Assessing and strengthening the quality of VL testing data within HIV programmes and patient monitoring systems – overview of WHO-UNAIDS-PEPFAR-GF Joint tool

Hiwot Haile-Selassie

Thursday 17th June 2021
Presentation outline

- Introduction into importance of data quality and common VL testing data challenges
- Overview of key recommended approaches for VL testing data quality assurance (joint WHO-UNAIDS-PEPFAR-GF module for strengthening VL data testing data quality assurance and patient monitoring systems)
- Highlight available tools included in the module for country adaptation
- Follow up on DQ assurance activities - examples recommended for long term DQI
Growing emphasis on data quality (DQ) & use - from Ministries of Health and partners to improve patient management, programmatic impact, enable performance monitoring and increase accountability

Achieving 95-95-95 targets - requires collecting and reporting accurate data in real time to understand where gaps in service delivery remain and data use to improve programme implementation

Need to strengthen DQ along the entire HIV cascade - historically DQ improvement (DQI) activities prioritised HIV treatment indicators but strengthening DQ and use along the entire cascade of HIV services is essential for ensuring quality and continuity of HIV care

Viral suppression as key outcome of HIV treatment - ensuring accurate and timely VL data, with the results available for use is critical for enhancing programmatic impact and improved clinical care and outcomes for PLHIV
**Context**

- **DQA tool developed:** In 2018 WHO-UNAIDS-PEPFAR-Global Fund launched an implementation tool for national data quality assessment (DQA) for HIV treatment and patient monitoring systems.

- **Uptake of DQA implementation:** A number of countries implemented national DQAs of HIV treatment data between 2018 and 2019 following release of the DQA tool.

- **Sustainability and moving towards long term DQI:** Need for routine DQ assurance activities to enable integration within programmes as part of efforts to strengthen health information systems and long-term DQ improvement strategies identified.

- **New DQ module:** In 2020 WHO-UNAIDS-PEPFAR-Global Fund developed a supplement data quality module for *routine* data quality assurance activities to assess and strengthen *viral load testing* data within HIV programmes and HIV patient monitoring systems.
Objectives of WHO-UNAIDS-PEPFAR-GF DQ module

➢ 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

➢ Assess bottlenecks to improving DQ, including those linked to the return of test results to facilities and patient records (including EMR and LIMS) 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
Objectives (cont.)

➢ Developing and implementing key remedial actions to address the root causes of identified DQ challenges in VL monitoring and strengthen data systems

➢ Ensure 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
Challenges linked to availability and use of VL testing data assessed by routine data quality assurance activities

**Challenges**

- Representativeness of VL testing data as routine VL testing may not be provided at all health facilities or to all populations
- Delays in timely transmission, receipt and use of VL testing data
- Inconsistency in data between different data sources (e.g. EMR vs. Laboratory information management system vs. paper laboratory forms)
- Lack of disaggregated data on VL coverage & suppression by age, sex, pregnancy status, key population and TB status

**Response**

- Assess completeness of VL monitoring at health facility and laboratory level and determine VL testing coverage
- Identify bottlenecks in reporting and return of VL results to support implementation of remedial actions to improve data flow and ensure use of results for improve patient care
- Identification and verification of level of concordance in VL test results between data sources to establish the origin of data quality issues
- Assess whether country data systems can meet needs for disaggregated information to support identification of gaps in service delivery for specific populations
Focus on VL suppression and coverage

• **VL suppression and testing coverage** recommended to be given priority for routine DQ assurance activities and should align with MoH indicators.

• **Turnaround time of VL results** should also be assessed given importance of timely transmission and receipt of VL results for data completeness and quality of care.

