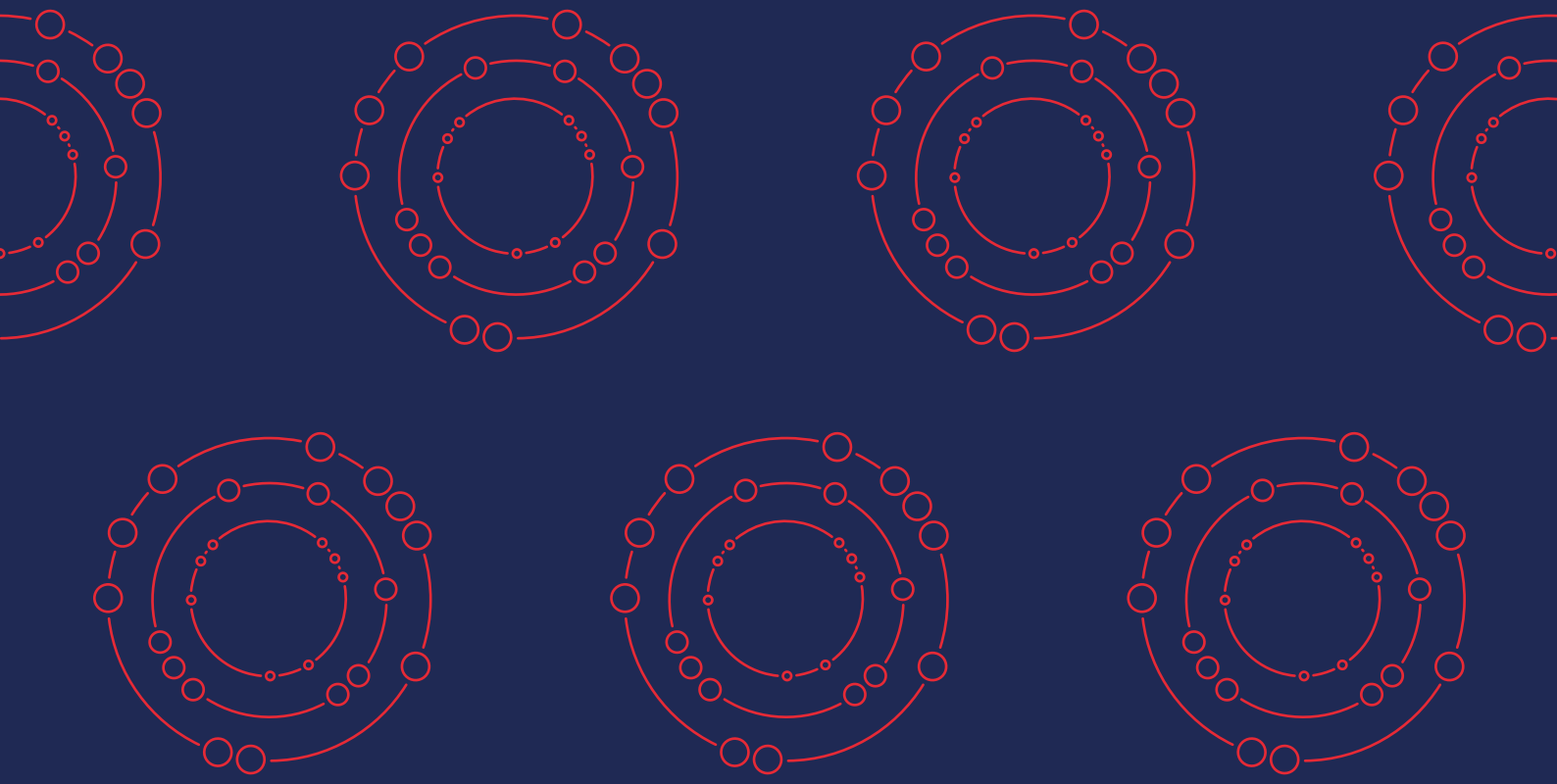
Module for assessing and strengthening the quality of viral load testing data within HIV programmes and patient monitoring systems: implementation tool

Second edition



World Health Organization

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Contents

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Introduction

In 2020, a module for assessing and strengthening the quality of viral load testing data within HIV programmes and patient monitoring systems *(1)* was developed through a collaborative effort between WHO, UNAIDS, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria. This implementation tool outlined four types of data quality assurance activities that are recommended to strengthen the quality of viral load testing data, depending on the specific needs and the context.

