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Assessing the effect of electronic health information exchange on the completeness and validity of data for measuring viral load testing turnaround time in Nigeria

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Abstract

Introduction: Implementation of health information exchange has been shown to result in several benefits which includes the improvement in the completeness and timeliness of data for public health program monitoring and surveillance.

Objective: The objective of this study was to assess the effect of implementing an electronic health information exchange (HIE) on the quality of data available to measure HIV viral load testing turnaround time (TAT) in Nigeria.

Methods: We measured viral load data validity and completeness before the implementation of electronic health information exchange, and 6 months after implementation. Records of specimens collected at 30 healthcare facilities and tested in 3 Polymerase Chain Reaction (PCR) labs were analyzed. We define data completeness as the percentage of non-missing values and measured

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Authors' Contributions

C.A. conceptualized and designed the study, design, and implementation of the data exchange data acquisition, analyzed the data, and drafted the initial manuscript, E.R.R analyzed the data, and reviewed the article. I.A., N.N, contributed to the conceptualization of the study, collection and interpretation of the data and revision of the article. B.I., M.N, T.A., M.D. contributed to the data acquisition, design and implementation of the data exchange and revision of the article. K.C. contributed to the analysis of the data and revision of the article. M.O., M.M., and R.S. conceptualized and designed the study, contributed to result interpretation and revision of the article.

Ethical Clearance

This project was reviewed in accordance with CDC human research protection procedures and was determined to be non-research.

Authorship Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

this value by specimens and by data elements in the dataset for calculating TAT. To examine data validity, we classified TAT segments with negative values and date fields that were not in International Organization for Standardization (ISO) standard date format as invalid. Validity was measured by specimens and by each TAT segment. Pearson's chi square was used to assess for improvements in validity and completeness post implementation of HIE.

Results: 15,226 records of specimens were analyzed at baseline and 18,022 records of specimens analyzed at endline. Data completeness for all specimens recorded increased significantly from 47% before HIE implementation to 67% six months after implementation ($p < 0.01$). Data validity also increased from 90% before implementation to 91% after implementation ($p < 0.01$)

Conclusion: Our study demonstrated evidence of significant improvement in the quality of data available to measure viral load turnaround time with the implementation of HIE.

Keywords

Health information exchange; Data quality; Viral load; Health information systems

1. Introduction

The implementation of electronic health information systems (HIS) have been pivotal in enhancing healthcare data quality on a global scale[1]. One of the many strengths of implementing HIS is its capability to securely share data between facilities within a network in what is referred to as a health information exchange (HIE). Several studies have reported HIE benefits that includes reductions in laboratory test costs, improvements in record completeness, and timeliness of reporting for disease surveillance[2,3]. A study showed number of days between testing and reporting to health departments reduced from 4 to 11 days to 2 days with HIE implementation[4]. There have also been 54% and 80% reduction in costs for clinical lab tests and diagnostic imaging respectively[5] and improved health outcomes with reduction in all-cause mortality and adverse events with HIE implementation[6].

HIE implementation may be challenged with issues around data quality, infrastructure and data security [7]. Technologies like blockchain and cloud computing, however, can help address some of the infrastructure and security challenges[8-10]. Evidence exists for potential errors that could be observed during the HIE process including wrong dates, inconsistent vocabulary, and invalid observations[11] and missing or incomplete patient demographics in the source system[12]. This study contributes to the body of evidence on the impact of HIE on data quality.

Accurate, reliable, and timely HIV viral load (VL) testing is not only essential for the successful treatment and management of HIV/AIDS[13], but it is also the preferred method of confirming the effectiveness of antiretroviral therapy (ART) for a person living with HIV (PLHIV). Global demand for HIV viral load testing has continued to increase as countries have scaled up their treatment programs towards achieving the joint United Nations Program on HIV/AIDS (UNAIDS) 95,95,95, targets by 2030[14,15]. Nigeria expects 95% of PLHIV receiving ART to achieve viral suppression which implies that VL testing will have to

be conducted for more than 1.8 million PLHIV annually. Achieving this goal requires consistent monitoring of the VL testing cascade to identify inefficiencies and develop mitigation plans. In general, the end-to-end VL turnaround time (TAT) is the time between requesting the VL test and receiving the results back for clinical decisions. Measuring TAT is a generally acceptable approach to understanding process inefficiencies in the VL testing life cycle[16]. However, examining TATs is often challenged by the quality of data documented during the life cycle[17,18].

