Session 4: Indicators for Scale-Up of Viral Load (VL) Testing and Program Outcomes

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Centers for Disease Control and Prevention (CDC), Division of Global HIV and Tuberculosis (DGHT)

Thursday April 1st, 2021
• Introductions

• Review of Key Concepts:
  – Understand the general components of the M&E framework for country’s VL testing
  – Determine the relevant stakeholders involved in M&E
  – Create M&E implementation process plan

• Session 4 Topics:
  – Mapping data flow for client oversight and national reporting
  – Reviewing the VL cascade to inform development/revision of measurable indicators
  – Identify indicators for VL coverage and outcome monitoring
  – Data collection, analysis, and reporting of VL indicators in national system
    ▪ Uganda’s experience with updating national and facility registers for VL testing
Review of Key Concepts
What does a monitoring and evaluation (M&E) strategy outline?

- What will be monitored and/or evaluated
- What data needs to be collected
- How the data will be used
- How monitoring and evaluation activities will be managed

What does a monitoring and evaluation (M&E) strategy include?

1. Description of overall program (problem statement and frameworks)
2. Indicators
3. Data sources and reporting systems
4. Data analysis for demonstrating program outcome/impact
5. Dissemination plan and information use
6. Data quality assurance plans
7. Implementation plan, including budget and timeline
### Program monitoring

- Main stakeholders
- Indicators that include definitions, disaggregation, data sources and frequency of reporting
  - Baseline data and targets to be achieved with time frame
  - Responsible parties
- Data systems and management
- Data quality assessment
- Data analysis
- Data use
- Estimated budget to conduct program monitoring

### Evaluation

- Purpose of the evaluation
- Evaluation questions
- Type of evaluation
- Individuals and roles in the evaluation team
- Users of the evaluation findings (stakeholders)
- Timeline
- Budget
Key Area of Focus: Stakeholders

Identifying and involving stakeholders in M&E for VL

• Key for strong and functional M&E systems.
• Multi-disciplinary: laboratory, clinical, and monitoring and evaluation staff
• Coordination and collaboration between stakeholders to ensure strong and functional:
  – Data capture and monitoring and evaluation tools
  – Data systems at facilities, laboratories, sub-national, and national levels
Engagement of Clinical, Lab, and M&E is Key

It’s not my problem, the hole is in their side of the boat!

It’s better to be on the main boat!

M&E
Overview

• Example of one way to approach developing template.

• Recommend having one part looking at **performance monitoring** and another looking at **evaluation**.

• We will provide a blank, adaptable template – make it your own!

- Data systems and management
- Data analysis and quality
- Using the data and disseminating results
M&E Plan Template Pt 2: Evaluation Plan

• Evaluation plan narrative:
  – Stakeholders
  – Purpose of the evaluation
  – Program goals and objectives
  – Logic model
  – Individuals and roles on the evaluation team
  – Users of the evaluation findings
  – Timeline
  – Budget

<table>
<thead>
<tr>
<th>Evaluation questions</th>
<th>Type of evaluation</th>
<th>Variables and indicators</th>
<th>Data sources</th>
<th>Data collection method</th>
<th>Dissemination and use</th>
</tr>
</thead>
<tbody>
<tr>
<td>What do we need to know or evaluate (fidelity and effectiveness) about the program?</td>
<td>What type of evaluation is it? Process? Outcome? Both?</td>
<td>What specific variables and indicators are needed to answer your evaluation question?</td>
<td>What will the data source be for the variables and indicators?</td>
<td>How will the data be collected? Qualitative, quantitative or mixed methods? Will interviews, document reviews and/or reviews of program data occur?</td>
<td>What dissemination and use strategies will be used to share evaluation findings? How will stakeholders use them to improve programs? Make sure to include where the evaluation findings will be publicly available (for PEPFAR-supported evaluations)</td>
</tr>
</tbody>
</table>

At the end of the last session, you were asked to:

• Develop or update your viral load data flow map, making sure to include all M&E data capture tools. Note gap areas, challenges, concerns, etc.

• Review any existing M&E implementation plans and/or national M&E plans for viral load. If none available, please prepare an outline of what should be included.

