Case Study

The Impact of COVID-19 Containment Actions on Extra-Analytical Phases of the Clinical Laboratory: A Case Report

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ABSTRACT

Laboratory information systems need to adapt to new demands created by the COVID-19 pandemic, which has set up new normals like containment measures and social distancing. Some of these have negatively impacted the pre- and postanalytical phases of laboratory testing. Here, we present an intriguing finding related to the generation of the accession number/specimen number on the investigation module of a hospital management information system and its impact on the dissemination of reports resulting in the wrong release of reports on a female patient amidst the background of COVID-19 containment measures. We analyze the situation that led to this false reporting and the importance of the proper customization of information software in laboratories along with a robust postanalytical framework of laboratory work culture to avert such untoward incidents. This introspection has made us realize that COVID-19 has been a scientific, medical, and social challenge. We need to redefine our priorities in the days to come because SARS-CoV-2 is here to stay.

Keywords: laboratory errors, extra-analytical phase, hospital information management system, laboratory information system

Laboratory information system (LIS) and hospital management information system (HMIS) play key roles in laboratories regarding meeting quality standards, decreasing transcription errors, reducing the turnaround time from specimen receipt to the reporting of results, and improving patient outcomes.[1] With the advent of evidence-based medicine, the LIS has become a necessity of every laboratory.[2] This increased use of the LIS has allowed end users to more clearly articulate detailed system requirements, in turn leading vendors to develop more attractive, viable, and customized LIS options. However, COVID-19 has brought about an unseen fear that has affected the functioning of the entire medical community, including laboratory services. All attempts have been directed toward the containment of infection, which has led to the implementation of new policies including the significant prohibition on the use of barcoded autogenerated tubes for specimen collection and testing. How the reintroduction of paper-based requisitions and handwritten labeled vacutainers intended to restrict the number of staff involved and the multiperson handling of automated phlebotomy tube labelers (APTL) and to minimize contact with contaminated surfaces, affected the functioning of an in-house hospital laboratory is discussed in this case report.

Abbreviations:

LIS, laboratory information system; HMIS, hospital management information system; APTL, automated phlebotomy tube labeler; IPD, inpatient department; TAT, turnaround time; LFT, liver function test; KFT, kidney function test; CR number, central registration number.

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Case Report

The biochemistry wing of a central laboratory received specimens for an admitted 20 year old woman who had tested positive for COVID-19 on 3 consecutive days as a part of routine monitoring. The values for the specimen processed on the third day differed remarkably from the values released on the second day, which was revealed after a manual delta check conducted on the third day (**Table 1**

Table 1. Investigation Tracking (delta check) on Day 1, Day 2, and Day 3

Name of Parameters/Date	Day 1	Day 2	Day 3	Reference Range	Units
Serum calcium	2.03	1.95	2.1	2.15–2.5	mmol/L
Serum phosphorus	2.65	0.62	2.35	0.87–1.45	mmol/L
Serum uric acid	0.66	0.17	0.54	0.20–0.42	mmol/L
Serum sodium	131.23	138.42	134.12	135–145	meq/L
Serum potassium	5.09	4.16	4.47	3.5–5	meq/L
Serum chloride	92.40	107.27	94.05	98–107	meq/L
Serum urea	22.99	2.96	20.67	2.16–7.15	mmol/L
Serum creatinine	480	36.24	561.34	61.88–114.9	µmol/L

shows her reports over the 3-day period). The delta check showed high values for urea and creatinine on the first day, normal values on the second day, and high values again on the third day. The fault was believed to be with the values released on the second day, with the following probabilities in mind:

i. Specimen misidentification with mismatched labeling sent from the intensive care unit (ICU) ward, with the specimen from the wrong person (preanalytical error).
ii. Specimen placed in the wrong position in the autoanalyzer instead of the one intended and programmed for (analytical error).
iii. Incorrect data transfer because the bar-code labeled tubes were no longer in use and incorrect manual programming of specimen numbers resulting in mismatched data transfer (postanalytical error).

A recheck of the third day specimen revealed values that were identical to those obtained earlier in the run. This finding led to the analysis of the second day reports on the computer screen of the clinical chemistry autoanalyzer because it was difficult to analyse the first two options ie, whether the right sample was sent from the wards and whether is was run in the right slot in the autoanalyser. This was because of the fact that considerable time had lapsed between the day 2 sample was received and present day of reporting. Moreover the second day sample was discarded and hence a recheck could not be performed. The results seen on the monitor of the autoanalyzer differed from the results on the interfacing computer, showing values from the second day as being very much in sync with the values released on day 1 and day 3. This situation thus involved incorrect data transfer (postanalytical error), so further analysis was conducted to find the root cause of this incorrect data transfer.