These included:

(1) routine data quality assessment,

(2) data quality monitoring through supportive supervision visits,

(3) data quality monitoring using lot-quality assurance sampling and

(4) site-level routine review of data and performance.

Box 1 summarizes the available tools for each of the four recommended data quality assurance activities to support implementation.

Box 1. Tools and annexes available for the four recommended data quality monitoring activities

Routine data quality assessment: Web Annex A. Informed consent and confidentiality form, Web Annex B. Mapping tool for patient, viral load sample and documentation flow, Web Annex E. Viral load routine data quality assessment tally sheet, Web Annex F. Generic templates to display the output of data quality assurance activities, Web Annex G. Site summary report template for external data quality assurance activities, Web Annex H. Generic budgets for viral load testing data quality monitoring activities, Web Annex I. Site-level template for a data quality improvement action plan.

Data quality monitoring through supportive supervision visits: Web Annex A. Informed consent and confidentiality form, Web Annex C. Short clinical facility viral load service and data quality tool, Web Annex D. Detailed clinical facility viral load assessment tool, Web Annex F. Generic templates to display the output of data quality assurance activities (only the relevant tabs), Web Annex H. Generic budgets for viral load testing data quality monitoring activities, Web Annex I. Site-level template for a data quality improvement action plan.

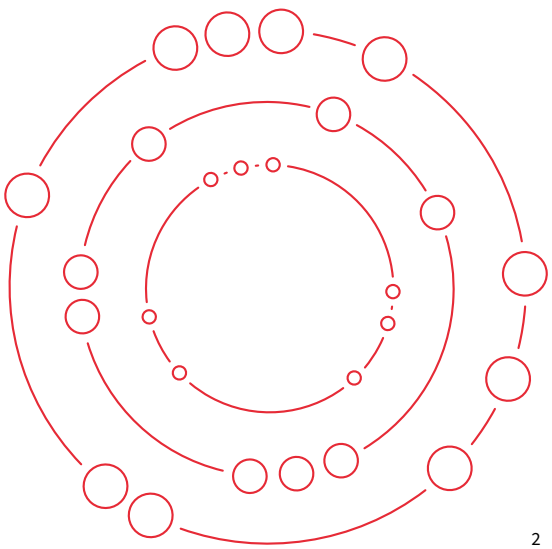
Box 1. Tools and annexes available for the four recommended data quality monitoring activities (continued)

Data quality monitoring using lot-quality assurance sampling: Web Annex A. Informed consent and confidentiality form, Web Annex B. Mapping tool for patient, viral load sample and documentation flow, monitoring and evaluation component of Web Annex D. Detailed clinical facility viral load assessment tool, Web Annex G. Site summary report template for external data quality assurance activities, Web Annex H. Generic budgets for viral load testing data quality monitoring activities, Web Annex I. Site-level template for a data quality improvement action plan, Web Annex J. User guide for the data quality monitoring tally sheet for viral load testing, Web Annex K. Viral load data quality monitoring tally sheet.

Monthly data quality review: Web Annex F. Generic templates to display the output of data quality assurance activities (only the relevant tabs), Web Annex H. Generic budgets for viral load testing data quality monitoring activities, Web Annex I. Site-level template for a data quality improvement action plan

Updated version of these tools (Web Annexes B. Mapping tool for patient, viral load sample and documentation flow, D. Detailed clinical facility viral load assessment tool, E. Viral load routine data quality assessment tally sheet, G. Site summary report template for external data quality assurance activities, J. User guide for the data quality monitoring tally sheet for viral load testing and K. Viral load data quality monitoring tally sheet) with improvements to support use, including to facilitate data entry and verification, are available as part of this technical update.

