMRs and/or laboratory result forms across all data elements. This is calculated by dividing the total number of column discrepancies by the total number of records compared (see the data cross-validation worksheet in Web Annex F).

4.3. DQ monitoring through supportive supervision

Supportive supervision is a facilitated approach to quality improvement that provides mentorship and leadership to health-care workers and data clerks to strengthen the quality of services. DQ monitoring can be combined with routine supportive supervision and is typically implemented more frequently than routine DQA and therefore enables more periodic assessment. DQ monitoring implemented via supportive supervision includes the same DQ checks for completeness and consistency described above. It may not, however, include recalculating and verifying VL indicators, since this requires more time and might not be feasible since supportive supervision focuses on mentorship and more detailed assessment of service delivery and quality. Supportive supervision is included as an option in this module to enable more frequent but less extensive review of the quality of facility and laboratory data.

As with routine DQA, it is recommended that Web Annex B be completed first to describe and understand data and service flow in the facility. This is then followed by administering the supervision assessment tool, which includes both service delivery and DQ. Web Annex C, which is a short tool, or Web Annex D, which is more comprehensive, can be used for supportive supervision. Finally, a DQI plan should be developed and shared with the facility during the site outbrief (Web Annex I).

4.4. DQ monitoring using LQAS

LQAS is a method for site-level assessment and supervision that enables assessment of the completeness and consistency of records and investigation of suspected DQ problems. It enables programme implementers to use small sample sizes of records and more frequent sampling to categorize and set priorities for areas by their performance on key indicators *(12)*. The approach involves establishing a predetermined DQ standard for each indicator and data element, and this can be for both completeness and consistency across the source document(s) (such as an ART register). A decision rule is then set that determines how many records (such as patient files) need to be sampled within the source document (such as an ART register) for the entire lot to be classified as acceptable. Using this, lots that do not meet the predetermined standards for quality are identified as requiring DQI and can be targeted for more extensive DQ review, including routine DQA. Acceptable lots that meet the DQ standards can be skipped until the next round of monitoring.

The key implementation steps for DQ monitoring using LQAS include the following:

- introductory discussions with key staff of the site, including facility management and service providers;
- reviewing and completing informed consent forms (Web Annex A);
- determining the source document to be assessed such as an ART register;
- defining the reporting period over which the completeness and consistency of the source document will be assessed;
- determining the sample size and number of sampled patient files within the source document that must be assessed as acceptable for the entire lot to be considered acceptable (decision rule for skipping);
- determining the data elements (such as the date of the last VL test and the result) to be assessed within a patient file;
- determining the number of patient files to be assessed;
- sampling the patient files; and
- feeding back the findings to the facility or laboratory team and developing a DQI plan for site(s) (Web Annex I).

A detailed description of the methods of this approach, including sampling, is available in the *"measuring the quality of HIV/AIDS client level data using lot quality assurance sampling" (12)* guide along with an accompanying LQAS data collection and analysis tool *(10)*.

4.5. Site-level routine review of data and performance

Routine site-level reviews of data and performance involving facility and laboratory staff held to verify and check reports of VL testing and suppression data before monthly reporting to the ministry of health represent a low-cost DQ assurance approach facilities can use to check and correct their data at source. In addition, this enables on-the-spot mentoring and feedback to staff engaged in data entry and reporting. These reviews can be part of broader continuous quality improvement processes seeking to strengthen the quality of VL testing services using VL testing and suppression data. Clinical teams should review the completeness of VL testing data recorded within the ART register and then tally the number and proportion of eligible PLHIV with a VL test and suppressed VL in the registers for that month compared with the numbers included in the ministry of health monthly report and/or in an alternative documenting source, such as laboratory result forms, LIMS database or EMR. In addition, the turnaround time for VL tests should also be assessed, since this affects both data completeness and service delivery. Key indicators for HIV testing and ART should also be tallied and reviewed along with VL indicators so that key services in the HIV cascade can be reviewed together and used to inform continuous quality improvement activities. Web Annex F (site-level data review tab) includes templates of tables that can be used and adapted to record and display the results of monthly data reviews.