The United States Centers for Disease Control and Prevention (CDC) supports the provision of healthcare services to PLHIV in Nigeria by working with local and international organizations (implementing partners) and the government of Nigeria to provide both technical and financial support to healthcare facilities (n = 956). Implementation of electronic medical record (EMR) systems for HIV programs in Nigeria dates as far back as 2004[19]. As of March 2020, 98% of the CDC-supported healthcare facilities have had an EMR system implemented for their HIV programs. The EMR systems implemented include OpenMRS, an open-sourced EMR system, (98% of the population) and other proprietary EMR systems. 99% of the healthcare facilities use their EMR only for the HIV program. Additionally, Nigeria implements a national laboratory information management system (LIMS) used by the polymerase chain reaction (PCR) laboratories for the management of VL testing data. To improve overall VL TAT for all time points during VL testing process, the President's Emergency Plan for AIDS Relief (PEPFAR) program in Nigeria began the implementation of an electronic data exchange between the EMR at the treatment facilities and the LIMS at the PCR labs as part of routine program activity in 2021. This study assesses the effect of implementing this electronic health information exchange between the EMR and LIMS on the quality of data available for measuring VL TAT. In this article, we described the implementation of HIE between the EMR and LIMS, examined the completeness and validity of data pre- and post-implementation of HIE, and then compared the results to determine the impact of HIE on data completeness and validity.

2. Methods

We examined the validity and completeness of VL TAT data by comparing data of specimens from healthcare facilities collected between October 2020 and January 2021, as baseline, and those collected between August 2021 and January 2022, as endline. We defined the study intervention as the implementation of automated HIE. Baseline VL TAT data were collected before the implementation of an automated HIE, and endline VL TAT data were collected 6 months postimplementation.

We used purposive sampling to select 3 high volume PCR labs with a functional LIMS that were supported by two CDC Nigeria implementing partners. Purposive sampling was also used to select 30 treatment facilities that: 1) were supported by CDC Nigeria's implementing partners; 2) had onsite clinical laboratories for specimen collection and processing; and 3) were linked with the selected 3 PCR labs. Consideration was also made to ensure the 30 selected treatment facilities had an adequate representation of a mix of urban, semi-urban and rural sites, as well as ease of access to the locations.

Secondary data (Table 1) from routine VL testing was used for the analysis both at baseline and at endline. Given the EMR-LIMS data exchange was not established at baseline, we performed manual data abstraction from EMR and paper registers at the treatment sites at baseline. At endline, data was extracted from the EMR, and LIMS as shown in table 1. The two datasets from EMR and LIMS were merged using both specimen identifier and patient's treatment identifier at the treatment facility as linkage keys. All specimen identifier and the patient treatment identifier were removed from the dataset prior to analysis. Informed consent was waived as this was secondary use of data and patients' identities could not be determined during analysis. We used both Microsoft Excel®, R studio and OpenEpi[20] for data collation and analyses.

2.1. Analysis of data completeness for VL TAT

Data completeness measures the proportion of observations made during an encounter or a process that are recorded[21,22]. We measured data completeness for: 1) each specimen and 2) per data element for calculating VL TAT. We defined data completeness for VL TAT per specimen as the percentage of specimens with all the data elements (table 1) required to calculate all TAT segments for the end-to-end VL testing life cycle (i.e., the date a VL test was requested to the date the result was filed into patient folder). TAT segments are intermediary steps during the specimen's life cycle and were calculated as the difference in calendar days between two consecutive steps (e.g., the difference between the date a specimen was collected and the date a specimen was picked up for transport to the PCR Lab). Data completeness was also assessed per data element and was defined as the percentage of non-missing values in each of the columns or data elements (table 1) required in calculating all TAT segments. We used Pearson's chi-square to assess for improvements in VL TAT data completeness from baseline and endline.