Don’t worry if you attempted to do this and got stuck!
Session 4
Mapping the data flow
Key First Step: Map the Data Flow

Idea of how data flow from each source and how data are captured

- Consider the flow for specimens and data!
- Do you have...

- Physical movement of specimen and results?
- Physical movement of specimens and electronic exchange of data/results?
- Electronic Patient Information Systems for all data?
- Other?
How Does VL Data Flow in Your Setting?

• Samples move physically from a site to a lab, but how do the data flow?

Data from site/patient to lab/testing

Results from lab/testing back to site/patient

Physical only

Combination of physical and electronic

Electronic only
Sample to central lab example from Uganda

Health facilities
- Data collection tools being used:
  - Lab request form
  - Daily activities log (HMIS 095)
  - HIV/ART Patient Card (HMIS 122a)
  - ART Register (HMIS 081)

Hub (collection site)
- Hub Register to record data of when samples were collected from sites and sent to CPHL

Central Public Health Lab (CPHL)
- Data from Lab Request form input into LIMS system
Bringing Data Flow and Collection Tools Together

Results to site example from Uganda

Central Public Health Lab (CPHL)
- VL Test Result Form
- Sent back to site via hub
- Data from Lab Request form input into LIMS system and displayed on VL Dashboard

Hub (collection site)
- Hub Register to record data of when results were delivered to sites

Health Facilities
- Data collection tools being used:
  - ART Register (HMIS 081)
  - HMIS Form 071, 072, and/or 078
  - HIV/ART Patient Card (HMIS 122a)
  - ART Quarterly Reporting Form (HMIS 106a)
Aggregating Data for Oversight

Sub-National and National-Level Tools: Reports, DHIS2, LIMS etc.

Site-Level Tools: Patient Cards, Patient Charts, Lab Requisition Forms, Patient Registers, Quarterly Reporting forms etc.
Indicators to Monitor Viral Load Coverage and Outcomes
Things to consider when developing or adapting indicators:

• Program priorities
• Desired outcomes as shown in the logic model
• Gaps or challenges in the program
• Feasibility, resources, and relevance
• Reporting requirements
Identifying Indicators for Viral Load: Where to Start?

List the key steps in the viral load testing cascade

• Helps to inform routine monitoring indicators and how each step would be measured.
  – Table 2 and Annex 5 in the WHO document provide many examples of indicators that can be adapted.

• Can be used for development and/or revision of indicators.
### Example: Outlining key steps and core indicators for viral load testing at sites

<table>
<thead>
<tr>
<th>List Key steps in the cascade of viral load testing</th>
<th>Examples of core indicator for routine monitoring</th>
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<td>Request a viral load test</td>
<td></td>
</tr>
<tr>
<td>Process viral load test sample</td>
<td></td>
</tr>
<tr>
<td>Return viral load test result</td>
<td></td>
</tr>
<tr>
<td>Access to VL Test</td>
<td></td>
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<tr>
<td>Document VL test result in patient chart and other monitoring tools</td>
<td></td>
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<td>Monitor Outcome of VL test result</td>
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## Example: Outlining key steps and core indicators for viral load testing

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<td>Return viral load test result</td>
<td>% of viral load tests results returned to sites within one month of the sample being taken</td>
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<td>Access to VL Test</td>
<td>% of people receiving antiretroviral therapy with viral load results at 12 months after initiating antiretroviral therapy [WHO: VLS.2]</td>
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<tr>
<td>Document VL test result in patient chart and other monitoring tools</td>
<td>% of patient charts with documented VL Test and result in the last 12 months</td>
</tr>
<tr>
<td>Monitor Outcome of VL test result</td>
<td>% of ART patients with a suppressed viral load (VL) result (&lt;1000 copies/ml) documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months</td>
</tr>
</tbody>
</table>
Cascade with Key Indicators for VL Testing and VL Suppressed

- Number of people living with HIV receiving antiretroviral therapy
  - Number of people living with HIV receiving antiretroviral therapy who require at least one annual routine viral load test (depending on the viral load algorithm)

- PLHIV on ART
  - Access to VL Test
    - Number of people living with HIV receiving antiretroviral therapy who have access to viral load testing

