



**Global Health Security
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U.S. DEPARTMENT *of* STATE



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20 YEARS OF IMPACT

Need for Quality and Timely Laboratory Data to Ensure Correct Clinical and Public Health Decision Making

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ASLM 2023, December 12th -15th

Introduction

- According to the CDC, 70% of medical decisions depend on laboratory test results.
- A 1% test error is huge in the context of total tests performed. For example, 1% HIV test error in 1000 tests is 10 errors.
- Diagnostic errors have ethical, clinical and policy implications.
- Timely delivery of accurate test results has huge clinical, programmatic, and public health implications.
- There is need for more innovations to support laboratory quality and timely data



PEPFAR's Five-year Strategy | **Enabler #3 Data**



ENABLER 3: DATA

1. Strengthening laboratory information management systems (LIMS)
2. Timely and quality assured data
3. Integration lab data/surveillance systems
4. Information/data-driven decisions in laboratory policy development and program implementation



Quality and Timely Data

Quality Data

Data quality is the measure of how well suited a data set is to serve its specific purpose. Measures of data quality are based on data quality characteristics such as accuracy, completeness, consistency, validity, uniqueness, and timeliness.

Timely Data

This refers to expected time of availability and accessibility of data in making business decisions.



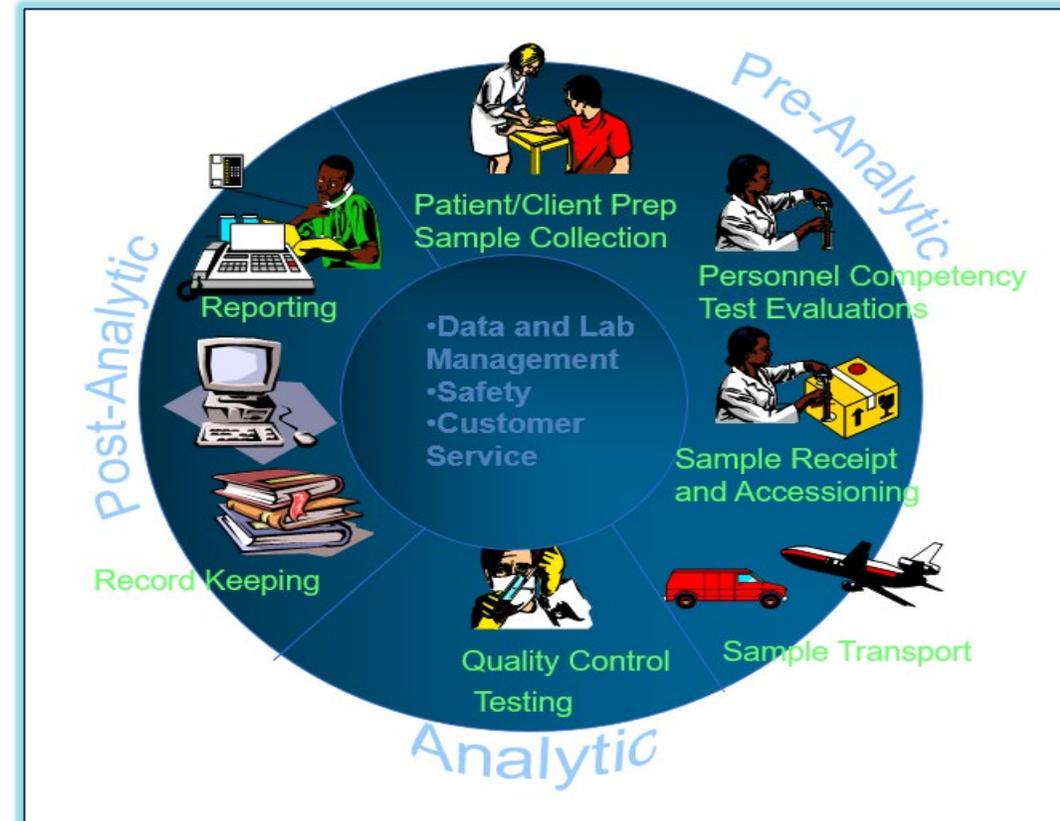
Types of Data Timeliness Checks

- Is the data up-to-date and is it available?
- How fresh is the data?
- What is the lag between adjacent records?
- What is an average lag between records?
- What is the delay in data upload?