2.2. Analysis of VL TAT data validity

Validity is the degree to which data values are consistent within a defined domain[23]. For this study, we looked at how consistent the data elements (table 1) are as one moves across the VL testing lifecycle. Our definition of TAT segments (Table 2) implies a sequence in activity occurrence. Hence, a VL test will be requested before specimen is collected as in TAT1, and specimen will be collected before it is picked up for transport as in TAT2 and so forth. Thus, when TATs result in a negative value, it implies that activities have not occurred in sequence. This is generally not possible in practice, so we classified these records as invalid. Additionally, we expect all dates fields to be reported in the International Organization of Standards (ISO) standard date formats. Date fields that were not reported in and could not be converted to ISO standard date formats automatically resulted in erroneous TAT values and where also classified as invalid. We then calculated validity of VL TAT data by specimen as the percentage of specimens with no invalid TAT segments. We also assessed validity by TAT segments by measuring the percentage of valid records for each TAT segment. We then used Pearson's chi-square to assess for improvements in data validity from baseline to endline.

2.3. Description of the automated HIE intervention

VL samples are collected at the clinical labs and the records are entered into the EMR system. The lab staff uses an interface built into the EMR to extracts a JavaScript Object Notation (JSON) file containing key data elements for specimens collected during a particular time frame (Fig. 1). These files are then used to create a transport manifest following the national specimen transport form. Extracted data from the EMR is then exchanged with the LIMS via web Application Programming Interface (APIs) following a standard defined in an implementation guide. The physical samples are then shipped with the transport manifest to the PCR lab where the samples are tested, and results uploaded to LIMS. When results are approved at the PCR labs, LIMS allows API requests from verified EMR systems to query results. The EMR automatically updates the patients' records with the test results received from LIMS. This process was implemented between all healthcare facilities selected for this study and the PCR labs. All lab staff at the healthcare facilities and the PCR labs were trained on how to exchange data between the EMR and LIMS.

3. Results

There was a total of 15,226 specimens from 28 healthcare facilities included in the analysis at baseline and 18,022 specimens from 23 facilities included at endline. There were 4 facilities from one partner that were initially included in the baseline analysis that were subsequently excluded from the endline analysis because these facilities did not implement an electronic HIE and opted to implement a different intervention. Records from two healthcare facilities at baseline and three at endline were excluded from the analysis due to missing pertinent information including missing specimen unique identifiers and test types.

3.1. Viral load TAT data completeness

We found a significant improvement in overall data completeness by specimen when baseline and endline data were compared ($p < 0.01$). Overall, at baseline, 47% (n = 7,219) of specimens had complete data. At endline, the overall proportion of specimens with complete data significantly increased to 67% (n = 12,065) ($p < 0.01$). We further examined for improvements in percentage completeness by each data element (Table 3) and found significant improvements in several data elements. The data element with the most notable improvement was the date the result was filed into the patient folder which accounted for the least complete data at baseline (54% (n = 8,158) complete). However, the completeness of this data element increased to 98% (n = 17,597) completion for all specimens assessed at endline ($p < 0.01$). The date & time results were received at the facility, and the date & time specimens were picked up and transported to PCR labs showed the second and third highest improvements in data completeness from 58% to 91% and from 62% to 99% respectively. We observed however, that some data elements showed significant decreases in the percentage of data completeness. Specifically, the date the test results were available accounted for the least complete of all data elements at endline with 83% (n = 14,879) complete for all recorded specimens ($p < 0.01$).

Specimen accessioned dates and date specimen was tested in the lab remained the same (96% and 98%, respectively) both at baseline and endline. Percentages of records with

complete dates for the date a VL test result was available and the date a VL test result was sent back to the facility decreased from 98% to 83% and 97% to 86% respectively, from baseline to endline.