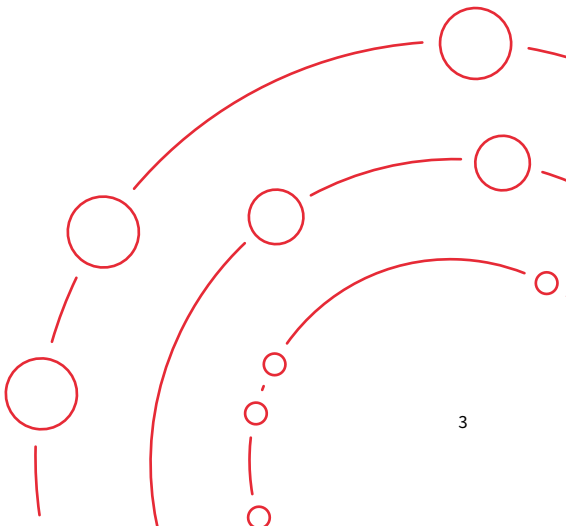
Based on experience in implementing the 2020 viral load data quality module and feedback from countries and partners, the tool has been updated to provide further guidance on the recommended data quality assurance activities and the web annexes updated to support country implementation. These are summarized in this technical update, which was jointly developed by WHO, UNAIDS, PEPFAR and the Global Fund as part of ongoing efforts to harmonize approaches to ensure that accurate and timely HIV viral load data and results are available for both clinical use and to strengthen programme monitoring, in accordance with the recommendations of the 2022 WHO consolidated guidelines on person-centred HIV strategic information on data quality assessment and improvement (Box 2) *(2)*.



Box 2. A paradigm shift in measuring the turnaround time of viral load testing to capture the return of results to patients

The return of viral load test results is a significant programmatic issue in most settings. HIV programmes urgently need to shift towards assessing the return of results to patients as the final end-point for measuring the turnaround time of viral load test results. This has the ultimate objective of supporting the clinical utilization of results and is crucial, since this step is often the longest in many settings and therefore has the greatest impact on the viral load testing cascade. Measuring the return of results to patients will enable remedial actions to be identified to enhance the use of results for clinical decision-making and to improve patient care. This in turn requires improving and updating patient monitoring and the laboratory–clinic interface to record when results are returned to patients.

At present, patient monitoring systems and tools in most settings do not yet include data elements that capture or enable direct assessment of when viral load test results are returned to patients, which means this is not feasible to measure and validate within data quality monitoring activities. In addition, numerous parameters, including patient-related factors beyond data quality issues, could determine when patients ultimately receive their results. Thus, this technical update, for practical considerations, uses return of results to patient records as the end-point for assessing viral load turnaround time (see sections below on considerations for assessing viral load test turnaround time). Going forward, WHO and partners will provide further guidance and support to countries on assessing the return of viral load test results to patients as the end-point for measuring viral load test turnaround time within data quality monitoring activities.



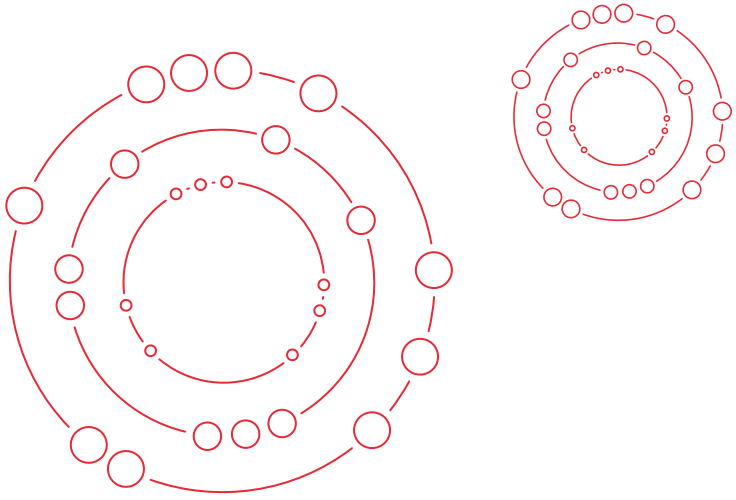
What is new in this technical update?

To enhance stronger country implementation and institutionalization of data quality assurance activities, this technical update provides updated guidance on the priority indicators related to viral load testing that are the main focus of data quality assessments (Box 3) and key elements of data quality assurance activities, including:

- the calculation of viral load test turnaround times;
- considerations for data quality assessments for sites with electronic data systems;
- sampling for national data quality assessments of sites and clinical records;
- data quality monitoring via lot-quality assurance sampling;
- considerations for facilities with point-of-care or near point-of-care viral load testing;
- considerations for data quality assessments of viral load testing data for pregnant and breastfeeding women; and
- recording the limitations and challenges of data quality monitoring assurance activities.

a) Key indicators of interest to be included in data quality monitoring activities

For routine data quality assurance activities, the core indicators of viral load testing coverage and suppression should be given priority for data quality assurance activities (see Box 3 for the latest indicator definitions). In addition, this technical update recommends that viral load test turnaround time from sample collection to receipt in the laboratory, receipt of the sample in the laboratory to dispatching of the results as well as results dispatch to receipt in facility and finally to patient records are also assessed and included within data quality assurance activities given how they affect both patient management and data completeness. Key considerations for assessing viral load test turnaround times are provided below.