Lab Data Errors Occur in Pre-analytical, Analytical, or Post-analytical Phases

Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia

- Overall, 1124 (58.5%)
- Pre-analytical phase 807 (71.8%)
- Analytical phase 85 (7.6%)
- Post-analytical phase 232 (20.6%)



<https://www.dovepress.com/assessment-of-types-and-freque232> ency-of-errors-in-diagnostic-laboratories-peer-reviewed-fulltext-article-PLMI#:~:text=Laboratory%20error%20is%20defined%20as,interpreting%20and%20reacting%20to%20them%E2%80%9D.&text=An%20error%20in%20the%20clinical,impossible%20to%20perform%20error%2Dfree.

https://iris.who.int/bitstream/handle/10665/44665/9789241548274_eng.pdf?sequence=1



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WHO, 2011

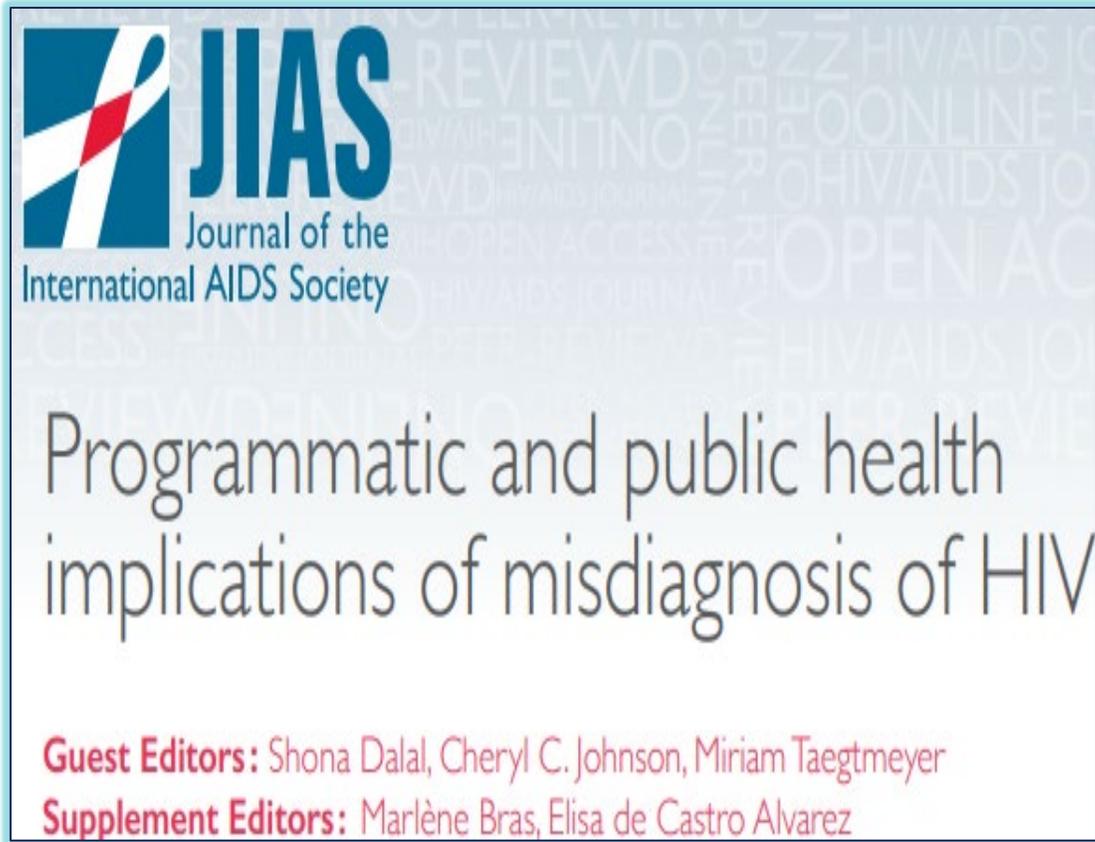
The Laboratory is Blamed for Every Error