3.2. Viral load TAT data validity

Overall, the percentage of specimens with valid data improved from 90% at baseline to 91% at endline ($p < 0.01$). TAT8 was not assessed at endline because physical test results were no longer dispatched after the implementation of the HIE. There were several increases in the percentages of records with valid data. Specifically, percentages of valid data increased post-HIE implementation for four of the TAT segments including TAT1, TAT2, TAT5, and TAT10 (Table 4). There were two TAT segments, TAT4 and TAT7, that remained at 100% pre- and post-HIE implementation. Lastly, there were reductions in the percentage of valid data for three TAT. Specifically, TAT3 decreased from 99.7% at baseline to 97.3% at endline ($p < 0.01$), TAT6 reduced from 100% at baseline to 99.9% at endline ($p < 0.01$), and TAT9 declined from 98.3% at baseline to 94.1% at endline ($p < 0.01$).

4. Discussion

This study assessed for improvements in both data completeness and validity of data for VL specimen testing through the entire VL testing lifecycle from the date a VL test was requested, to the date VL testing results were placed in a patient's folder. Study findings include overall significant improvements in both percentage completeness and validity post-implementation of a HIE. There were also observed decrease in validity and completeness for some TAT segments and data elements respectively. Previous studies have shown similar findings when assessing for improvements in data quality post implementation of a HIE[24,25]. One study that examined the effect of leveraging a HIE to support public health situational awareness in Indiana showed more than 40% increase in data completeness[24]. Another study that accessed the impact of exchange between immunization information system and an EMR system recorded an increased completeness score from 75.0% to 81.6% after 6 months[25].

While this study did find significant improvements in VL TAT data quality overall, there were still opportunities for improvements as demonstrated by decreases in validity and completeness in specific TAT segments three, six, and nine. Several reasons can be attributed to the current existing gaps in record completeness and validity. First, the process workflow in LIMS at the PCR labs has yet to be updated to be in line with the automated data exchange. As the automated data exchange was introduced, the workflow on LIMS was not reviewed to ensure proper documentation of the newly automated steps such as specimen arrival at the PCR lab, automated result update from the PCR machines, and automated result update to the EMR at the facilities. Consequently, this resulted in reduced completeness for data elements including date specimen was resulted, and date results were sent back to facility and reduced percentage validity for TAT3, TAT6, and TAT9. Second, there were data standardization challenges specifically pertaining to inconsistent use of data types. Upon further investigation, we found that LIMS at the different PCR labs reported the same data elements in different data types which was most profound in the date fields.

Consequently, some date fields on LIMS were documented as data type datetime while others were documented as data type date. Hence, some TAT segments that occurred on the same calendar day (TAT3 and TAT6) resulted in invalid values.

The next steps include a review of the workflow for HIE and updating the necessary HIS (EMR or LIMS) to align with this workflow. This will ensure that all the necessary steps are properly documented and will result in increases in the percentage of specimens with complete data. Secondly, the standardization of data (common data formats) across all labs is crucial especially for VL TAT data validity. Data standardization activities including the development and implementation of a data dictionary following standard terminologies and vocabulary such as Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) for electronic exchange of clinical health information, Logical Observation Identifiers Names and Codes (LOINC) for identifying medical lab observations, and other available data standards will enable semantic interoperability. This will not only improve on the quality of the data but also support ease of data integration [8,26]. Continuous monitoring and evaluation of data quality is also a very important step to identifying and quickly resolving gaps[27,28]. A standard approach for addressing such issues in data completeness and validity needs to also be implemented. Strategies including a problem solving approach such as the Plan Do Study Act (PDSA) cycle[29], and a root cause analysis[30] can be performed to assist in identifying the sources or root causes of the gaps in data quality and then implementing appropriate solutions to address them.