• Countries may also consider including other indicators that are of programmatic and clinical priority in accordance with their needs and context.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
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<tbody>
<tr>
<td>PLHIV who have suppressed VL (WHO 2020 GL code: AV.3)</td>
<td>% of PLHIV on ART (for at least 6 months) who have virological suppression (based on routine VL testing)</td>
</tr>
<tr>
<td>Viral load testing coverage (WHO 2020 GL code: AV.6)</td>
<td>% of people on ART (at least 6 months) with viral load test results</td>
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</table>
Implementation of DQ assurance activities

Six key implementation steps

1. Determine the purpose
   - Will guide the selection of the most appropriate DQ assurance activity

2. Select levels and sites to be included

3. Identify indicators, data sources, and reporting period
   - Example of recommended indicators: VL coverage, suppression and test turnaround time. Data sources and elements and time period for assessing the reported data to be also determined

4. Conduct site visits

5. Review outputs and findings

6. Develop a system strengthening plan, including follow-up actions
   - Feedback of the output and findings of DQ assurance activities provided to facility or lab staff incl. management, as part of the site out-brief

Standardized tools developed for VL monitoring indicators should be used and pilot tested before use. Selected HF and/or labs contacted to identify date and time for DQ assurance activity.
# Menu of recommended DQ assurance activities (1)

## 1. Routine data quality assessment

<table>
<thead>
<tr>
<th>Description</th>
<th>Strengths</th>
<th>Limitations</th>
<th>Implementation considerations</th>
</tr>
</thead>
</table>
| 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 (Annex B)** | ✓ Enables on the spot feedback & mentoring  
✓ Cross-validation enables DQ issues to be identified that may only be evident in one data source  
✓ Verified recounts from source documents of no. of eligible PLHIV receiving VL test & verification of the viral suppression indicator enable site-level correction of data  
✓ Mapping of data & 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 & 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 |
## Main activities implemented during a routine DQA

<table>
<thead>
<tr>
<th></th>
<th>Activity Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Introductory discussions with key staff of the site including facility management and service providers</td>
</tr>
<tr>
<td>2</td>
<td>Review and completion of informed consent (see Annex A)</td>
</tr>
<tr>
<td>3</td>
<td>Assessment of service delivery and data flow processes for VL testing from the facility to lab and from lab to facility to identify &amp; address data deficiencies or bottlenecks within the data workflow in real time (see Annex B)</td>
</tr>
<tr>
<td>4</td>
<td>Completeness checks of VL monitoring data within all or sample of patient files (see Annex C and Annex D)</td>
</tr>
<tr>
<td>5</td>
<td>Cross-validation of data elements of sample of patient files with lab forms, LIMS and/or EMR (see Annex C and Annex D)</td>
</tr>
<tr>
<td>6</td>
<td>Recount and recreation of viral suppression and coverage indicators (see Annex E)</td>
</tr>
<tr>
<td>7</td>
<td>Feedback of findings to facility &amp; lab team &amp; developing a DQI plan for site(s) (see Annexes F and I)</td>
</tr>
<tr>
<td>8</td>
<td>On-the-spot mentoring and feedback as required throughout the exercise</td>
</tr>
</tbody>
</table>
Tool available for assessing data flow and bottlenecks

Annex B

<table>
<thead>
<tr>
<th>Name of interviewer</th>
<th>Name of facility</th>
<th>Facility code</th>
</tr>
</thead>
</table>

**Introductory script for data and service mapping**

Thank you for having us at your facility today. We would like to locate and fix any data defects or bottlenecks within the data workflow to improve the quality of information gathered in real-time and moving forward. We would like to help to streamline and standardize the process for validating patient health information.

Today, we are interested in learning about the data and service quality challenges and successes at your site. These guiding questions and the site visit will be an opportunity to delve deep into the challenges, successes, best practices and innovation in the health information systems here at your facility. To begin, we would like you to walk us through the process of entering a viral load test for a patient. Where does the patient go for sample collection, what happens if a patient does not get a sample done? What happens when viral load test results are not received? Is there a mechanism to follow up with the laboratory on tests that have entered but no results received? Are there any bottlenecks in the process and, if so, where are they?

**Instructions:** Sketch a rough map and make notes of specific best practices or potential improvements for efficiency in data flow.

**Coding questions**

- Is viral load testing performed on every patient at specific populations?
- Are any practices or best practices to order a viral load test for eligible patients?
- What tests are used to order viral load test and who completes them?
- Even when a viral load sample picked up for transport to the laboratory, is the schedule to pick up followed? Reasons for deviations?
- How are results transmitted from the lab to the antiretroviral therapy clinic?
- What tests are used to receive viral load results?
- Are any tools to support the follow-up of patients who received viral load test?
- How are the results entered into patient flow and back to whom?
- How are viral load results provided to patients?
- What is the process of auditing responses after patient visits?
- Who enters the data into the electronic medical records?
- Are any tools used to enter sample collection to result and blood donor-related data?