[Laboratory errors – why the laboratory is not (always) to blame]

More than half of the so called "laboratory errors" has already happened before the analysis starts in the laboratory and many mistakes are made after the analysis itself. Pre- and post-analytical errors cause 60 to 90 % of all unexpected or erroneous values; only 10 to 15 % are caused by analytical problems. Internal quality control and external quality assessments are a matter of course today while



Programmatic and Public Health Impact of Misdiagnosis



- Worsening the condition,
- Confusion,
- Being prescribed the wrong medication,
- Not being prescribed medication,
- lost time seeing other healthcare providers,
- Overall impact on the national surveillance system
- Impact on programmatic and policy decision making

<https://www.hst.org.za/publications/NonHST%20Publications/Programmatic%20and%20public%20health.pdf>



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How do we Minimize Diagnostic Errors?

Close any Gap within the Clinical/Laboratory Interface

AIDS RESEARCH AND HUMAN RETROVIRUSES
Volume 00, Number 00, 2020
© Mary Ann Liebert, Inc.
DOI: 10.1089/aid.2019.0266

REVIEW ARTICLE

Clinical/Laboratory Interface Interventions to Improve Impact of Viral Load and Early Infant Diagnosis Testing Scale-Up

George Alemnji,^{1,2} Rituparna Pati,¹ Helen Chun,¹ Clement Zeh,¹
Fausta Mosha,³ George Siberry,⁴ and Pascale Ondo⁵

- Strong communication and collaboration between the clinical and laboratory teams throughout the cascade,
- Joint performance review,
- Site visits,
- Continuous quality improvement activities/trainings,
- Implementation of agreed innovations and best practices,



Minimize HIV Diagnostic Errors

PEPFAR Rapid HIV Testing Continuous Quality Improvement (RT-CQI)



Consolidated Guidelines on HIV Testing Services

Quality Improvement and Accreditation | Key to Minimizing Diagnostic Errors

Laboratory Accreditation is most Efficient Approach to Sustainability

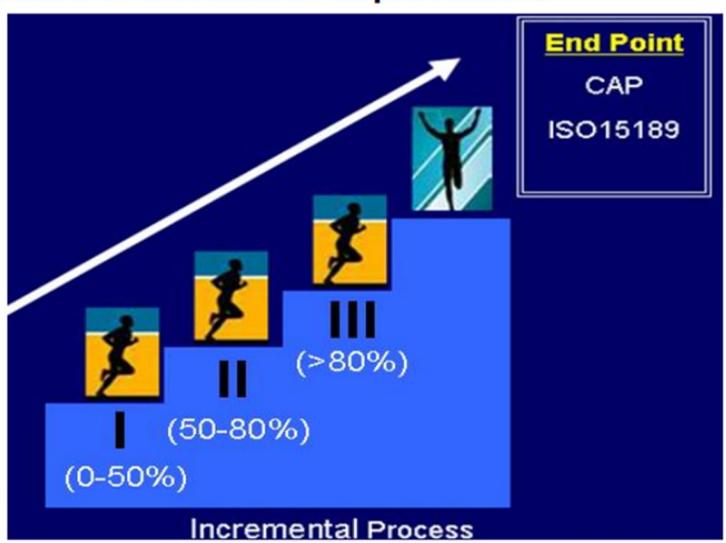
Strengthening Laboratory Management Toward Accreditation (SLMTA)