It is recommended that data and performance be routinely reviewed in all health facilities. However, if this is not feasible, monthly data reviews are recommended for facilities identified to have substantial or recurring DQ issues based on findings of previous routine DQAs, DQ monitoring via supportive supervision or using LQAS.

5. OUTPUTS OF DQ ASSURANCE ACTIVITIES

The results of DQ assurance activities should be documented and presented to the facility and/or laboratory staff in a format that is easily digested. When possible, graphical display or a dashboard with results is preferable and should be presented as part of the site outbrief. A copy of these results should be left with facility and laboratory staff for their documentation and to motivate and encourage future improvement. See Web Annex F for generic templates to display the results of the output of routine DQA, DQ monitoring via supportive supervision and routine site-level data reviews and the MEASURE Evaluation LQAS tool *(10)* to display the results of data completeness and consistency assessment using this method.

Data ownership for DQ assurance activities will be under the ministry of health. The ministry of health will maintain the results to monitor DQ issues and to track any follow-up action necessary as a result of the assessment. The data collected as part of DQ assurance activities will not be publicly available since they will comprise tallies and counts of data consistency. The value of the data set to the public is limited, and the cost of making the data sets accessible is prohibitive *(4)*. The ministry of health should ensure that the results and documentation of DQ assurance activities reach the appropriate levels (such as facility, district, subnational and national), relevant focal points and partners (see Web Annex G for suggested template).

Regardless of the type of DQ assurance activity implemented, the main output should be development of a site-specific action plan based on the findings for improving DQ. This should include the identified remedial actions and measures, the organization and staff responsible, the timeline for completion, the resources required and follow-up (Web Annex I provides a template for a DQI action plan). Plans for remedial action and follow-up should be based on dialogue with site-level staff and should be feasible to implement immediately to address DQ issues. This will assist with ensuring buy-in and ownership of the action plan and will obtain insights from facility staff. Action plans should include a site-level and above-site-level point person for following up on the progress of remedial plans.

6. FOLLOWING UP DQ ASSURANCE ACTIVITY FINDINGS

Depending on the findings from the initial DQ assurance activities, five main scenarios can be envisioned in terms of follow-up actions, of which the first three relate to following up routine DQA.

Scenario 1: routine DQA reveals no significant issues (discrepancy less than 5%)

A. DQ monitoring combined with routine supportive supervision visits or using the LQAS method will be conducted, during the next quarter, in sites not reached by the routine DQA.

- If DQ monitoring via supportive supervision or LQAS fails:[3]
  – conduct in-depth data review;
  – conduct refresher training for staff responsible for data management and reporting in this facility; and
  – fix the issues identified and revise the report submitted.

- If DQ monitoring via supportive supervision or LQAS does not fail:
  – conduct refresher training for staff responsible for data management and reporting in this facility; and
  – fix the issues identified (discrepancy of the routine DQA) and revise the report submitted.

B. Routine DQA should be conducted one year later (assuming that the frequency for VL testing is once a year) in facilities not reached by the previous routine DQA.

C. Monthly facility-level data review will be conducted as planned.

Scenario 2: routine DQA reveals issues (discrepancy 5–10%)

A. DQ monitoring combined with routine supportive supervision visits or using the LQAS method will be conducted, during the next quarter, in the same sites reached by the routine DQA.

- If DQ monitoring via supportive supervision or LQAS fails:
  – conduct data review led fully by ministry of health staff or other staff not working in this specific facility;
  – conduct refresher training for staff responsible of data management and reporting; and
  – conduct DQ monitoring via supportive supervision or LQAS in 10% of the same facilities one quarter later.

- If DQ monitoring via supportive supervision or LQAS does not fail:
  – conduct in-depth data review supervised by at least one staff member not working in this specific facility;
  – conduct refresher training for staff responsible for data management and reporting in this facility;
  – conduct DQ monitoring via supportive supervision or LQAS in 5% of the same facilities one quarter later.