A limitation of this study was that there were no control group given that the HIE was implemented as a routine program activity. Therefore, only facilities that had implemented the automated health information exchange at endline were used for the analysis. It is important to have had a study control because while we have recorded statistically significant improvement in data completeness and validity for these specimens, there could have been other factors that have contributed to these improvements which the study may not have accounted for. Excluding 2 and 3 healthcare facilities, at baseline and endline respectively, from the analysis due to missing information was on itself a data quality issue that could not be accessed in this study as complete datasets could not be developed for these healthcare facilities. Additionally, facility level clustering effect was not included in the analyses. However, it may be noted that all the significant results have p-values of<0.01, and the conclusions would not change if there was some clustering effect. Specifically, results would hold for any design effect of 2 or less. Finally, this was a small-scale study and may not be a good representation of the population of specimens tested for VL in Nigeria. Hence, it may be difficult to generalize the findings of this study.

5. Conclusion

Results from this study raise evidence to support automated HIE for improving data completeness and validity. It also highlights key lessons that can help programs that are planning or already implementing automated HIE understand important areas to focus on as they plan and implement their systems. While this study has shown improvement in data quality with the implementation of HIE, it will be important to conduct further analysis to understand how automated HIE impacts VL TAT, which is the goal of such implementation.

Summary Table

What was already known on the topic	What this study added to our knowledge
• Implementation of Health Information Exchange (HIE) results in improvements on data completeness and timeliness of data available for surveillance and program monitoring Evidence has shown poor quality of data in the labs which poses challenges with measuring viral load turnaround time	• Implementation of HIE for data exchange between the electronic medical record systems at the treatment health facilities and the laboratory information management system at the PCR labs resulted in improved data completeness and data validity The study highlighted the need for continuous monitoring of data quality with HIE implementation as a necessary step towards improvement

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Abbreviations:

VL	Viral Load
TAT	turnaround time
HIE	Health Information Exchange
PCR	Polymerase Chain Reaction
LIMS	Laboratory Information Management System
EMR	Electronic Medical Record

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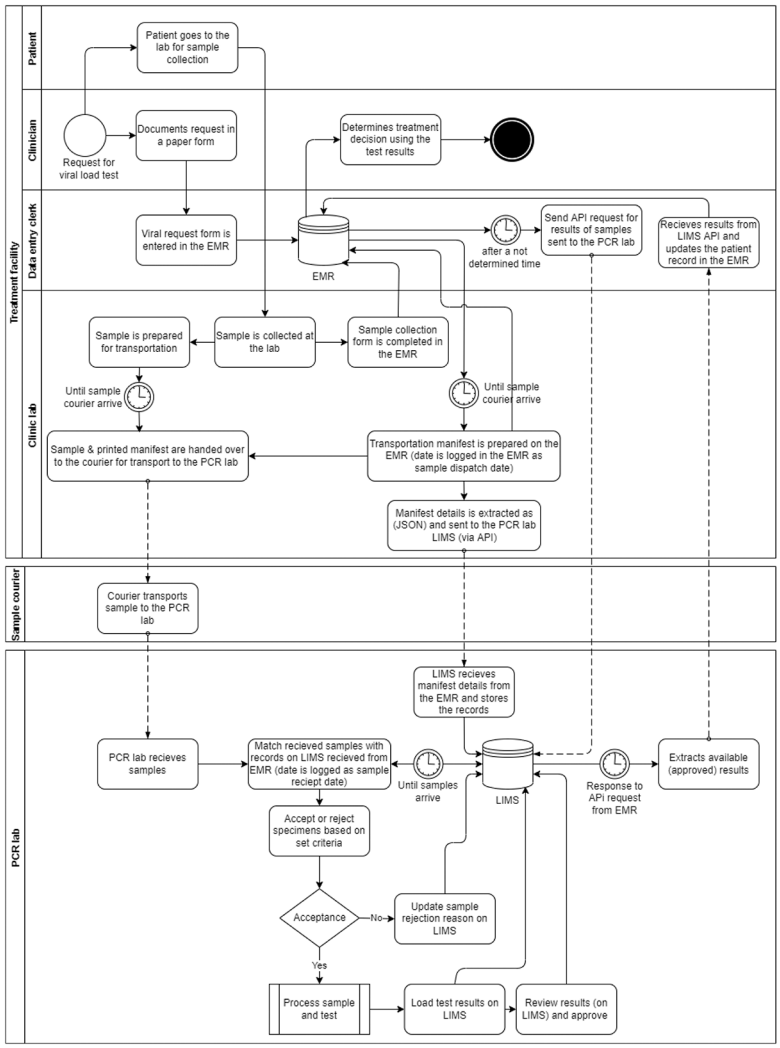

