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Monitoring, Evaluation, and Reporting (MER) Guidance (v.2.6): Viral Suppression

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Video Outline

1) **Section 1:** Overview of the technical area and related indicators
2) **Section 2:** Indicator changes in MER 2.6
3) **Section 3:** Review of numerator, denominator, and disaggregations.
   - What is the programmatic justification and intention for the data being collected?
   - How are program managers expected to use this data to make decisions that will improve PEPFAR programming?
   - How does it all come together? How should the data be visualized (e.g., cascades)? How do these indicators relate to other MER indicators?
4) **Section 4:** Overview of guiding narrative questions
5) **Section 5:** Data quality considerations for reporting and analysis
6) **Section 6:** Additional Resources and Acknowledgments

Section 1:
Overview of Viral Suppression

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Overview of Treatment and Indicators

- Viral Suppression-specific indicators covered in this video include:
  - TX_PVLS
- Found in the “Viral Suppression” program area group in MER Guidance

Summary of FY21 Treatment-Specific Indicators

Program Area Group	Indicator Code	Indicator Description	Reporting Frequency	Reporting Level
Viral Suppression	**TX_PVLS**	Percentage of ART patients with a suppressed viral load (VL) result (<1000 copies/ml) documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months	Quarterly	Facility

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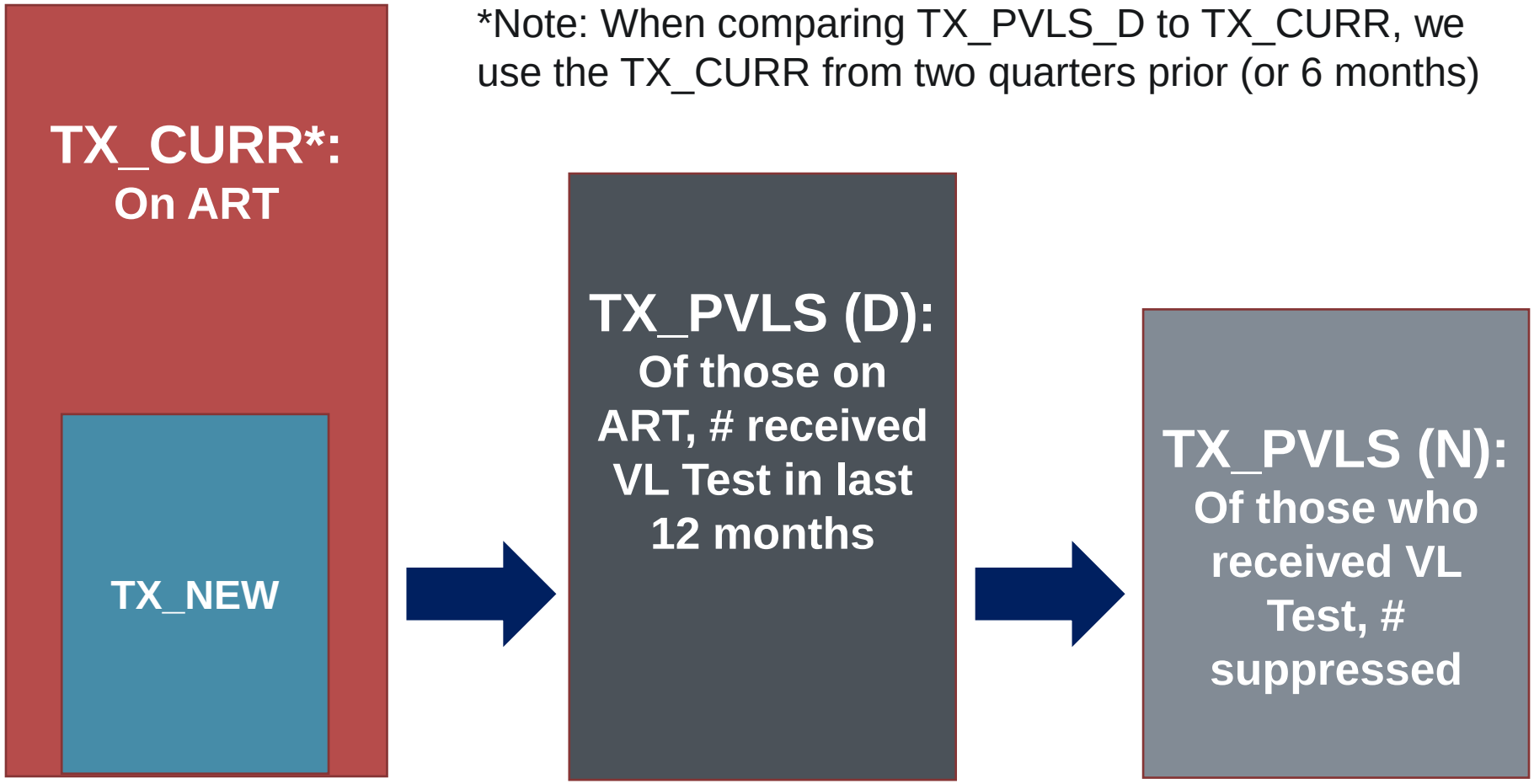
Relationship Between Treatment and Viral Suppression Indicators

TX_CURR, TX_NEW, TX_PVLS

*Note: When comparing TX_PVLS_D to TX_CURR, we use the TX_CURR from two quarters prior (or 6 months)



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Section 2:

Indicator changes in MER 2.6

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What's Changed?