Box 3. WHO updated indicator definitions of viral load testing coverage and suppression

ART.3 People living with HIV on antiretroviral therapy (ART) who have suppressed viral load

Indicator definition: Percentage of people living with HIV on ART (for at least six months) who have viral suppression.[a]

Numerator: Number of people living with HIV on ART for at least six months and with at least one routine viral load test result who have viral suppression (≤1000 copies/mL)[b] during the reporting period.

Denominator: Number of people living with HIV on ART at least six months with at least one routine viral load result in a medical or laboratory record during the reporting period. In addition, this can also be presented as the number with suppressed viral load among all people living with HIV to calculate population-level viral suppression.

Method of measurement for the numerator and denominator: Patient monitoring tools (for example, ART register, patient records, electronic medical records, laboratory records) or acquired HIV drug resistance or population-based surveys (such as the Population-Based HIV Impact Assessment) that collect data on ART coverage and viral suppression.

This indicator must be interpreted along with viral load testing coverage to assess the potential for bias: that is, whether viral load testing occurs in only a particular subset of people receiving ART.

Note: First routine viral load testing is recommended with results available at six months after ART initiation. The time window for early viral load monitoring can include a margin of ± one month:- that is, for reporting purposes a routine viral load test can take place with results available any time from five to seven months after initiation of ART.

ART.5 viral load testing coverage

Indicator definition: Percentage of people living with HIV on ART (for at least six months) with viral load test results.

Numerator: Number of people living with HIV on ART for at least six months with at least one routine viral load test result during the reporting period.

Denominator: Number of people living with HIV on ART eligible for viral load monitoring at six months after initiation of ART during the reporting period.

Method of measurement for the numerator and denominator: Patient monitoring tools (for example, patient records or electronic medical records, ART register, cohort reporting forms or laboratory information system).

It is critical to de-duplicate records and avoid double-counting when identifying the appropriate numerator. The denominator excludes patients who have died, transferred to another facility or been classified as lost to follow-up.

[a] WHO recommends the following viral load thresholds to distinguish between treatment failure or unsuppressed (>1000 copies/mL), suppressed (detectable <1000 copies/mL) and undetectable (not detected by assay used) levels *(3)*.

[b] This includes people with undetectable viral load.

Source: Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact *(2)*.

b) Main activities to be included in the viral load testing data quality assessment process

The main activities to be included in data quality monitoring activities of viral load testing data are clarified and summarized below. These include:

- understanding and verifying the level of concurrence in viral load test results between different sources: paper-based patient records versus electronic medical record, viral load testing databases, laboratory information management systems and laboratory test result forms;
- assessing the availability of disaggregated data on viral load coverage and suppression by age, sex, pregnancy status, key population (if available) and tuberculosis status, which is important for programme monitoring and identifying gaps in service delivery for specific populations and groups;
- assessing the completeness of viral load monitoring data at the facility and laboratory level and determining the coverage of viral load testing in terms of the proportion of eligible people living with HIV who receive a test and have their results documented in their patient records and used;
- mapping data and service delivery flow to identify potential bottlenecks in reporting or returning viral load results that 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;
- understanding the flow of results and assessing the average turnaround time from sample collection to the laboratory and from the laboratory to facility and ultimately patient records, which is essential to identify delays in reporting results; and
- using the findings from data quality assurance activities to guide data quality improvement action planning, identifying quality improvement interventions that will address the root causes of systematic data quality issues.

c) Considerations for assessing viral load test turnaround time for facilities that send specimens off site for viral load testing

The following caveats are highlighted to support countries when assessing viral load test turnaround time at sites that only collect samples that are then sent to an off-site laboratory for testing.

- For data quality monitoring activities, turnaround time is currently from the moment of specimen collection to the return of results to patient records; however, the goal should be to ultimately measure the return of results to patients. If electronic access to results is available at the health facility, the date and time the result is completed at the laboratory should be considered as the end of the turnaround time measure.
- If paper results are provided, the date and time these are received at the facility should be considered as the end-point for assessing turnaround time. However, because of frequent delays in the filling and entry of paper-based results in clinical records, time can elapse before the results end up in the patient files. This additional delay may be difficult to measure and is a limitation affecting many countries that rely on paper-based forms for transmitting viral load test results.