- Virally Suppressed
  - Number of people living with HIV receiving antiretroviral therapy who received a viral load test
    - Number of people living with HIV receiving antiretroviral therapy who have suppressed viral loads

- Less Intense model of care
  - Number of people living with HIV with suppressed viral loads referred to a less intensive model of care

Cascade with Key Indicators for Those Not Virally Suppressed

- **Not virally Suppressed**
- **Enhanced Counseling**
- **Received 2nd VL Test**
- **Switch to 2nd Line**
- **Access to VL Test**

- **Number of people living with HIV receiving antiretroviral therapy with viral load ≥1000 copies/ml**
- **Number of people living with HIV receiving antiretroviral therapy with viral load ≥1000 copies/ml who received enhanced adherence counselling**
- **Number who received a follow-up viral load test**
- **Number who had viral load ≥1000 copies/ml on a follow-up test**
- **Number with suppressed viral loads on follow-up test**
- **Number with follow-up viral load test at viral load ≥1000 copies/ml switched to second-line regimen**

## Annex 5: Core Program Indicators for VL

### ANNEX 5. Health outcome indicators for monitoring viral load scale-up and implementation

<table>
<thead>
<tr>
<th>Monitoring question</th>
<th>Indicator</th>
<th>Numerator and denominator</th>
<th>Disaggregation</th>
<th>Data sources and considerations</th>
<th>Programme relevance and importance</th>
<th>Indicator guidance source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What proportion of people receiving antiretroviral therapy received a viral load test at six months after initiating antiretroviral therapy and had suppressed viral loads?</strong></td>
<td>Percentage of people receiving antiretroviral therapy who had viral load test result available within the first six months after initiating antiretroviral therapy</td>
<td>Numerator: number of people living with HIV and receiving antiretroviral therapy with at least one viral load test result in their medical record within the first six months after initiating antiretroviral therapy; Denominator: number of people living with HIV and receiving antiretroviral therapy for at least six months</td>
<td>Demographic: Age, Sex, Pregnant, Breastfeeding; Of those tested, number with suppressed viral loads</td>
<td>Programme records, such as antiretroviral therapy and/or viral load testing registers, cohort reporting forms, patient medical records and electronic medical records; Laboratory information management system (if treatment information and unique patient identifier are available on the viral load test result form and entered into the laboratory information management system)</td>
<td>This indicator, WHO VLS.6, tracks the coverage and outcomes of early viral load testing of people receiving antiretroviral therapy at six months. This indicator assesses the extent to which viral load testing is available in the country and by six months after initiating antiretroviral therapy, everyone receiving it should have received at least one viral load test.</td>
<td>WHO Consolidated strategic information guidelines for the HIV sector (1)</td>
</tr>
<tr>
<td><strong>What proportion of people receiving antiretroviral therapy have suppressed viral loads at 12 months after initiating antiretroviral therapy?</strong></td>
<td>Percentage of people receiving antiretroviral therapy tested for viral load &lt;1000 copies/mL at 12 months after initiating antiretroviral therapy</td>
<td>Numerator: number of people living with HIV receiving antiretroviral therapy with viral load &lt;1000 copies/mL at 12 months after initiating antiretroviral therapy; Denominator: number of people living with HIV receiving antiretroviral therapy with a viral load test result available at 12 months</td>
<td>Demographic: Age, Sex, Pregnant, Breastfeeding; Of those tested, number with suppressed viral loads</td>
<td>Programme records, such as antiretroviral therapy and/or viral load testing registers, cohort reporting forms, patient medical records and electronic medical records; Laboratory information management system (if treatment information and unique patient identifier are available on the viral load test result form and entered into laboratory information management system)</td>
<td>This indicator will allow programmes to monitor viral load suppression of patients 12 months after initiating treatment and to estimate the percentage of PEPFAR-supported people living with HIV who have suppressed viral loads.</td>
<td>WHO Consolidated strategic information guidelines for the HIV sector (1)</td>
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Considerations for VL Indicators

Key disaggregations for indicators:

- Age/sex
- Pregnant Women
- Breastfeeding Women
- Key Populations
- TB-status
- Others?
- See Annex 5 for a list of indicators with disaggregations.