**Quick flow**

**Let any best practices in viral load patient, sample and documentation flow**

**Provide any comments or recommendations to improve efficiency in patient, sample and documentation flow**

**Let 5-5 critical challenges impacting viral load monitoring and scale-up to your facility**

**Provide any comments, best practices or recommendations for strengthening viral load monitoring and scale-up that could be applicable in other settings**
Annex E

TOOL FOR RECOUNTING VIRAL LOAD TESTING INDICATORS

SECTION 1 REPORTED SITE DATA

SECTION 2 RECREATING THE INDICATORS

WEB ANNEX E TOOLS FOR RECOUNTING VIRAL LOAD TESTING INDICATORS

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

WEB ANNEX E TOOLS FOR RECOUNTING VIRAL LOAD TESTING INDICATORS

AUGUST 2011

TOOL AVAILABLE FOR INDICATOR RECOUNT AND VERIFICATION

World Health Organization
### 2. DQ monitoring via supportive supervision

<table>
<thead>
<tr>
<th>Description</th>
<th>Strengths</th>
<th>Limitations</th>
<th>Implementation considerations</th>
</tr>
</thead>
</table>
| External assessment conducted at the same time as supportive supervision for programme monitoring focusing on assessing:  
- 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 (Annex B)  
- Assessment of service delivery and quality, including clinical care and laboratory aspects (Annexes C and D) | ✓ Enables on the spot feedback & 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 thus quicker to conduct | • Usually involves assessing both service delivery and quality as well as DQ and 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 |
DQ monitoring via supportive supervision – tools available

Annex C: Abbreviated tool for joint assessment of service delivery and quality & DQ

Annex D: Detailed tool for joint assessment of service delivery and quality & DQ
Menu of recommended DQ assurance activities (3)

3. DQ monitoring via lot quality assurance sampling

<table>
<thead>
<tr>
<th>Description</th>
<th>Strengths</th>
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</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>✓ 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</td>
<td>✓ Sampling &amp; defining the DQ standard for a programme area may be challenging and requires piloting ✓ More often applied to ART, and less implementation experience for VL monitoring ✓ Assessing concordance can be limited by non-standardized recording of data elements across data sources ✓ Focuses on assessing DQ and does not include service delivery and quality</td>
<td>• <strong>Criteria for selection:</strong> LQAS is useful for identifying sites where routine DQA could be done with recount of the indicators and more in-depth completeness and cross-validation checks of a sample or all the active patient files • <strong>Frequency:</strong> quarterly or semi-annually</td>
</tr>
</tbody>
</table>
DQ monitoring via lot quality assurance sampling – tools available

Available at:
https://www.measureevaluation.org/resources/publications/ms-19-176

Available at:
https://www.measureevaluation.org/resources/publications/tl-19-51

**LQAS Triage System: Instructions**

The LQAS Triage System is a method for assessing the completeness of data elements in source documents using a sample of client records. Concordance of data elements across data sources can also be assessed. Please see the guidance document “Measuring the Quality of HIV/AIDS Client-Level Data Using Lot Quality Assurance Sampling (LQAS)” for more details and definitions. Learn more at:

https://www.measureevaluation.org/resources/publications/ms-

**Figure 1. Process for Assessing Data Completeness in HIV/AIDS Records using the LQAS Method**

**APPLIED LQAS PROCESS**

- Identify source document(s) of interest
- Select data completeness scenarios
- Collect data
- Sample records
- Assess data completeness based on completeness benchmarks for data elements
- Assess data completeness based on program requirements

**Using the Tool**

The Excel workbook contains macros to help configure the tool for use. When launching Excel, be sure to click on “enable content” when prompted.

After selecting health facilities to evaluate for source document data quality, enter the information for each site on the Facility Info tab. The Facility Info tab has three fields that describe all sites, and seven fields specific to each site.