Implement Practical and sustainable Quality Management Systems

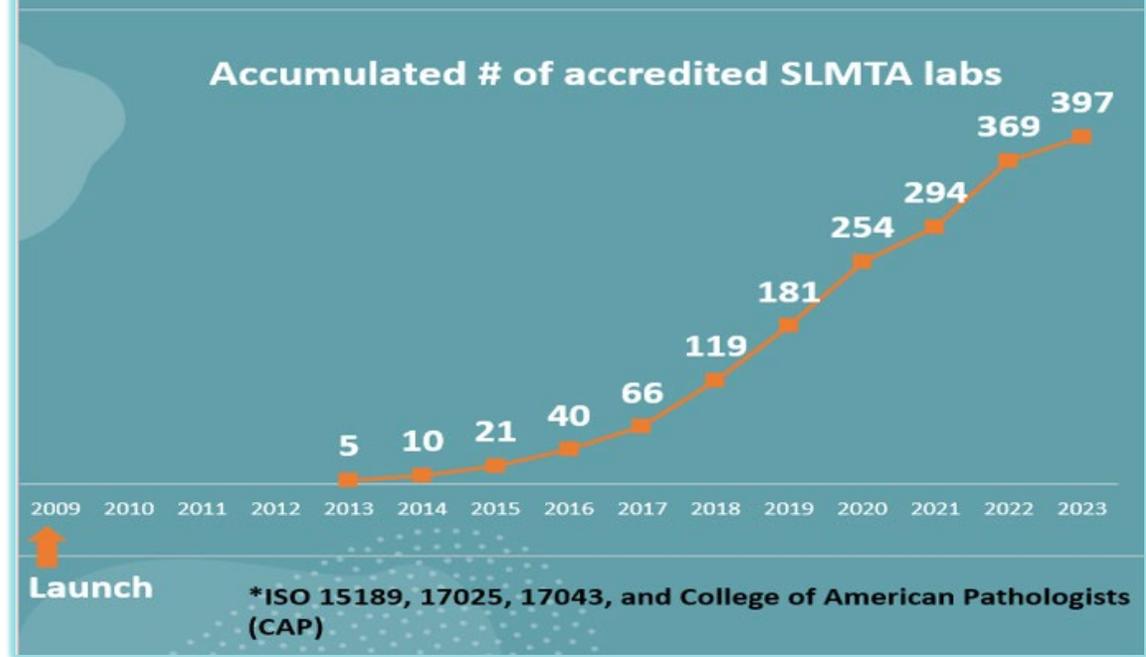
WHO AFRO Laboratory Accreditation -

Commitment to continuous improvement

- WHO AFRO *
- WHO AFRO **
- WHO AFRO ***
- WHO AFRO ****
- WHO AFRO *****



397 SLMTA laboratories in 26 countries have attained accreditation to international standards*



Integrated Laboratory Information Systems (LIMS)

> [Comb Chem High Throughput Screen](#). 2023;26(8):1451-1460.
doi: 10.2174/1386207325666220914112713.

The Role of Laboratory Information System in Improving the Delivery of Laboratory Services: A Recent Systematic Review

[Souad Marwan Alenazi](#) ^{1 2}, [Bussma Ahmed Bugis](#) ³

Affiliations + expand

PMID: 36111772 DOI: 10.2174/1386207325666220914112713

Results: The literature searches yielded a total of 30 articles that were then initially screened based on the titles and abstracts. Seven articles were excluded because they did not primarily address LIMS for biosafety, automated verification of test results in the core clinical laboratory, clinical biochemistry, or the impact of health information technology on patient safety, or were not written in English. The remaining 23 articles were then screened in full text.

Conclusion: Advanced laboratory information systems may eliminate diagnostic errors in the preanalytical, analytical, and postanalytical phases. In addition, they can incorporate genomic data at the analytical stage to generate useful reports for providers and patients.

Keywords: Laboratory; health services; information system; multidimensional impact; postanalytical phases; service delivery.