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<th>Data sources</th>
<th>Frequency of collection and reporting</th>
<th>Responsibility</th>
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<tr>
<td>What is the monitoring question?</td>
<td>What performance measure (indicator) will be used? Specify disaggregation (such as &lt;1 male, &lt;1 female etc.) Define the target as needed. Example: X individuals receiving antiretroviral therapy will receive a viral load test in year 1.</td>
<td>Where will the data be obtained? Example: The laboratory information management system, antiretroviral therapy registers, patient charts, viral load testing registers or logbooks etc.</td>
<td>When will the data be gathered and reviewed? Example: Data will be recorded during viral load sample collection from a patient and reported to the health ministry monthly.</td>
<td>Who will capture the data? Example: Site staff will capture data by using the viral load laboratory requisition form. Laboratory staff will enter data from the form and results into the laboratory information management system.</td>
</tr>
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- Data systems and management
- Data analysis and quality
- Using the data and disseminating results
Data collection, analysis and reporting
## Data Collection

- **Two general categories of data:**
  - Routine sources: provide data that are collected on a continuous basis.
    - VL example: viral load testing forms; patient monitoring systems
  - Nonroutine sources: provide data that are collected on a periodic basis, usually annually or less frequently.
    - VL example: viral load coverage

- **Refer to your M&E plan!**

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- **Ensure data quality starts before data are collected:** develop high-level protocols or standard operating procedures for service delivery, district, and national levels
Data Quality

• Review data quality regularly for:
  – Validity
  – Accuracy
  – Availability
  – Completeness
  – Timeliness

• Conduct routine data quality assessments and use findings to improve data.
  – May lead to updating of indicators and trainings to improve data capture and collection!

• Stay tuned for upcoming session of data quality.
• Analyze viral load testing coverage and outcomes at site and above-site levels.
• May be cohort-based or cross-sectional
• Analysis conducted on:
  – Sub-populations
  – Geography
  – Site type
  – Age/sex
  – Pregnant/BF women
  – Other vulnerable populations, if data available (e.g., key populations)
  – TB co-infection
• Use visuals and dashboards to analyze and present data
• Link back to your M&E Plan
Data Visualization Examples

### Viral Suppression

- **Total ART patients**: 4760
- **1st VL done**: 4289
- **Suppressed**: 3600

### Viral Re-suppression

- **VL > 1000**: 599
- **Eligible for analysis**: 534
- **At least 1 EAC**: 410
- **VL 2 done**: 288
- **Re-suppressed**: 107

**Viral suppression cascade**

**Viral re-suppression cascade**
The VL cascade SHW: from first VL>1,000 to 2\textsuperscript{nd} line ART switching (1)

- Where are the biggest gaps?
- Which gaps can we easiest address?
- New approaches to address the gaps?
Data Visualization Examples

1,326,750 
SAMPLES RECEIVED

91.3% 
SUPPRESSION RATE

0.3% 
REJECTION RATE

88.1% 
CURRENT REGIMEN

Disaggregated Data

Key Metrics
Data Visualization Examples

Routine VLs Outcomes by Age (2021)

Justification for tests (2021)

Clinical Failure: 978 (0.59%)
Single Drug Substitution: 10033 (4.79%)
Confirmation of Treatment Failure (Repeat VL): 7609 (3.59%)

Routine VL: 195456 (90.79%)

https://viralload.nascop.org/
• Here are other dashboard examples for you to visit and explore.
  – [Uganda Viral Load Dashboard (cphluganda.org)]
  – [Dashboard (nascop.org)]
  – [EID MALAWI]
  – [Sierra Leone Viral Load Dashboard (nas.gov.sl)]
At the end of the February session, the presenter asked the following:

- What are the major challenges of VL M&E?
  - There is no defined list of indicators
  - Lack of clear VL scale up logic frame
  - Poor knowledge or understanding on the basic concept of M&E
  - No M&E framework at all

- All  

**Answer most selected**

<table>
<thead>
<tr>
<th>Resources</th>
<th>Annexation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No defined list of indicators</td>
<td>Annex 5</td>
</tr>
<tr>
<td>Lack of clear VL scale up logic frame</td>
<td>Annex 1</td>
</tr>
<tr>
<td>Poor knowledge/understanding of basic M&amp;E concepts</td>
<td>MEASURE Evaluation, CDC Program Evaluation</td>
</tr>
<tr>
<td>No M&amp;E framework at all</td>
<td>You now have these tools in your toolbox!</td>
</tr>
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</table>
Uganda’s experience with updating national and facility registers for VL testing
Outline of the Presentation