B. Conduct routine DQA one year later (assuming that the frequency for VL testing is once a year) in a sample of facilities, including some of those reached by the previous routine DQA.

Scenario 3: routine DQA identified issues (discrepancy exceeds 10%):

A. Conduct DQ monitoring combined with routine supportive supervision visits or using the LQAS method during the next quarter in the same sites reached by the routine DQA.

- If DQ monitoring via supportive supervision or LQAS fails:
  – conduct data review led fully by ministry of health staff or other staff not working in this specific facility;
  – conduct refresher training for staff responsible for data management and reporting;
  – conduct DQ monitoring in the same facilities (100%) one quarter later; and
  – conduct in-depth external DQA through a third-party contractor.

- If DQ monitoring via supportive supervision or LQAS does not fail:
  – conduct in-depth data review supervised by at least one staff member not working in this specific facility;
  – conduct refresher training for staff responsible for data management and reporting in this facility; and
  – conduct DQ monitoring in 10% of the same facilities one quarter later.

B. Conduct routine DQA one year later (assuming that the frequency for VL testing is once a year) in a sample of facilities, including some of the ones reached by the previous routine DQA.

[3] LQAS fails if the number of sampled records meeting the predefined criteria to be considered as acceptable is not reached, as defined as a decision rule.

Scenario 4: no routine DQA, but DQ monitoring via supportive supervision or using LQAS has been implemented

A. If DQ monitoring via supportive supervision or LQAS fails:

- conduct data review led fully by ministry of health staff or other staff not working in this specific facility;
- conduct refresher training for staff responsible for data management and reporting; and
- conduct monthly facility-level data review.

B. If DQ monitoring via supportive supervision or LQAS does not fail:

- conduct monthly facility-level data review; and
- conduct refresher training for staff responsible for data management and reporting in this facility.

C. Conduct routine DQA six months later in at least 50% of these sites.

D. Conduct DQ monitoring via supportive supervision or LQAS in 50% of the same facilities one year later.

Scenario 5: no routine DQA, or DQ monitoring via supportive supervision or LQAS implemented at the site - only routine data reviews

A. If routine site-level data reviews identify significant persistent issues:

- conduct data review led fully by ministry of health staff or other staff not working in this specific facility; and
- conduct refresher training for staff responsible of data management and reporting.

B. If routine site-level data reviews do not identify significant persistent issues:

- conduct refresher training for staff responsible for data management and reporting in this facility.

C. Conduct DQ monitoring via supportive supervision or LQAS in all these facilities one quarter later.

D. Conduct routine DQA six months later in all these facilities.

7. ETHICAL CONSIDERATIONS

Before collecting data at the site level, teams will discuss the consent process with facility and laboratory staff and will provide a copy of the informed consent form (Web Annex A), 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 personal identification of staff will be collected or recorded.

The above is applicable to routine DQA, DQ monitoring via supportive supervision and using LQAS, which involve site-level visits and data abstraction. The interviewer will sign the consent form, and the interviewee may retain a copy. Supervision teams may take notes on discussions with the site staff, but these discussions will not be recorded. Depending on the type of DQ assurance activity, members of the review teams may be viewing patient files, 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 indicator, completeness and cross-validation checks of specific data elements to ensure that double-counting does not occur and to ensure that data can be viewed for the same patients from different data sources. 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 (Web Annex A). This is intended as an extra measure to protect patient confidentiality during the DQ assurance activity.

All members of the review team will receive training on ensuring the confidentiality of patient information before conducting any DQ assurance activity and will not share or disclose in any way patient information with non-assessment staff. They will be escorted by designated facility and/or laboratory staff through the following areas and other areas as appropriate, including patient check-in, waiting areas, the records area, patient examination rooms and the laboratory and/or phlebotomy areas.

8. COST CONSIDERATIONS

DQ assurance activities included in this module vary considerably in terms of cost and need careful consideration and forecasting. Indicative generic budgets for the four recommended DQ assurance activities (see Web Annex H) have been developed to support country planning and implementation and can be adapted as required.

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