There are no changes to TX_PVLS in MER 2.6

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Section 3:

Review of numerator, denominator, and disaggregations

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Indicator: TX_PVLS

Indicator Definition: Percentage of ART patients with a suppressed viral load (VL) result (<1000 copies/ml) documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months

Numerator: Number of ART patients with suppressed VL results (<1,000 copies/ml) documented in the medical or laboratory records/LIS within the past 12 months

Denominator: Number of ART patients with a VL result documented in the medical or laboratory records/LIS within the past 12 months

Required Disaggregations: (for both numerator and denominator)

- Age/Sex (by Routine, Targeted)
- Pregnant or BF (by Routine, Targeted)
- Key Population (by Routine, Targeted)

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TX_PVLS: Viral Load Suppression benchmark

Note that the WHO Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring define Viral Load Suppression as an undetectable viral load of less than 50 copies/mL.

TX_PVLS uses the less then 1,000 copies/mL because some methods of viral load testing (e.g. dried blood spot, Roche PSC) are not able to detect viral loads as low as 50 copies/mL.

TX_PVLS: Definitions of Disaggregates

- **TX_PVLS Indicator Disaggregate Definitions:**
  - Indication:
    - **Routine:** Refers to VL tests obtained at standard intervals following ART initiation to monitor virologic response to ART (testing frequencies and interval are dependent on the National guidelines but should be recommended to occur at least annually for patients on ART) and includes follow-up VL tests done after an initial VL result of VL≥1000.
    - **Targeted:** refers to viral load tests ordered based on a specific clinical indication, (e.g., concern about disease progression or failure to respond to ART).

TX_PVLS: How to Count

Data Source(s):

- Clinical sources (e.g. electronic or paper patient records)
- If clinical sources are unavailable, electronic laboratory information system (LIS)
- The data source used for reporting on this indicator should be specified and data reported should be de-duplicated and used to inform patient care at sites.

*Only VL tests with recorded results and VL results that are linked back to patients should be included in the numerator or denominator

How to Calculate Annual Totals:

- Snapshot Indicator. Results are cumulative at each reporting period. (FY21 Q4=Annual Total)

TX_PVLS: How to Count (cont.)

Key Considerations for Reporting (FAQs):

- Reporting period covers a 12-month period and will include data from the previous fiscal year.
- Individuals, not tests should be reported.
- VL results should be reported for patients who have been on ART for at least 3 months (or according to national guidelines).
- Where more than one result is available for the reporting period, the most recent result should be reported.

TX_PVLS Reporting Timeframe	FY 2019			FY 2020			
	FY19 Q2	FY19 Q3	FY19 Q4	FY20 Q1	FY20 Q2	FY20 Q3	FY20 Q4
	Jan Feb Mar	Apr May Jun	July Aug Sep	Oct Nov Dec	Jan Feb Mar	Apr May Jun	Jul Aug Sep
FY20 Q1 Reporting	FY20 Q1: 12 Months Reporting						
FY20 Q2 Reporting		FY20 Q2: 12 Months Reporting					
FY20 Q3 Reporting			FY20 Q3 12 Months Reporting				
FY20 Q4 Reporting				FY20 Q4: 12 Months Reporting			