1. Picture of current VL coverage and suppression
2. Process for identifying the gaps in VL data/monitoring,
3. Updating national tools to address the gaps, improving data flow etc.
In FY20 VL suppression maintained above 90% but VL coverage declined from 94% in Q1 to 88% in Q4 due to COVID restrictions.
Uganda’s Process for Identifying the Gaps in VL Data and Monitoring

Consists of: Regular (quarterly) granular data analysis and visualization, tracking of volumes in the viral load dashboard, and data mining.

- Annual site level targets
- Regular review of total outputs against targets
- Maps for geographic distribution of trends
- Analysis by regimens
- Analysis by age-bands
- Review of turnaround time
How Uganda has Evolved VL Monitoring Tools and Data Flow

- VL request form developed at the start of national testing program in 2014
- Central testing lab returns results using electronic system for accuracy and efficiency

### Treatment information not changed:
- Duration on ART, pregnancy status, TB co-infection, line of ART regimen

### Reason for VL test modified slightly:
- Routine, suspected failure, intensive adherence counseling

### Patient ART regimen revised:
- Regimens revised based on WHO guidance
The VL Data Flow: Now and the Future

- Sample collection done on paper forms
- Referral VL/EID lab enters data into LIS
- VL/EID results returned electronically to recipient facility
- Recipient facility enters VL/EID result in patient file
- EMR updated after clinic visit

Referral VL/EID lab

Only one step of electronization
Conclusion

• The success of VL M&E highly depends on how effective the sample collection step is handled at facilities.

• The future of effective VL M&E is point of care EMR integration.

• Step-wise approaches to facility adaptation to electronic systems ensures minimal stress.

• There is increased demand in tracking VL against ART regimen, HIVDR and pregnancy/breastfeeding status. These are opportunities for improved VL M&E.
Acknowledgments

• Bill Elur, CDC Uganda
• Government of Uganda
• PEPFAR
• WHO
Thank you for your time!

Please send any questions to nsolehdin@cdc.gov
Extra Slides
Refresher: What is Monitoring and Evaluation?

• **Monitoring**
  – Tracking program inputs, activities or outputs, and outcomes.
  – Regular and ongoing.
  – Answers the question “What have we done?”

• **Evaluation**
  – Provides information to help make judgments about the merit of the program, improve the effectiveness of the program, and inform decisions about future programming.
  – Periodic.
  – Answers: “Why?” “So what?” “How well have we done?” or “What difference have we made?”
Refresher: Indicators

What are indicators?

• A unit of data elements that documents change over time.
• *Indicator* of change, does not provide proof or explanations about specific changes resulting from programs.

Why are indicators important?

• Provide a reference point for program planning, management, and reporting.
• Act as early warning signals for corrective action.
• Allows you to track questions, assess trends, and identify problems.
Things to consider when developing or adapting indicators:

• Linked to logic model and monitoring questions?
• Clearly defined?
• Able to measure change?
• Appropriate for the problem being addressed?
• Too costly or difficult to collect and analyze?
• Too many?
• Relevant for program management decisions?
Indicators

What makes a good indicator?
• Valid
• Reliable
• Precise
• Measurable
• Timely
• Programmatical importance

What makes a poor indicator?
• Not linked to program activities
• Ill-defined
• Unrealistic to collect
• Not sensitive to change
Knowledge check

Is this a good indicator?

Percentage of women accessing health services who received appropriate care and assistance.