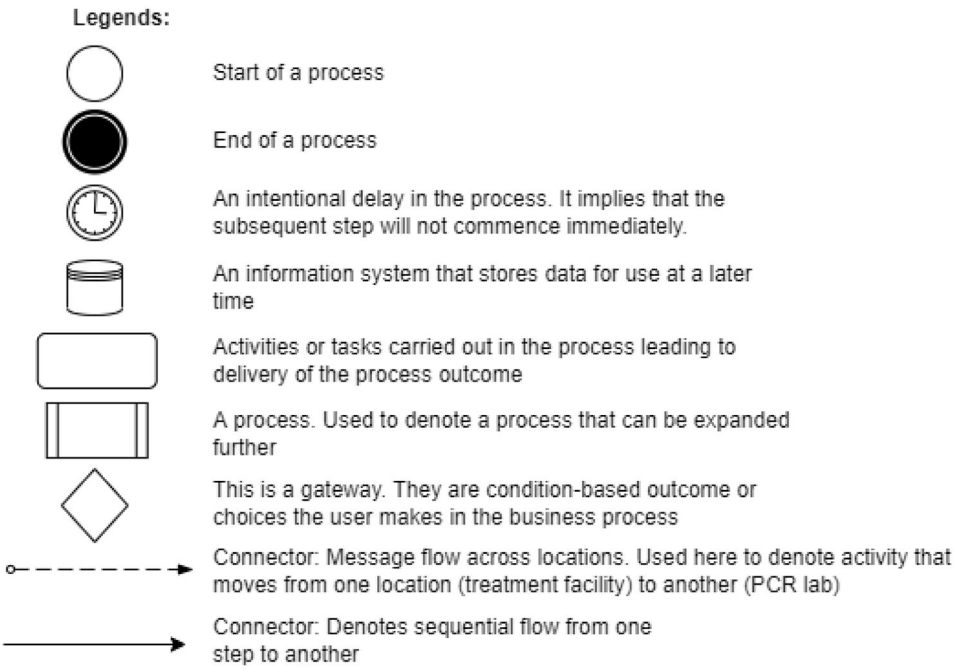

Fig. 1.

Business process model for viral load sample testing and EMR-LIMS data exchange.

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Table 1

Source definitions for each of data elements used for the study (All data elements were formatted as datetime with the format: dd-month-yyyy hh:mm).

S/N	Data Element	Data Source
1	Date & Time VL test was requested	EMR
2	Date & Time specimen was collected	EMR
3	Date & Time specimen picked up for transport to the PCR Lab	EMR
4	Date & Time specimen arrived at the PCR Lab	LIMS
5	Date &Time specimen accessioned in the PCR Laboratory	LIMS
6	Date & Time specimen tested in the Laboratory	LIMS
7	Date & Time specimen resulted	LIMS
8	Date & Time results approved	LIMS
9	Date & Time results sent back to the facility	LIMS
10	Date & Time results received at the facility	EMR
11	Date & Time results filed into patient folder	EMR

Table 2

Definition of each of turnaround time (TAT) values as the difference between two sequential steps in the viral load testing life cycle.

TAT Segment	Description of Sequence
TAT1	Difference between date specimen was collected and date test was requested
TAT2	Difference between date specimen was picked up for transport to the PCR lab and date specimen was collected
TAT3	Difference between date specimen arrived at the PCR lab and date specimen was picked up for transport to the PCR lab
TAT4	Difference between date specimen accessioned in the PCR lab and date specimen arrived the PCR lab
TAT5	Difference between date specimen tested and date specimen was accessioned
TAT6	Difference between date specimen test results is available and date specimen was tested
TAT7	Difference between date specimen test results were approved and date specimen test results were available
TAT8	Difference between date results were sent back to the facility and date specimens were approved
TAT9	Difference between date results were received at the requesting facility and date specimen was sent back to the facility
TAT10	Difference between date result was filed back into patient folder and date result was received at the requesting facility

Table 3

Completeness scores at baseline and at endline for each of the data elements used for calculating viral load turnaround time.