The turnaround time between when samples are received at the laboratory and results are available is the laboratory turnaround time. Several other components within the measure of viral load test turnaround time require monitoring from the point of sample transport to the return of results to patient files and going forward ultimately to patients. All the specific time points identified below are therefore critical to identify where the delays in turnaround time reside. This provides opportunities to address specific points of the journey between sample collection and results being returned in which specific issues may surface.

The components to be assessed for turnaround time include:

- sample collection date and time to sample pick-up date and time;
- sample pick-up date and time to sample received in a processing hub or laboratory;
- date and time tested at the laboratory;
- date and time the result is completed at the laboratory;
- if electronic access to results is available at the health facility, the date and time the result is completed at the laboratory should be considered as the end of the turnaround time measure; and
- if paper results are used then additional measures can be added:
  - date and time of result pick up for delivery to facilities; and
  - date and time received at the facility, which would be considered the end-point. This may be difficult to measure however, given frequent delays in filing paper-based results in clinical records.

Facilities should ideally monitor the dates and times of collection and sample pick-up and results available (for electronic transmission) or results received. Any delays should be actively followed up.

d) Considerations for facilities with point-of-care or near point-of-care viral load testing

Since 2021, WHO has recommended that point-of-care viral load may be used to monitor treatment among people living with HIV receiving ART *(4)*. As a result, countries have scaled up the use of point-of-care and near point-of-care testing, with varying rates of site implementation, time taken to deliver results to patients (in some cases within one to two hours) and giving priority to specific populations such as pregnant and breastfeeding women or people living with HIV with suspected treatment failure among others. The turnaround time of results for these testing modalities should be more rapid and have fewer steps in the cascade than viral load testing performed in laboratories since there is no need for sample transportation. It is important to understand the flow of data for viral load point-of-care and near point-of-care testing as part of data quality monitoring activities and to identify the data points in the cascade that are appropriate for these testing modalities. Web Annex B can be used to assess data flow, with prompts to identify potential bottlenecks and challenges.

e) Considerations for facilities with electronic health information systems

This section summarizes additional caveats for sites with electronic health systems (electronic medical records or laboratory information management systems). For countries that have widely rolled out electronic medical records or are using any form of electronic platforms for patient-level data management, an in-depth deduplication exercise should be conducted before data quality assessment. When indicators are recreated in facilities with an electronic patient-level database with built-in report generation features, the following two steps should be considered.

- Request that the site staff or database manager for the software report or query used run the calculations for the indicator and validate the consistency of that query with the ministry of health and, if relevant, partner definitions for each indicator, where possible.
- Extract the relevant data from the health facility electronic database and enter these data in the data quality assessment electronic tool (see Web Annex E, WHO viral load routine data quality assessment tally sheet). This can be done by copying and pasting after extraction or applying direct data transfer from the database to the tally sheet.

In sites where the electronic medical record is the point-of-service record, interoperability between the electronic medical record and the laboratory information management systems should be assessed. This is important since interoperability between these two systems should lead to a reduction in potential delays and prevent risks of missing or inaccurate data on viral load test results.

The data and service flow mapping tool (Web Annex B) included in the 2020 viral load data quality assurance module has been updated with specific questions added to assess data flow and interoperability issues for sites with electronic systems (electronic medical records and laboratory information management systems).

f) Updates to the scope of national routine data quality assessments and sampling guidance for sites and clinical records

Routine data quality assessments that entail recounting and verifying indicators can be conducted either at one specific site, in a sample of sites in a specific district or subnational level, in a representative sample of sites at the national level or as a full census of all sites providing related ART and viral load testing services in a country.

All national data quality assessments that are a full census or sample based will be conducted under the leadership of the ministry of health in collaboration with relevant partners and stakeholders.

The full census option, which entails reaching either 100% or 80% of the people receiving ART for at least six months, should be envisioned if:

- high discrepancies (greater than 10%) between reported indicators and recreated indicators have been observed in at least 50% of the sites during the last routine data quality assessment conducted in a national representative sample of sites;
- data quality monitoring using lot-quality assurance sampling flagged data inconsistencies in at least 25% of the sites assessed during a follow-up data quality assessment; or
- Significant changes in reporting patterns of indictors across the country during a period of disruptions caused by natural disasters, conflict, pandemics or social or political unrest.