Percentage of women accessing health services at facility X from time A to time B who received X services during a visit.
Examples of Mapping Data Flow

• Visual

Fig. 2. Example of a map of a sample transport network and the return of results for viral load testing

- Health facilities
- Site for gathering samples and results from facilities in the catchment area (such as a lab hub)
- Central lab
- Samples
- Results
- Results for facilities can be sent via post or delivered to site

• Descriptive

- Consultation room: Clinical practitioner assess the eligibility of a client in the consultation room.
- Mini lab: Eligible clients are sent to the mini lab for VL tests. Patients demographics are entered into VL log book. A lab request form is completed at the same time and send together with the samples (every Tue and Thur).
- Mini Lab: Samples are received by the lab and entered into the log book. The data is also entered into VL electronic database.
- Mini Lab: Samples processed and results are entered in the log book as well as the database.
- Main Lab: Patient results are printed at the main lab and packed according to the clinics and places in the pigeon hole for collection by the drivers.
- Clinic: Phlebotomist receives results and enters date received as well as the number of copies in the log book.
# Core Indicators Along the VL Testing Cascade

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<th>Key steps in the cascade of viral load testing</th>
<th>Core indicators for routine monitoring (see Annex 5 for more detailed indicator information, including numerator and denominator guidance)</th>
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<td>Order viral load test</td>
<td>• % of sites in the specimen transport network that are submitting samples for viral load testing</td>
</tr>
<tr>
<td></td>
<td>• Number of viral load tests submitted by sites to the laboratory and specimen transport network</td>
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<tr>
<td>Process viral load test sample</td>
<td>• Number of viral load tests received by the laboratory from sites</td>
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<td>• Number of viral load tests run by the laboratory</td>
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<tr>
<td>Returned viral load test result</td>
<td>• % of viral load tests results returned to sites within one month of the sample being taken</td>
</tr>
<tr>
<td>Coverage, documentation and outcome of viral load test result</td>
<td>• % of people receiving antiretroviral therapy with viral load results at 12 months after initiating antiretroviral therapy [WHO: VLS.2]</td>
</tr>
<tr>
<td></td>
<td>• % of people receiving antiretroviral therapy tested for viral load with level &lt;1000 copies/mL at 12 months after antiretroviral therapy initiation [WHO: VLS.1]</td>
</tr>
<tr>
<td></td>
<td>• % of people with a viral load result documented in the medical records and/or laboratory information systems within the past 12 months with a suppressed viral load (&lt;1000 copies/mL) [PEPFAR MER: TX, PVLs]</td>
</tr>
<tr>
<td></td>
<td>• % of people living with HIV receiving antiretroviral therapy who have suppressed viral loads [WHO VLS.3]</td>
</tr>
<tr>
<td></td>
<td>• % of people living with HIV with suppressed viral loads (&lt;1000 copies/mL) who have been referred to a less intense model of care or differentiated service delivery</td>
</tr>
<tr>
<td>Intervene on viral load test result if viral load ≥1000 copies/mL</td>
<td>• % of people receiving antiretroviral therapy with viral load ≥1000 copies/mL who have received enhanced adherence counselling</td>
</tr>
<tr>
<td>Order follow-up viral load test if viral load ≥1000 copies/mL</td>
<td>• % of people receiving antiretroviral therapy with viral load ≥1000 copies/mL who received a follow-up viral load test within 3–6 months after enhanced adherence counselling (or according to the national guidelines)</td>
</tr>
<tr>
<td></td>
<td>• % of people receiving antiretroviral therapy who had viral load ≥1000 copies/mL and then had suppressed viral load &lt;1000 copies/mL on follow-up testing</td>
</tr>
<tr>
<td>Modify antiretroviral therapy regimen after two consecutive results of viral load ≥1000 copies/mL</td>
<td>• % of people living with HIV receiving antiretroviral therapy with two documented viral load test results ≥1000 copies/mL switched to second- or third-line antiretroviral therapy regimen</td>
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### Data flow for reporting (cont’d from February session)

<table>
<thead>
<tr>
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<th>Collection</th>
<th>Collation and Storage</th>
<th>Analysis</th>
<th>Reporting</th>
<th>Use</th>
</tr>
</thead>
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<tr>
<td>What are we collecting?</td>
<td>Who collects this data, from where, and how often?</td>
<td>How are data aggregated? Where are the data stored?</td>
<td>List any possible opportunities to transform the data into more meaningful information. Are there other pieces of information available?</td>
<td>To whom will this information be reported?</td>
<td>How can this information be used to make informed decisions? List specific opportunities for use.</td>
</tr>
<tr>
<td>Data elements</td>
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.