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

Second edition

Web Annex J.
User guide for the data quality monitoring tally sheet for viral load testing
Web Annex J: User guide for the data quality monitoring tally sheet for viral load testing

This summarizes user instructions to support the use and completion of the accompanying data quality monitoring tally sheet for viral load testing (Web Annex J).

Overall context

Based on the numbers of clients reported to be receiving ART for six months or more and 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 and a golden number (decision rule) will be generated for each site selected for data quality monitoring, using the lot-quality assurance sampling. 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 lower quality thresholds. This range can be narrowed down as a better understanding of the data quality in the sites selected for data quality monitoring is obtained.

Structure of the data quality monitoring data collection tally sheet for viral load testing

This tally sheet is a semiautomated Excel-based tool designed to be used jointly with a lot-quality assurance sampling calculator. The users will have interactions with two interconnected components or Excel tabs: the DATA ENTRY tab and the DQM RESULTS SUMMARY tab. This tally sheet has been designed to focus on only one reporting period. For specific activities focusing on more than one reporting period, one tally sheet will be needed for each reporting period of interest.
1) DATA ENTRY

As a very first step, users are expected to enter in rows 1 and 2 all information related to the assessment: district name, site name, assessment period or quarter assessed and assessment date.

Then, using the patient’s charts (ART patient card or electronic medical records) as a primary data source and viral load form or laboratory information management system as a secondary data source, the users will extract and enter all relevant information related to each of the variables or data points below for each client receiving ART for six months or more. The unique ART number for each client will be extracted from the primary data source, which is the starting-point for the data entry process.

- **Primary data source:** Patients charts (ART patient cards or electronic medical records (column headings highlighted in green).
  - CURRENT ART REGIMEN: from the selected primary data source or relevant secondary data source, extract for each beneficiary the CURRENT ART REGIMEN and enter related data.
  - LAST VIRAL LOAD TEST DATE: from the selected primary data source or relevant secondary data source, extract for each beneficiary the LAST VIRAL LOAD TEST DATE and enter related data.
  - LAST VIRAL LOAD TEST RESULT: from the selected primary data source or relevant secondary data source, extract for each beneficiary the LAST VIRAL LOAD TEST RESULT and enter related data.
  - DATE OF LAST CLINICAL VISIT OR DRUG PICK-UP: from the selected primary data source or relevant secondary data source, extract for each beneficiary the DATE OF LAST CLINICAL VISIT OR DRUG PICK-UP and enter related data.
  - NEXT VISIT DATE: from the selected primary data source or relevant secondary data source, extract for each beneficiary the scheduled NEXT VISIT DATE for the facility and enter related data.

- **Secondary data source:** Viral load form or laboratory information management system (column headings highlighted in blue).
  - CURRENT ART REGIMEN: from the laboratory information management system or relevant secondary data source, extract for each beneficiary the CURRENT ART REGIMEN and related data.
  - LAST VIRAL LOAD TEST DATE: from the laboratory information management system or relevant secondary data source, extract for each beneficiary the date when the blood specimen was taken for the last viral load test and enter relevant information.
  - LAST VIRAL LOAD TEST RESULT: from the laboratory information management system or relevant secondary data source, extract for each beneficiary the LAST VIRAL LOAD TEST RESULT and enter related data.
  - DATE OF LAST CLINICAL VISIT OR DRUG PICK-UP: from the laboratory information management system or relevant secondary data source, extract for each beneficiary the DATE OF LAST CLINICAL VISIT OR DRUG PICK-UP and enter related information.
  - NEXT VISIT DATE: from the laboratory information management system or relevant secondary data source, extract for each beneficiary the scheduled NEXT VISIT DATE to the facility and enter relevant information.

The columns RESULT COMPARISONS (with column headings highlighted in red) will be automatically filled out with the values SAME if there is full match and consistency between the primary and secondary data sources for each specific variable or data point or DIFFERENT otherwise.
2) DQA RESULTS SUMMARY

In the first section of this specific Excel sheet, users are expected to enter the values generated by the lot-quality assurance sampling calculator for the sample size and the decision rule. All the other information will be automatically entered from DATA ENTRY.

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<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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</table>

DATA CONSISTENCY

This subcomponent outlines the analysis of consistency between the primary and secondary data sources for five data points or variables: CURRENT ART REGIMEN, LAST VIRAL LOAD TEST DATE, LAST VIRAL LOAD TEST RESULT, LAST CLINICAL VISIT OR DRUG PICK-UP DATE and NEXT VISIT DATE.

CURRENT ART REGIMEN

- **NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA**: number of beneficiaries with identical information related to CURRENT ART REGIMEN in the primary and secondary data sources.

- Lot-quality assurance sampling decision: acceptable if the NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA is greater than the LOT-QUALITY ASSURANCE SAMPLING DECISION RULE automatically generated from the calculator.¹

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¹ Lot-quality assurance sampling calculator: http://www.brixtonhealth.com/hyperlot-quality-assurance-sampling.html
LAST VIRAL LOAD TEST DATE
a. NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA: number of clients with identical information related to LATEST VIRAL LOAD TEST DATE in the primary and secondary data sources.
b. LOT-QUALITY ASSURANCE SAMPLING DECISION RULE: acceptable if the NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA is greater than the LOT-QUALITY ASSURANCE SAMPLING DECISION RULE automatically generated from the calculator.

LAST VIRAL LOAD TEST RESULT
a. NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA: number of clients with identical information related to LAST VIRAL LOAD TEST RESULT in the primary and secondary data sources.
a. LOT-QUALITY ASSURANCE SAMPLING DECISION RULE: acceptable if the NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA is greater than the LOT-QUALITY ASSURANCE SAMPLING DECISION RULE automatically generated from the calculator.

LAST CLINICAL VISIT OR DRUG PICK-UP DATE
a. NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA: number of clients with identical information related to LAST CLINICAL VISIT OR DRUG PICK-UP DATE in the primary and secondary data sources.
b. LOT-QUALITY ASSURANCE SAMPLING DECISION RULE: acceptable if the NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA is greater than the LOT-QUALITY ASSURANCE SAMPLING DECISION RULE automatically generated from the calculator.

NEXT VISIT DATE (to the facility)
a. NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA: Number of clients with identical information related to the NEXT VISIT DATE in the primary and the secondary data sources.
b. LOT-QUALITY ASSURANCE SAMPLING DECISION RULE: acceptable if the NUMBER OF SAMPLED PATIENTS WITH CONSISTENT DATA is greater than the LOT-QUALITY ASSURANCE SAMPLING DECISION RULE automatically generated from the calculator.