Given limited resources, routine data quality assessments will be mostly conducted either in a nationally representative sample of sites or at the subnational level, considering the parameters and sampling process outlined below. With larger site sample sizes, countries can also consider analysing and adjusting their subnational viral load testing data based on country need and interest.

Guidance on selection of sites where data quality assessment activities will be conducted

The sampling scheme must be developed with the aim of providing a representative sample of sites reporting on the indicators of interest while keeping the number of sites to be visited to a minimum and still ensuring a solid level of rigour. The sampling frame will include only sites that provide treatment services and report at least on the indicators of people living with HIV currently receiving ART and viral suppression. Before any decision on the number of facilities to sample, the following key factors that may influence access to facilities or certain geographical regions should be considered.

- Are there any cost-related issues that would exclude sites? For example, some facilities may be very remote and more expensive to reach; other facilities may be low-volume sites in terms of people receiving ART for at least six months, making a visit financially less viable than a visit to other facilities with a high volume of patients.
- Are there any security or safety concerns or travel restrictions that would exclude some sites (such as conflict) in the region of interest?

Those factors should be considered, and the affected facilities should be excluded from the sampling frame. In addition, the sample should consider which of the following characteristics are most relevant and ensure the representativeness accordingly:

- facilities with versus without an on-site laboratory;
- facilities with paper versus electronic patient monitoring records; and
- facilities with potential data quality issues, based on the programme performance data reported or the findings from previous data quality assessments conducted or data reviews.

Other important considerations that should guide facility sampling relate to how the data that will be collected are envisioned to be used.

The following are important characteristics to consider in the sampling framework.

- Urban versus rural split. Could there be a difference in the findings from facilities that are considered rural versus urban? This level of stratification will support understanding patterns of quality issues that could potentially be linked to geographical factors.
- Patient volume. Do facilities with more clients for the targeted service (such as clients receiving ART for at least six months) have better quality of data than facilities with fewer clients? Classifying facilities into high-, middle- and low-volume facilities would then enable the country to be stratified by client volume. Classifying a facility into these three strata requires evaluating client volumes across all sites and then splitting these sites into strata in which each stratum contains one third of the total patient volume.
- Facilities supported versus not supported by partners (such as PEPFAR or the Global Fund). Classifying a country into these strata may help to identify the potential need to build or strengthen the synergy of the efforts around viral load testing coverage and ultimately suppression across the country.

Within these domains, additional strata can be sampled. This should be balanced against the sample size implications of increasing the number of strata.

In implementing the sampling approach, the following steps must be followed.

- Create a sampling frame: a list of all ART sites nationally, including the following information:
  - site name and location, such as province, district, etc.;
  - the number of clients receiving ART for at least six months;
  - domains (such as PEPFAR support, Global Fund support etc.);
  - facility with versus without an on-site laboratory; and
  - facility with an electronic information management system versus paper-based information management system.
- Decide on the number of ART sites to be sampled nationally and by strata. The country team should determine the appropriate sample size based on country priorities.
- ART sites should be selected for the assessment by probability sampling or probability proportional to size sampling in which size would be based on the number of clients reported to be receiving ART for at least six months.
- Some countries may have sites that are very small (such as fewer than 100 people receiving ART for at least six months) or may be difficult to access because of geographical remoteness or political instability. In these cases, the country team may consider excluding some or all these sites from the evaluation. In general, if these sites represent less than 10% of the population receiving ART in the country, countries may choose to exclude these facilities from the sampling frame. Facilities should be excluded from the sampling frame before site selection. The final report should include a list of all excluded facilities and reasons for their exclusion.

In addition to the probability sampling described above, if the country team also chooses to sample certain sites with certainty (probability = 1.0), the data quality assessment 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.

Guidance on sampling client records to be reviewed

Systematic random sampling may be used to sample client records. This process requires a sampling interval and a random selection of the first client record. The sampling interval is calculated by dividing the total number of records to be assessed (total number of clients currently receiving ART within the assessment period (such as the last three or 12 months) by the sample size. Specifically:

- For data quality monitoring using the lot-quality assurance sampling method (see section below for a summary of this approach), the sample will be obtained from using the Brixton hypergeometric lot-quality assurance sampling calculator *(5)*, based on the total number of clients currently on treatment for at least six months (between the initiation date and the end of the data quality assessment period).
- For routine data quality assessments, the sample size can be generated using the using the sample-size estimation tool in Annex C of the 2018 data quality assessment of national and partner HIV treatment and patient monitoring system implementation tool *(6)*.