Assessment information:
- Period for review
- Quality thresholds
- Number of facilities to be reviewed
- Health facility information:
  - Facility name
  - Region
  - District

The tool is general and can be used with any health program, data source, or data elements. It can accommodate data from up to 40 health facilities at once, if more sites are to be evaluated, multiple copies of the tool can be employed.
4. Routine site-level performance review and data review meetings

<table>
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<tbody>
<tr>
<td>• 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</td>
<td>✓ Enables rapid and frequent review</td>
<td>✓ DQ checks implemented are not as comprehensive as the above activities</td>
<td>• <strong>Criteria for selection</strong>: ideally implemented in all facilities; however, if not feasible in facilities in which previous routine DQAs or DQ monitoring via supportive supervision or using LQAS have identified DQ challenges</td>
</tr>
<tr>
<td>• The turnaround time for VL test results should also be assessed, given its importance for both data completeness and quality of care</td>
<td>✓ Low cost</td>
<td>✓ 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</td>
<td>• <strong>Frequency</strong>: monthly</td>
</tr>
<tr>
<td></td>
<td>✓ Supports the rapid implementation of site-level correction of data as needed</td>
<td>✓ Enables the facility to develop plans to improve the patient monitoring system</td>
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<tr>
<td></td>
<td>✓ Enables the facility to develop plans to improve the patient monitoring system</td>
<td>✓ Can be integrated into routine performance review and continuous quality improvement activities to improve service delivery</td>
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<td></td>
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</tbody>
</table>
Routine site-level performance review and data review meetings

- Represents low-cost DQ assurance approach facilities can use to check and correct their data at source
- Reviews can be part of broader continuous quality improvement processes
- Implemented by facility and laboratory staff to verify and check reports of VL testing and suppression data before monthly reporting to MoH
- Turnaround time for VL tests should also be assessed along with completeness of VL testing data and VL suppressed data in registers vs MoH monthly report or alternative source e.g. lab result forms/LIMS database or EMR
- 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
Resource and time requirements of recommended DQ assurance activities

1. Routine DQA
2. DQ monitoring using LQAS
3. DQ monitoring through supportive supervision
4. Site-level routine review of data and performance

Time to implement

Cost/human resource requirements
Data visualization of outputs of DQ assurance activities

- Results of DQ assurance activities should be documented and presented to facility and/or laboratory staff.
- When possible, graphical display or dashboard with results preferable and should be presented as part of the site out brief.
- A copy of results should be left with facility and laboratory staff for documentation and to motivate and encourage future improvement.
Tools available for data visualization of outputs of DQ assurance activities

Annex F

Table A6.1. VI coverage indicator

<table>
<thead>
<tr>
<th>Facility code</th>
<th>VL coverage, reconfirmed</th>
<th>VL coverage, reconfirmed, public health</th>
<th>VL coverage, DQ 2 data</th>
<th>VL coverage, public health data</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>60</td>
<td>80</td>
<td>85</td>
<td>87</td>
</tr>
<tr>
<td>B</td>
<td>65</td>
<td>85</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>C</td>
<td>66</td>
<td>86</td>
<td>85</td>
<td>82</td>
</tr>
<tr>
<td>D</td>
<td>72</td>
<td>81</td>
<td>85</td>
<td>82</td>
</tr>
</tbody>
</table>

Verification factor (VF) calculated as follows: [reconfirmed indicator/report indicator] * 100

Table A6.2. VI suppression indicator

<table>
<thead>
<tr>
<th>Facility code</th>
<th>VL suppression, reconfirmed</th>
<th>VL suppression, reconfirmed, public health</th>
<th>VL suppression, DQ 2 data</th>
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<td>C</td>
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<tr>
<td>D</td>
<td>72</td>
<td>81</td>
<td>85</td>
<td>82</td>
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</tbody>
</table>

Verification factor calculated as follows: [reconfirmed indicator/report indicator] * 100

Interpretation:
A verification factor above 100% indicates underreporting, while under 100% indicates overreporting of the indicator. 100% indicates full alignment or concordance between the reconfirmed indicator during the routine data quality assurance and the reported indicator to the ministry of health.