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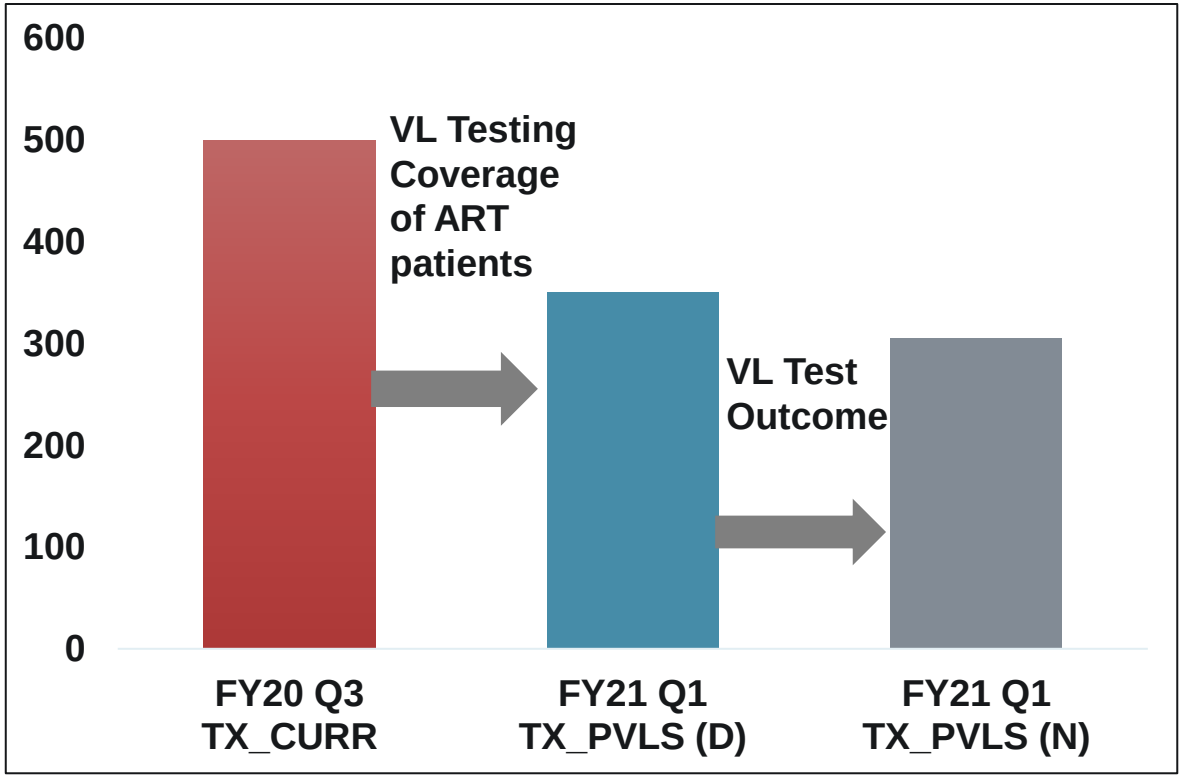
TX_PVLS: Comparison of TX_CURR and TX_PVLS

- **Considerations:**
  - Eligibility for first VL test (e.g. 6 months on ART)

- **VL Testing Coverage:** TX_PVLS (D)/TX_CURR
- **VL Suppression:** TX_PVLS (N)/TX_PVLS (D)



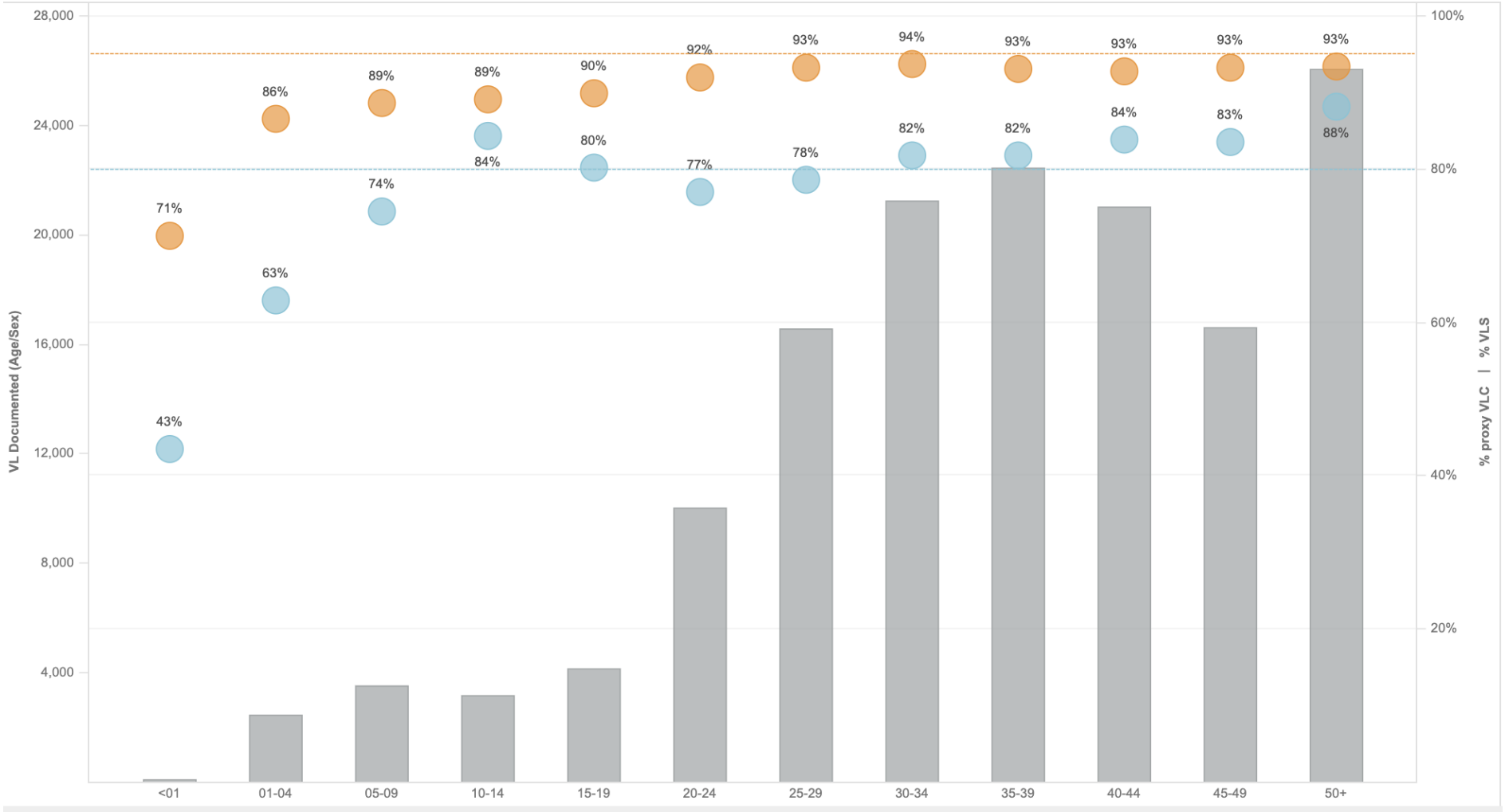
TX_PVLS: Use of Results for Program Oversight and Improvement