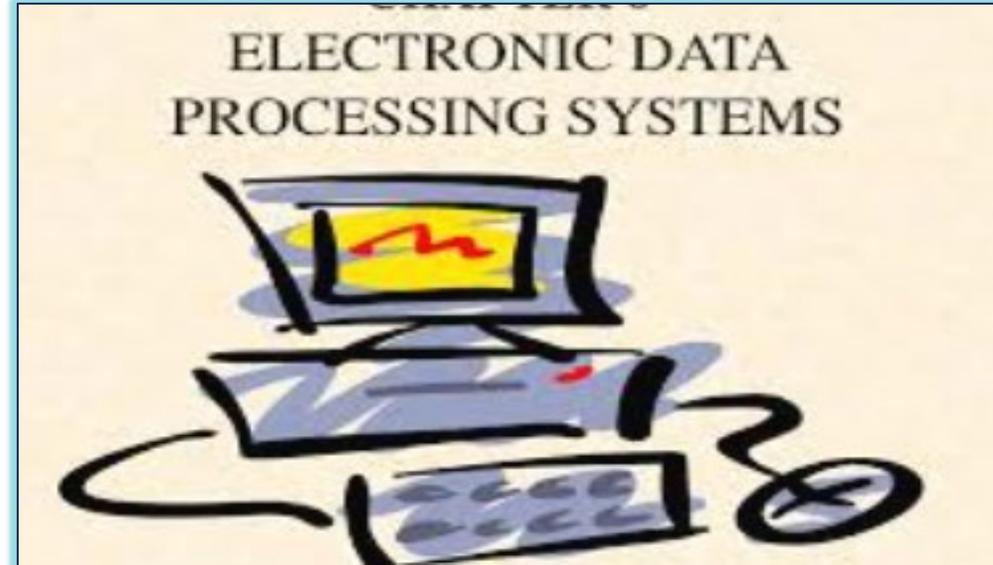
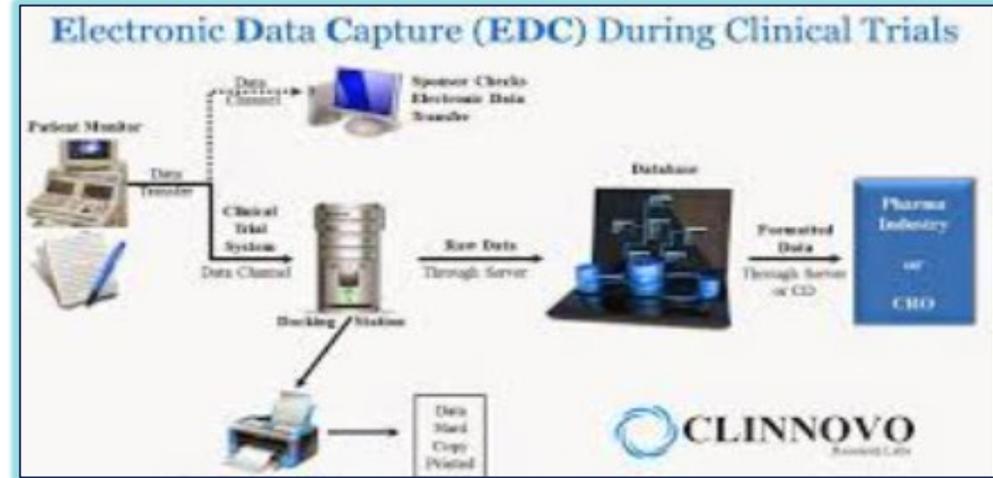


Transition from paper base to Electronic Data Systems to Improve TAT and Minimized Error

Paper Based System



Electronic Based System

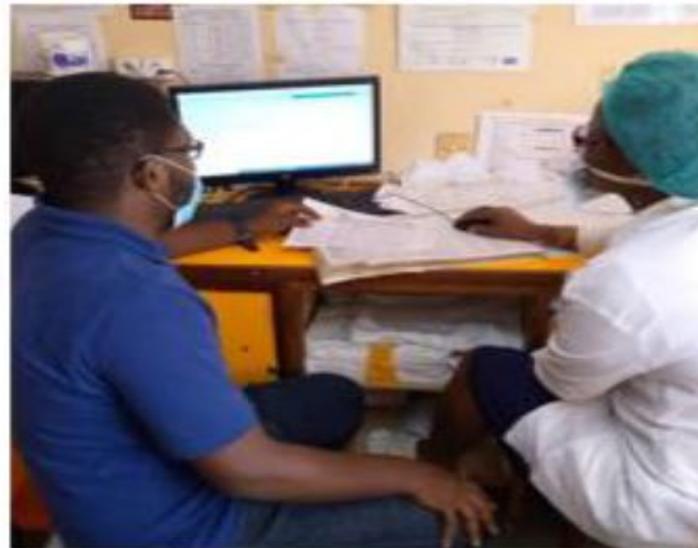


Cameroon's Data Reporting Systems Pre & Post PEPFAR

Pre-PEPFAR Era



PEPFAR intervention (2011)