Over- and underreporting are calculated as follows: [1 minus reconfirmed/report indicator] * 100

Table A6.3. VI coverage indicator verification

<table>
<thead>
<tr>
<th>Facility code</th>
<th>VL coverage, reconfirmed</th>
<th>VL coverage, ministry of health report</th>
<th>VL coverage, DQ 2 data</th>
<th>VL coverage, public health data</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>60</td>
<td>80</td>
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<td>87</td>
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<td>B</td>
<td>65</td>
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Interpretation:
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Over- and underreporting are calculated as follows: [1 minus reconfirmed/report indicator] * 100
Facility/laboratory data quality improvement plan

Annex I

### Site-level Data Quality Improvement Action Plan

<table>
<thead>
<tr>
<th>Identified data quality issues</th>
<th>Potential root causes</th>
<th>Description of proposed remedial action</th>
<th>Requirements to complete action</th>
<th>Responsible individuals</th>
<th>Timeline (by when)</th>
<th>Planned follow-up monitoring visit date to ensure that the intervention is being implemented</th>
<th>Comments</th>
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Dissemination of results of DQ assurance activities

MoH to ensure results and documentation of DQ assurance activities reach the appropriate levels (e.g. facility, district, subnational and national), relevant focal points and partners.

Template available: Annex G
Cost considerations

- Indicative generic budgets for the recommended DQ assurance activities available to support country implementation and can be adapted as required.

### Indicative Generic Budgets

#### 1. Training,Subnational and district HIV programme focal people, monitoring and evaluation officers, health management information system officers,rophics

<table>
<thead>
<tr>
<th>Activity</th>
<th>Cost Unit</th>
<th>Cost Rate</th>
<th>Total Cost</th>
</tr>
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<tbody>
<tr>
<td>Training</td>
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<td>$30,000</td>
</tr>
<tr>
<td>Subtotal</td>
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<td></td>
<td>$30,000</td>
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</table>

#### 2. Printing tools and communication

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<th>Total Cost</th>
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</thead>
<tbody>
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<td></td>
<td>$5,000</td>
</tr>
<tr>
<td>Subtotal</td>
<td></td>
<td></td>
<td>$5,000</td>
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</table>

#### 3. Data abstraction

<table>
<thead>
<tr>
<th>Activity</th>
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<th>Cost Rate</th>
<th>Total Cost</th>
</tr>
</thead>
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<tr>
<td>Subtotal</td>
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<td>$20,000</td>
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</table>

#### 4. Technical support

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<th>Cost Rate</th>
<th>Total Cost</th>
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<td>$5,000</td>
</tr>
<tr>
<td>Subtotal</td>
<td></td>
<td></td>
<td>$5,000</td>
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</table>

#### 5. Report production, dissemination

<table>
<thead>
<tr>
<th>Activity</th>
<th>Cost Unit</th>
<th>Cost Rate</th>
<th>Total Cost</th>
</tr>
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<tr>
<td>Subtotal</td>
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#### Total (USD)

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**Annex H**
Following up DQ assurance activities – examples included recommended for long term DQI
A. Conduct DQ monitoring via SS or LQAS next quarter

Fail
- Conduct data review led by MoH/staff not working at HF
- Conduct refresher training for staff on data management & reporting
- Conduct DQ monitoring via SS/LQAS in 10% of same HFs 1 quarter later

Does not fail
- Conduct in depth data review supervised by ≥1 staff from another HF
- Conduct refresher training for staff on data management & reporting
- Conduct DQ monitoring via SS/LQAS in 5% of same HFs 1 quarter later

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

B. Conduct routine DQA 1 year later in HF not reached by previous DQA

DQ = data quality assessment
HF = health facility
SS = supportive supervision
LQAS = lot quality assurance sampling
Future directions

- DQ assurance and improvement under the context of COVID-19
- Institutionalizing and integrating DQ assurance activities critical for strengthening patient monitoring systems and implementation of long term DQI strategies
- Sequencing and flow of different data quality assurance activities but also drawing on other activities e.g. mentoring, supporting data entry into EMR etc.
- 2022 consolidated HIV Strategic Information Guidelines currently under development – recommendations and guidance on data quality including long term DQI to be developed
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