- Monitor ongoing scale-up of VL testing coverage and VL suppression

- Analyze both VL testing coverage and suppression rates by geography, age/sex sub-population, and implementing mechanisms

- Real-time review of VL results trigger immediate response to follow-up on patients who are not suppressed and improve program services for populations with low suppression rates

VLC, VLS, and Patients with Documented VL



Single OU: Viral Load Dossier > Age/Sex Specific Chapter > By Age - VLC, VLS, TX_PVLS, D

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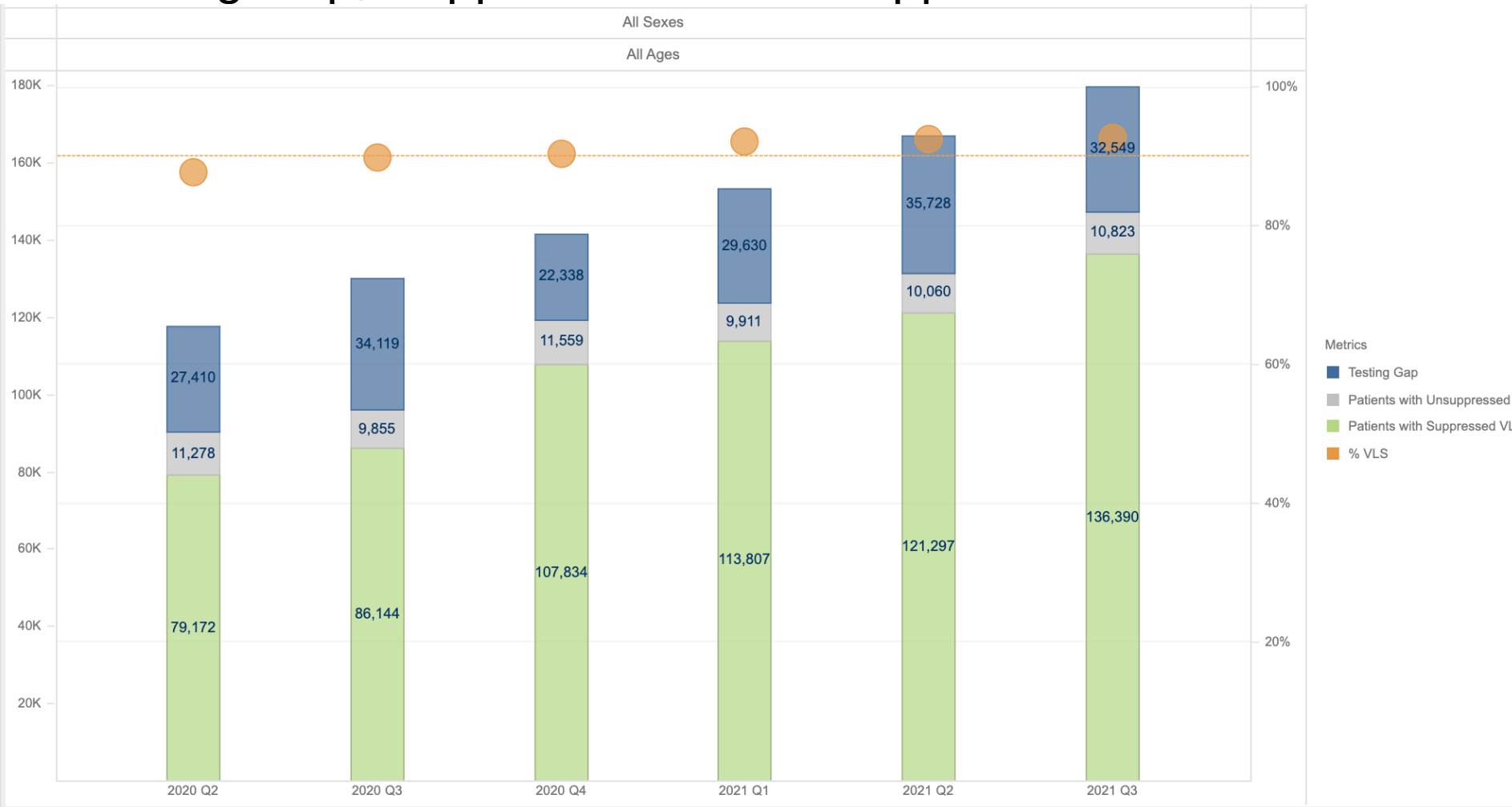
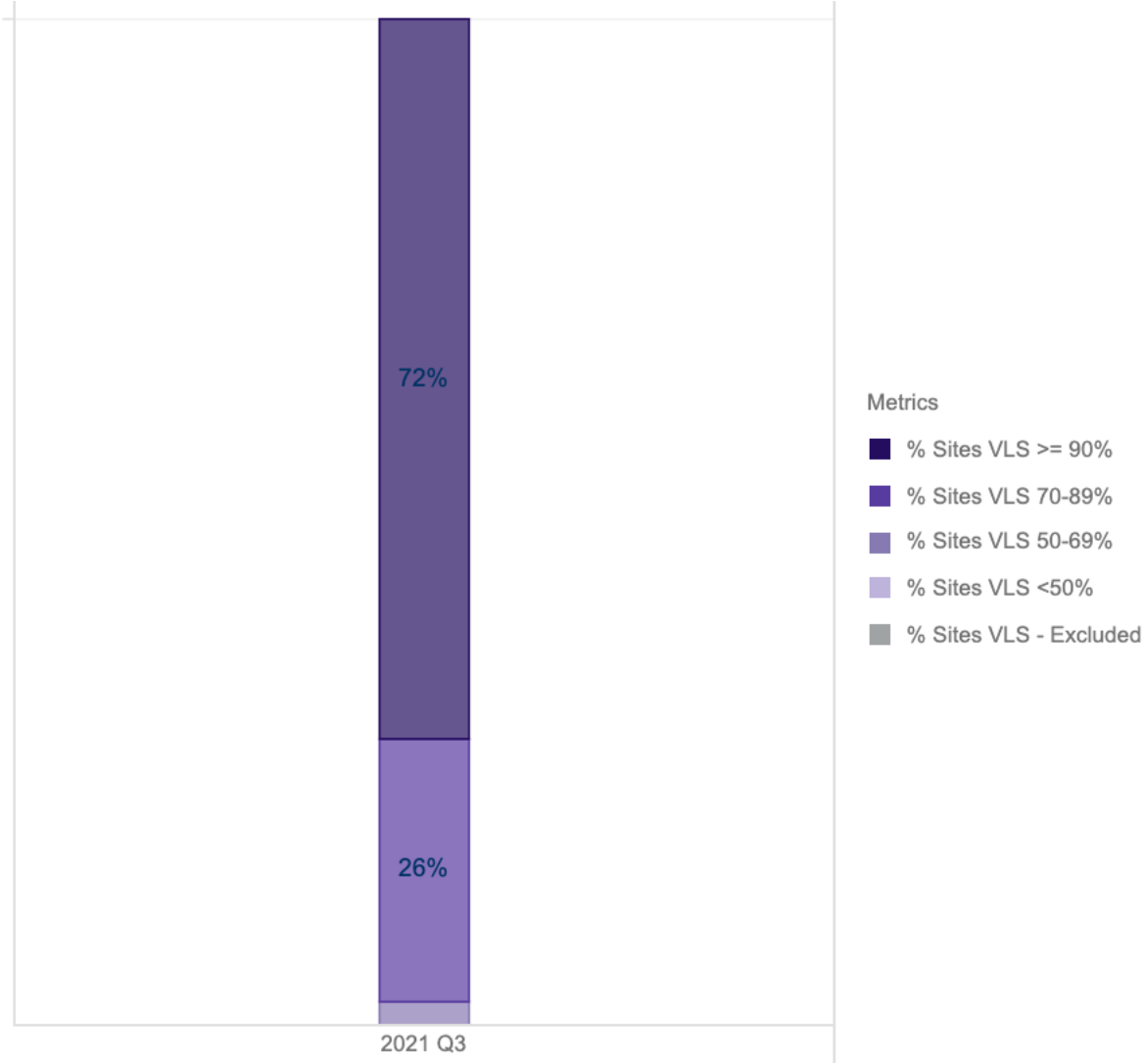
Viral Load Outcomes

VL Testing Gap, Suppressed and Unsuppressed Patients



VL testing gap: total patients eligible for VL test minus patients with VL result in medical record.