	Baseline/Pre-HIE Implementation (N = 15,226)		Endline/Post-HIE implementation (N = 18,022)		
	Specimens with complete data	Specimens with incomplete data	Specimens with complete data	Specimens with incomplete data	p value[1]
Data elements	**N (%)**	**N (%)**	**N (%)**	**N (%)**	
Date & Time VL test was requested	12,510 (82%)	2,716 (18%)	18,022 (100%)	0 (0.0%)	<0.01
Date & Time specimen was collected	12,502 (82%)	2,724 (18%)	18,022 (100%)	0 (0.0%)	<0.01
Date & Time specimen picked up for transport to the PCR Lab	9,451 (62%)	5,775 (38%)	17,931 (99%)	91 (1%)	<0.01
Date & Time specimen arrived the PCR Lab	15,063 (99%)	163 (1%)	18,022 (100%)	0 (0%)	<0.01
Date & Time specimen accessioned in the PCR Lab	14,615 (96%)	611 (4%)	17,370 (96%)	652 (4%)	0.06
Date & Time specimen tested in the Lab	14,978 (98%)	248 (2%)	17,688 (98%)	334 (2%)	0.12
Date & Time specimen resulted	14,927 (98%)	299 (2%)	14,879 (83%)	3,143 (17%)	<0.01
Date & Time results approved	14,891 (98%)	335 (2%)	17,786 (99%)	236 (1%)	<0.01
Date & Time results sent back to the facility	14,807 (97%)	419 (3%)	15,460 (86%)	2,562 (14%)	<0.01
Date & Time results received at the facility	8,817 (58%)	6,409 (42%)	16,325 (91%)	1,697 (8%)	<0.01
Date & Time results filed into patient folder	8,158 (54%)	7,068 (46%)	17,597 (98%)	425 (2%)	<0.01

[1]Calculated using Pearson chi-square for R by C table.

Table 4

Validity score at baseline and endline for each of the turnaround time (TAT) values or sequential steps. See Table 2 for description of each of the TAT segments.

TAT Segment	Baseline/Pre-HIE implementation		Endline/ Post-HIE implementation		p-value[1]
	Specimens with valid data	Specimens with invalid data	Specimens with valid data	Specimens with invalid data	
	N (%)	N (%)	N (%)	N (%)	N (%)
TAT1	14,949 (98.2%)	277 (1.8%)	17,975 (99.7%)	47 (0.3%)	<0.01
TAT2	15,110 (99.2%)	116 (0.8%)	18,019 (100.0%)	3 (0.0%)	<0.01
TAT3	15,181 (99.7%)	45 (0.3%)	17,532 (97.3%)	490 (2.7%)	<0.01
TAT4	15,225 (100.0%)	1 (0.0%)	18,022 (100.0%)	0 (0.0%)	0.28
TAT5	14,489 (95.2%)	737 (4.8%)	17,960 (99.7%)	62 (0.3%)	<0.01
TAT6	15,226 (100.0%)	0 (0.0%)	18,012 (99.9%)	10 (0.1%)	<0.01
TAT7[2]	15,226 (100.0%)	0 (0.0%)	18,022 (100.0%)	0 (0.0%)	
TAT8[3]	15,143 (99.5%)	83 (0.5%)	–	–	–
TAT9	14,974 (98.3%)	252 (1.7%)	16,952 (94.1%)	1070 (5.9%)	<0.01
TAT10	15,129 (99.4%)	97 (0.6%)	18,022 (100.0%)	0 (0.0%)	<0.01

[1] Calculated using Pearson chi-square for R by C table.

[2] p-vcdue for this TAT was not accepted as there were no invalid records at both endline and baseline.

[3] TAT8 was not assessed at endline because physical test results were no longer dispatched after the implementation of electronic HIE.