The value of the sampling interval determines the pace of the sampling. The first client record can be selected using the simple random selection method based on a random number.

Example of selection of client records (for a hypothetical situation)

(a) Data quality monitoring sample size calculation:

Assume that a data quality monitoring activity will be conducted in health facility X for the quarter January–March 2023. For the reporting period under review, 325 clients have received ART for six months or more. Using the Brixton hypergeometric lot-quality assurance sampling calculator *(5)* with an upper quality threshold of 95% and a lower quality threshold of 85%, the two types of error, alpha (α) = 0.05 and beta (β) =0.10, a sample size of 57 records and a decision rule number of 51 will be automatically generated. Alternative values can be envisioned as upper and lower thresholds, based on knowledge of the overall level of data quality associated with the site selected. For the first iteration of data quality monitoring at a site, the recommendation is to consider a wider range for the upper and the lower quality thresholds. This range can be narrowed down as the data quality at the sites selected for data quality monitoring is understood better.

(b) Random selection of records to be reviewed:

Selecting the 57 client records in the ART register requires calculating the sampling interval. The sampling criteria are as follows:

N = total number of clients receiving ART for at least six months at the end of the selected assessment period, i.e., 325

n = sampled number of ART client records, i.e., 57

Sampling interval = N/n = 325/57 = 5.70

Systematic random sampling should be used to sample client records following the following steps.

- The sampling interval is 5.7. However the 5.7th record cannot be exactly sampled. A whole number is required for selecting every nth record. Instead, choose 6, and when you reach the end of the collection, start over from the beginning.
- Randomly select a starting-point within the first six client records. If the records are folders in a filing cabinet (such as client medical records), begin with the first drawer. If you are using the ART register, start with the first page from the beginning of treatment. If the results are within a specific time frame, begin on the page corresponding to the beginning of that time frame.
- To select the random starting-point, you can write the digits 1–6 on slips of paper and randomly select one from a concealed place (or any other method to ensure randomization of the selection of the starting record).
- The client number that is drawn will be the first sampled client. Assume that client record 2 is the first sampled client.
- From the first sampled client (number 2 in the order), add 6 (the sampling interval) and select the next client number. In this example, the next sampled client will be the 8th client record, i.e., 2 + 6.
- Continue adding 6 to each sampled client record until 57 client records have been selected to be assessed. If you reach the end of the records and 57 have not yet been selected, go back to the beginning of the records to continue the selection.
- If you must start over at the beginning of the list and the record is already selected, choose the next record in order and continue sampling until you have sampled your target number.

The same process can be followed when using a sample size generated to conduct a routine data quality assurance activity not using the lot-quality assurance sampling method.

g) Updates to data quality monitoring using the lot-quality assurance sampling method

Lot-quality assurance sampling is a method for site-level assessment and supervision that enables the completeness and consistency of records to be assessed and suspected data quality problems to be investigated. The approach involves establishing a predetermined data quality standard for each indicator and data element that 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 classified as failing and requiring data quality improvement and can be targeted for more extensive data quality review, including routine data quality assessment.

Guidance is provided below on the concept of failure when analysing more than one indicator or variable during data quality monitoring using lot-quality assurance sampling. Each of the five data elements below is recommended to be analysed separately for failure or success. There is no overall categorization of sites as having "poor-quality" or "good-quality" data based on any of these five data elements. Immediate follow-up actions may need to be taken separately for each specific data element, if required.

Variables and data elements of interest to assess consistency

Data quality monitoring using lot-quality assurance sampling will focus on assessing consistency between a primary data source (such as HIV patient cards or electronic medical records) and a secondary data source (viral load form or laboratory information management systems) for each of the following data elements or variables:

- current ART regimen
- last viral load test date
- last viral load test result
- last follow-up date
- next visit date.

For each variable or data element, data quality monitoring will be considered as a failure if the number of records with consistency between the two data sources is lower than the lot-quality assurance sampling decision rule (which can be generated using the Brixton hypergeometric lot-quality assurance sampling calculator *(5)*). This will imply that there are data quality issues.

h) Considerations for reviewing and interpreting viral load testing data for pregnant and breastfeeding women during data quality assurance activities

Specific considerations for reviewing data and interpreting findings for pregnant and breastfeeding women may be needed when reviewing data for this population. Pregnancy is a time-limited experience, and cross-sectional proxy calculations for viral load coverage cannot be easily applied or understood. Without electronic medical records to track and monitor pregnancy and breastfeeding status at every visit, accurately reporting viral load coverage data for pregnant and breastfeeding women can be difficult. Monitoring and evaluation systems may not capture and/or easily aggregate data for reporting viral load coverage or outcomes for pregnant or breastfeeding women. The following are specific examples of monitoring and evaluation challenges.