Proportion of Site by Viral Suppression Category



Single OU: Viral Load Dossier > Facility: All Pop Chapter > Facility - Site by VLS Category

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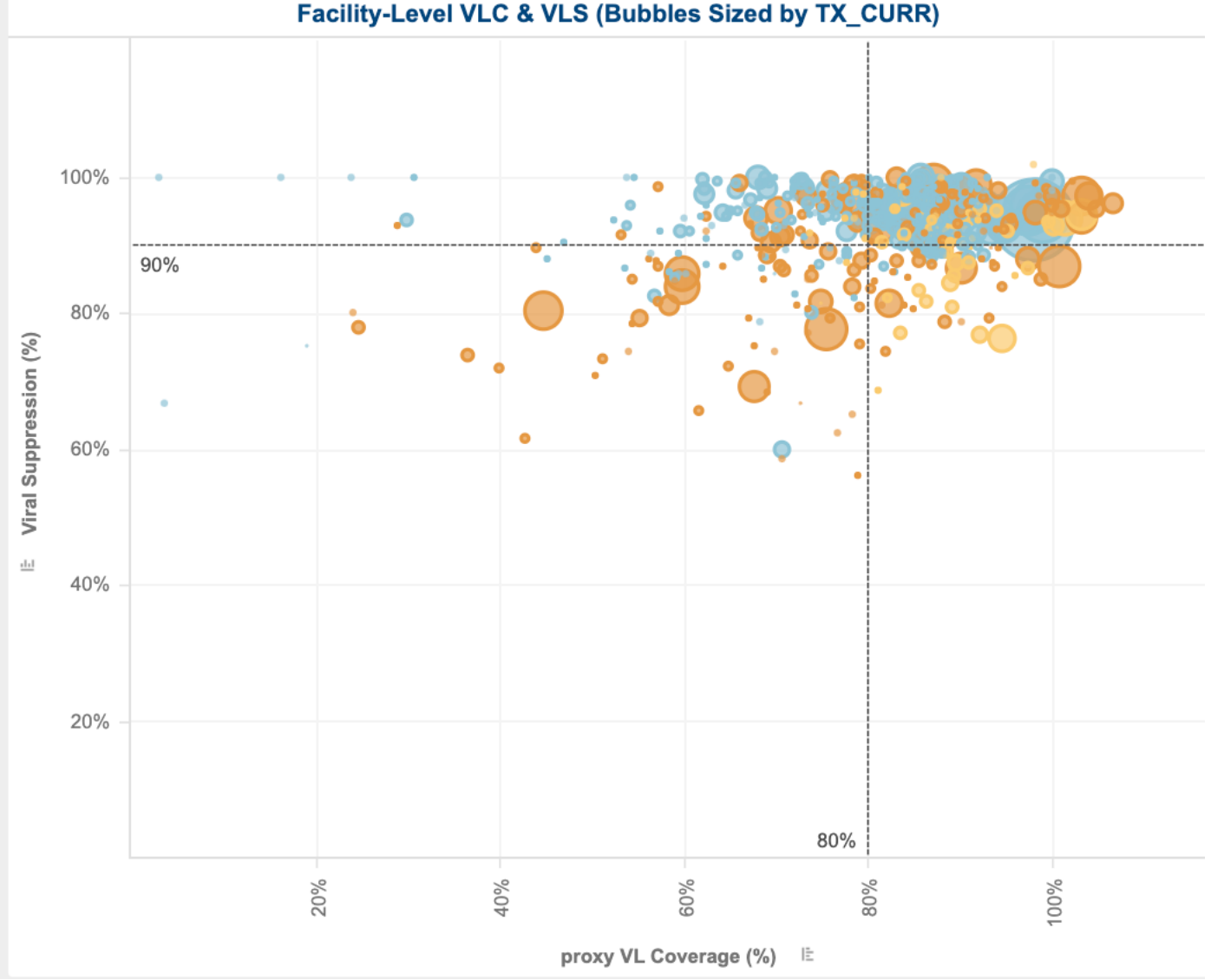
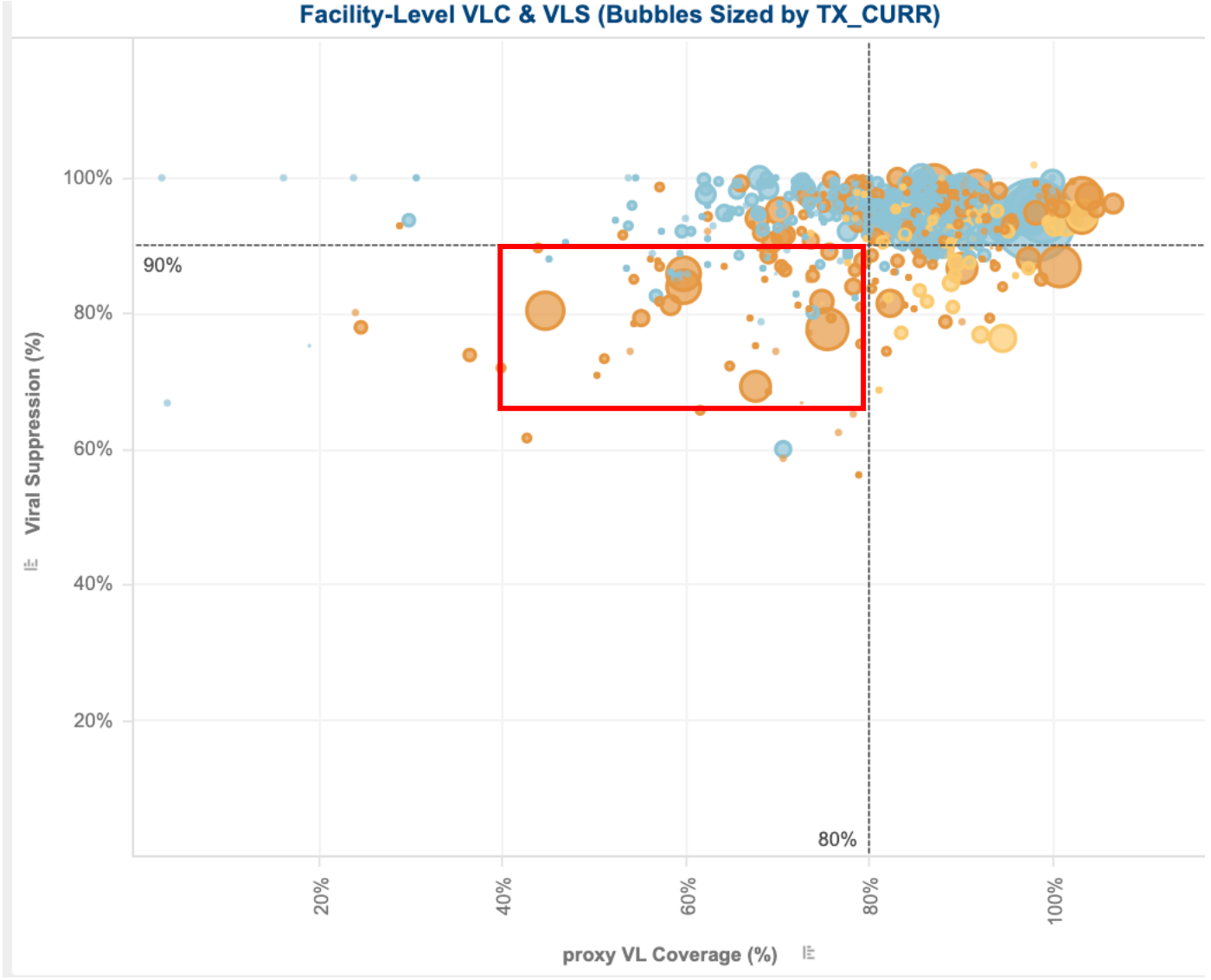
Facility-level VLC and VLS by SNU