Current state



Paper based Tools

- Paper based data collection & Reporting tools
- Unharmonized National Reporting tools
- Existence of Option B+ sites

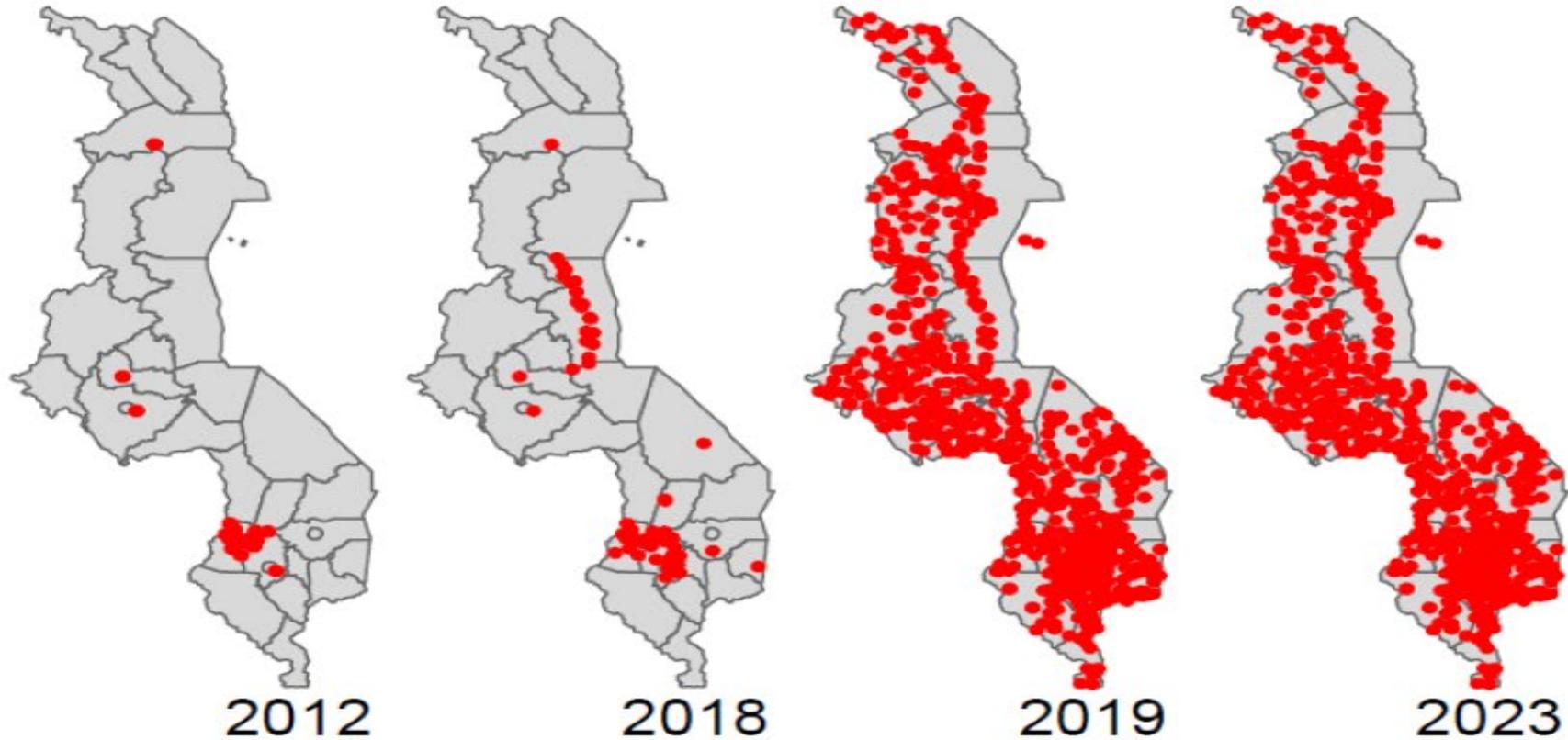
Electronic Systems

- Electronic tools: DHIS2, DAMA, EMR
- Harmonized National Reporting tools
- All Option B+ sites transitioned to Care and Treatment sites
- * Paper based tools remain primary data source for electronic tools