Before analyzing the root cause, we first depict the modifications implemented in the functioning of the clinical laboratory to contain the spread of COVID-19 infection. Significant changes were made regarding the day-to-day functioning of the hospital since April 2020, when it was declared a dedicated COVID-19 hospital in an effort toward containing the spread of infection; at that time, there was much speculation about the mode of infection transmission with scant scientific evidence. One of the major decisions made was to send handwritten vacutainers from wards to laboratories instead of the usual practice of sending bar-coded tubes to minimize the number of people handling the APTL machines located on alternate floors of the inpatient department (IPD). The APTL is a fully automated, prelabeled, barcoded vacutainer dispenser that operates according to the availability of necessary information in the LIS. Because there are multiple wards on each floor of the IPD block and the APTL is a costly machine, it was not practically feasible to install in all the wards. Before the pandemic, when requisition raising was done in the HMIS for a particular patient from a particular ward, a requisition would be transferred via health level 7 and was reflected in the LIS, and blood collection tubes would be generated from the APTL located nearest to the ward (**Figure 1** workflow related to specimen collection and report generation in the LIS before COVID-19). During the pandemic, because the collection of tubes requires hospital attendants to move from one floor to another wearing personal protective equipment and handle the APTL to generate the tubes, it was decided in the best interests of the hospital to stop the use of the APTL until the pandemic wanes. Moreover, using 1 system (HMIS alone) rather than 2 systems (LIS and HMIS integrated) with 2 different service providers is a better option during the pandemic. The handwritten vacutainers cannot be read by the barcode readers of the autoanalyzers in the laboratories (**Figure 1**, workflow related to specimen collection and report generation in the HMIS during the pandemic). The tests required for a particular patient must be manually programmed, and the data are transferred from the autoanalyzers directly to the HMIS because the LIS is not being used for the time being. Manual programming is associated with many errors, such as the wrong specimen being run, incorrect or partial selection of tests, and prolonged turnaround time (TAT) because of manual selection of tests.