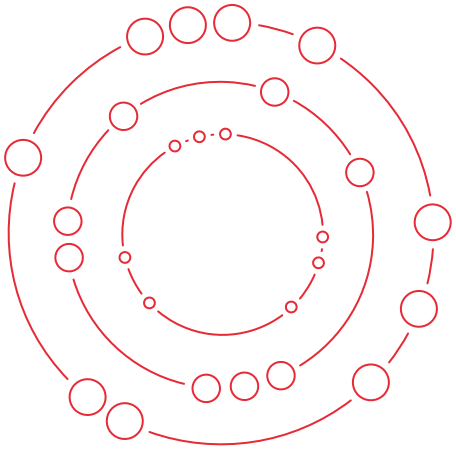
- Laboratory requisition forms may not include a variable field to capture whether a viral load test is for a pregnant or breastfeeding woman, and if a field is available, it may not be consistently or completely filled out.
- Viral load registers or electronic registers or electronic medical records may not have a way to indicate pregnancy and breastfeeding status.
- Breastfeeding women may be captured in general ART clinics without a way to disaggregate their results.
- There may be data quality challenges or difficulty in disaggregating data by pregnancy status.
- Suboptimal viral load testing among pregnant and breastfeeding women may result in limited or sporadic data.
- Depending on the indicator used, a viral load coverage proxy calculation for pregnant women may not accurately approximate true viral load coverage in this population.
- The status of pregnancy and breastfeeding may change within a reporting period and may not be adequately captured in the reporting period.

Given these challenges, data quality assessments verifying viral load coverage and suppression among pregnant and breastfeeding women should confirm how data are captured, aggregated and reported. Further, understanding how the denominator and numerator for pregnant and breastfeeding women are calculated for viral load coverage will be important. Completion of the data quality assessment check list for assessing site-level patient monitoring systems (Annex A of the 2018 WHO data quality assessment of national and partner HIV treatment and patient monitoring and data systems implementation tool *(6)*) or discussions with site-level staff who are familiar with data collection and reporting to better understand the facility data systems and reporting procedures will be particularly important for understanding findings for pregnant and breastfeeding women. The site checklist and discussions with facility staff with recounting and validating viral load testing data will provide greater insight into understanding findings for pregnant and breastfeeding women.

i) Recording the limitations and challenges of data quality monitoring assurance activities

Effective tracking of viral load testing and patient outcomes requires multiple monitoring and evaluation tools and systems from multiple locations (such as facilities, specimen transport networks and laboratories). Systems may be parallel and not interoperable, which makes data exchange difficult. The systems and tools being reviewed in any type of data quality assurance activity need to be clarified to ensure that the limitations of the review are clear. For example, if the data quality monitoring activity is recounting and comparing aggregate data from a site-level aggregate patient-based register to results in a laboratory information management system, the activity may not be able to assess what is recorded in the patient-level record or whether there was any breakdown during sample or results transport.

If significant discrepancies are found between the site-level aggregate register and the laboratory information system, teams may need to conduct a more in-depth review of the patient record, the site-level aggregated data register used for reporting and the laboratory information system. When findings are presented and interpreted, clarifying the monitoring and evaluation tools and systems reviewed as part of the data quality assessment, the method used and limitations to accurately frame findings and recommendations for follow-up action is recommended.



Conclusion

Ensuring accurate and timely HIV viral load data with testing results available is critical for improving patient care, quality and the outcomes of people living with HIV and enhancing programmatic impact, including achieving the third 95% HIV testing and treatment target of viral load suppression among 95% of people living with HIV receiving ART. This is supported by a systems approach to improving data quality in which routinely scheduled data quality assurance activities are included within long-term data quality improvement strategies. The guidance included in this technical update is intended to support countries in strengthening the implementation of these activities and their patient monitoring systems, linking assessments of data quality with remedial actions, including training, supportive supervision and mentoring among others, in accordance with the 2022 WHO HIV strategic information guideline recommendations *(2)*. Going forward WHO and partners will continue to support efforts to institutionalize such activities and integrate them within HIV programmes, to improve the quality of data and support the improvement of services.

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