Digital Health Strategic Plan

- Digital Health strategic plan operational
- Interoperability layer being developed
- National HISs strengthened to eliminate parallel reporting in the long run

Electronic Medical Record (EMR) Coverage in Malawi, 2012-2023





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How do we Ensure Availability of Timely Data

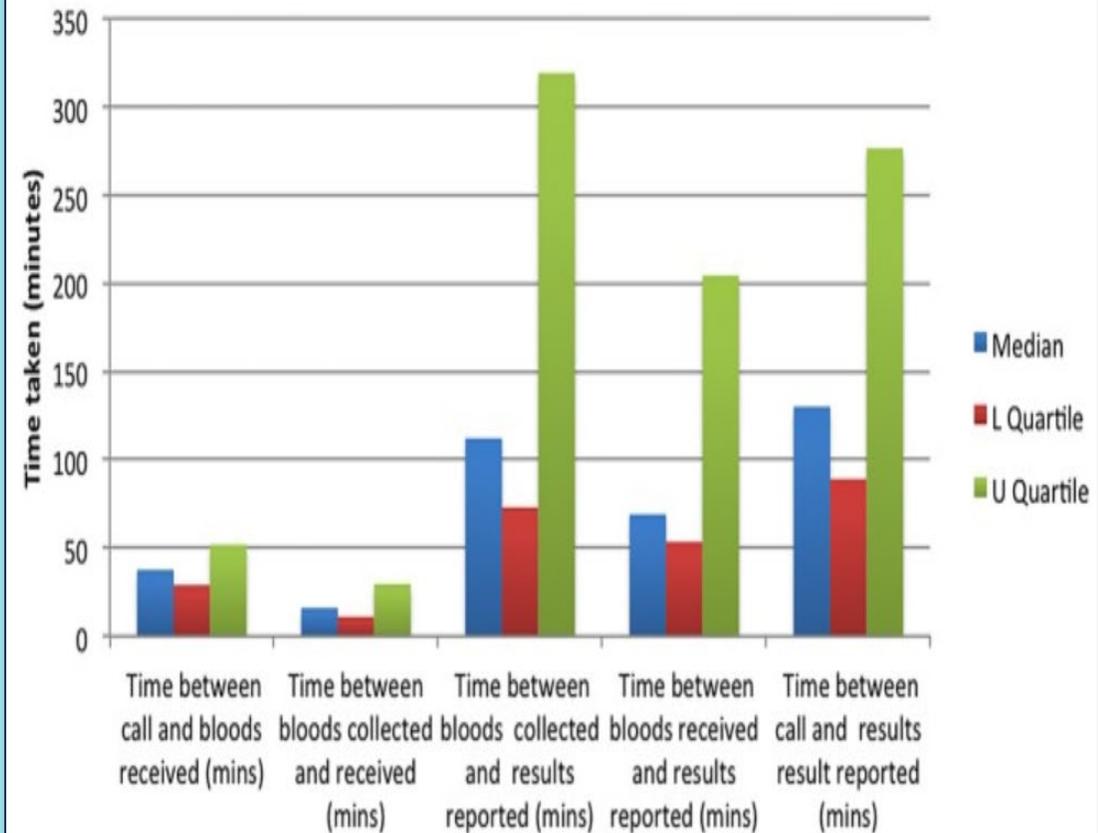
Turnaround Time (TAT) | Address Timeliness of Data