Single OU: Viral Load Dossier > Facility: All Pop Chapter > Facility – VLC and VLS

Facility-level VLC and VLS by SNU



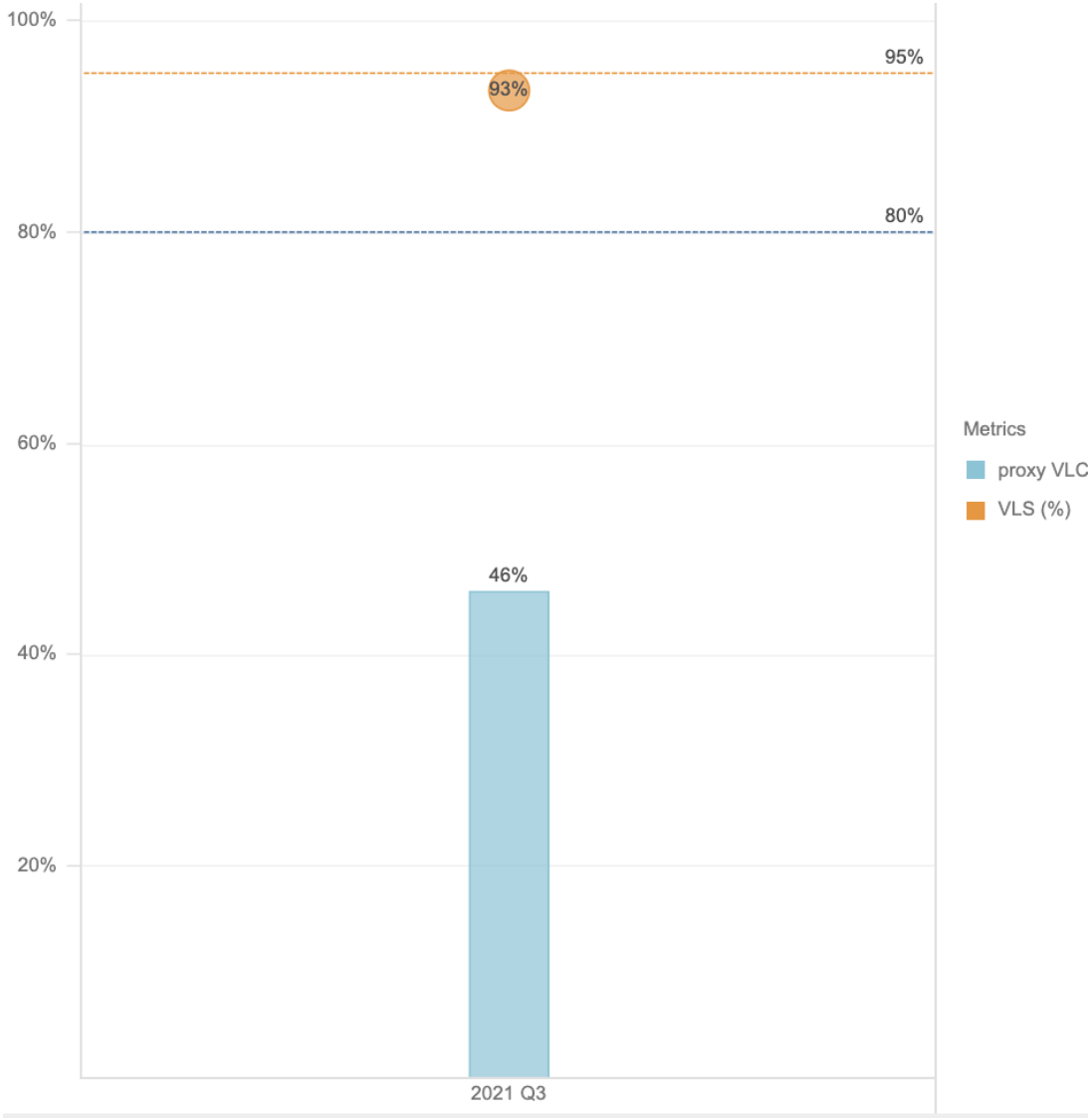
Single OU: Viral Load Dossier > Facility: All Pop Chapter > Facility – VLC and VLS

Estimating VL Coverage for Pregnant Women

- Compare TX_PVLS (D) “Pregnant” disaggregate to the sum of the last four quarters of PMTCT_ART “Already on ART” disaggregate.
- This coverage calculation may underestimate the number of pregnant women that need a viral load test as it does not include pregnant women newly initiating ART. When country level guidance indicates a viral load test for pregnant women newly initiating ART, the coverage denominator should include both PMTCT_ART “New on ART” and PMTCT_ART “Already on ART”

VLC among Pregnant Women

Single OU: Viral Load Dossier > Pregnant and Breastfeeding Women Chapter > PBFW VLC and VLS



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Section 4:

Overview of guiding narrative questions

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TX_PVLS Narrative Questions

1. Briefly **describe the VL testing algorithm** used in country. Please ensure that the description includes any differences in the VL monitoring algorithm for different sub-populations (e.g., pregnant women, breastfeeding women, children, etc.).
2. Specify and briefly **describe the data sources** used to report on this indicator (e.g., EMR, LIS, DHIS 2 etc.). If the LIS is used, please explain why clinical sources could not be used to report on this indicator.
3. **What efforts are made to ensure individuals, not tests are being reported** (e.g., processes of de-duplicating data to reflect unique individuals being tested and outcomes). Please describe the de-duplication methodology used, if applicable.

TX_PVLS Narrative Questions (cont.)

4. **Describe the overall coverage of VL testing** in the country, with any differences by region or age.
5. Describe any **association of ART regimen type with TX_PVLS.**

Section 5:

Data quality considerations for reporting and analysis

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TX_PVLS: Data Quality

- **Denominator ≥ Numerator:** The number of VL results from adults and children on ART must be greater than or equal to the number of VL results from adult and pediatric ART patients with a VL <1,000 copies/ml.
- **Numerator ≥ subtotal of each disaggregation:** The total number of VL results from adult and pediatric ART patients with a VL <1,000 copies/ml should be greater than or equal to the sum of all of the results disaggregated by age/sex, pregnancy/breastfeeding status, and test indication.
- **TX_CURR ≥ TX_PVLS (D):** TX_CURR should be greater than or equal to the number of adults and children on ART with VL results

Section 6:

Additional Resources and Acknowledgments

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Additional Resources

- WHO Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring
- Please refer to the COP guidance for additional information on viral load testing and suppression.

Acknowledgments

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- Thank you to George Alemnji for reviewing the presentation

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Thank you!