Turnaround Time Chart Key

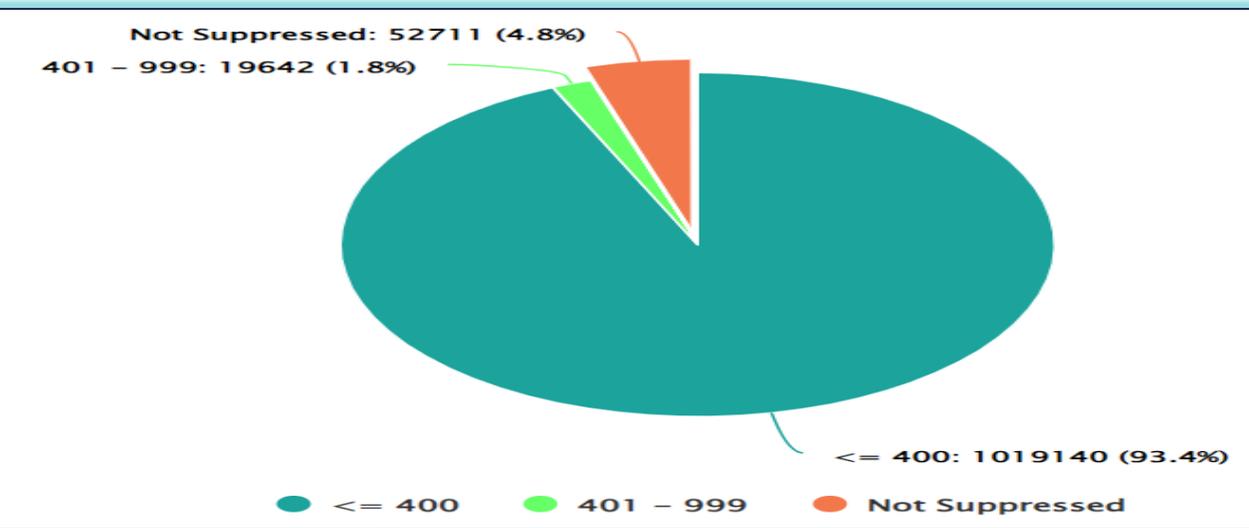
Line	Average Time Range Depicted
Average Overall Turnaround Time	From the requisition created date to first report signed date
Average Lab Turnaround Time	From the sample received date to first report signed date
Average Analytical Turnaround Time	From the sample batch creation date to workflow processing complete date
Average Post-Analytical Turnaround Time	From report generated date to first report signed date

1,112 x 598

Average time taken at baseline for each step in the process of laboratory sample reporting



Addressing Long TAT | Need for National Integrated Data Dash Boards



Integrated Laboratory Surveillance Systems | Ensure Real-Time Data Availability



World Health
Organization

REGIONAL OFFICE FOR
Africa

AFR/RC69/6
19 July 2019

REGIONAL COMMITTEE FOR AFRICA

ORIGINAL: ENGLISH

Sixty-ninth session
Brazzaville, Republic of Congo, 19–23 August 2019

Provisional agenda item 10

REGIONAL STRATEGY FOR INTEGRATED DISEASE SURVEILLANCE AND
RESPONSE: 2020–2030

Report of the Secretariat



PEPFAR Supported Surveillance

Genomics sequencing (HIV DR)

Recency Testing

PHIA

IBBS

Real-Time Patient Data Alert Systems

Original research | [Open access](#) | [Published: 04 December 2021](#)

Incorporating a real-time automatic alerting system based on electronic medical records could improve rapid response systems: a retrospective cohort study

[Seung-Hun You](#), [Sun-Young Jung](#), [Hyun Joo Lee](#) , [Sulhee Kim](#), [Eunjin Yang](#) & [SAVER team](#)

Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine **29**, Article number: 164 (2021)

| [Cite this article](#)

[PLoS Med.](#) 2021 May; 18(5): e1003650.

PMCID: PMC8186790

Published online 2021 May 24. doi: [10.1371/journal.pmed.1003650](https://doi.org/10.1371/journal.pmed.1003650)

PMID: [34029338](https://pubmed.ncbi.nlm.nih.gov/34029338/)

SMS messaging to improve retention and viral suppression in prevention of mother-to-child HIV transmission (PMTCT) programs in Kenya: A 3-arm randomized clinical trial



Addressing Supply Chain Data issues | Vendor Managed Inventory System



When a customer begins to run low on inventory, Advanced VMI creates an automatic replenishment order. The vendor receives the order, which is approved and shipped. Advanced VMI then triggers an advance shipping notice and the order is scanned by the customer upon receipt.



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Thank you