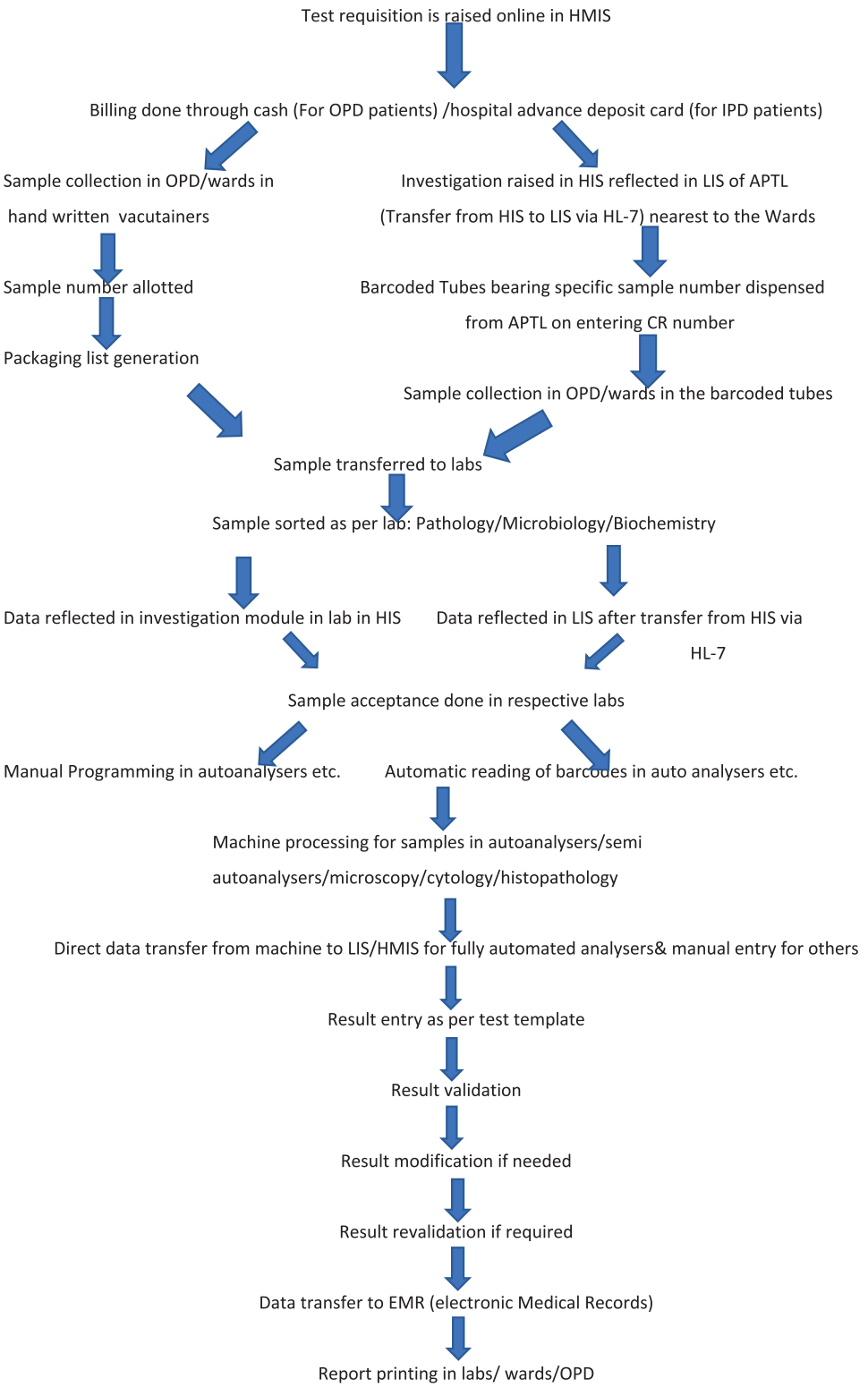

Figure 1

Workflow in HMIS during COVID-19 and workflow in LIS pre-pandemic. APTL, automated phlebotomy tube labeler; HMIS, hospital management information system; IPD, inpatient department; LIS, laboratory information system; OPD, outpatient department.

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What Happened?

When the specimen for day 2 was received in the laboratory, it bore the central registration (CR) number 109112000xxxxxx (actual number not revealed to protect patient identity) and the specimen number 0056 for a liver function test (LFT) and kidney function test (KFT) as generated upon requisition-raising in the HMIS. The specimen number in the HMIS for biochemistry is a 4-digit autogenerated number customized in the HMIS; it is generated daily and is not repeated for any 2 different specimen types on the same day. The number is generated starting from 0001, when the time changes at 0000 hours (midnight) in the HMIS marking the start of a new day. It varies for the same CR number depending on the number of vacutainers for different specimen types, eg, LFT/KFT, blood sugar, and complete blood count, withdrawn at the same time. Moreover, for a patient in the IPD, multiple specimens may be sent on the same day for the same analyte. The configuration of the specimen number is very important because it determines the transfer of data for the particular specimen. Problems can crop up if 2 specimens bearing the same specimen number are sent to the laboratory on the same day, as may happen when a requisition is raised on one day but the specimen is sent on the next day.

In our patient, the specimen was not tagged with the date or the patient's CR number in the HMIS. Moreover, specimen number 0066 generated on the HMIS on the same day arrived in the biochemistry laboratory before specimen number 0056. This is a common occurrence because wards are located on different floors and the requisition raising and specimen number generation in the HMIS always does not mean that the specimen with the specimen number generated first in the HMIS will reach the laboratory first. Specimens may not be drawn at the same time as requisition raising for many reasons such as inaccessibility of veins, inadequate staff for phlebotomy or transport of the specimen, or inadequate money in the patient's account. The sequence of events resulting in the release of the wrong reports for specimen number 0056 from the laboratory is described in **Figure 2**.

What Went Wrong?

Mistakes were made at multiple junctures, which were identified too late the next day when a repeat third day specimen came to the laboratory, as follows:

i. Stopping the use of autogenerated barcode tubes and hence the need for manual programming.
ii. Incorrect programming by the technical staff on duty and failure of the doctor to supervise and rectify what the technical staff had missed.
iii. Failure of technical staff and doctor on duty to realize that the specimen number 0056 was run as 0056 but the data for the same were never transferred.
iv. Failure of the doctor on duty to perform a manual delta check.
v. Faulty specimen number customization in the HMIS bearing no link or association to the CR number of the patient or the date.

What Could Have Been Done to Avoid It?

The above patient was in renal failure with altered urea and creatinine values according to the first day specimen received in the laboratory. The specimen in question revealed normal urea and creatinine values on the second day as opposed to the high values released the previous day. Had a delta check been performed manually, this release of the wrong reports could have been averted. Customization of the specimen number in the HMIS, which is generated on a daily basis without bearing any relation to the CR number or date, played a significant role in the incorrect data transfer. The specimen number should either be generated on monthly basis or be tagged with the date or CR number to ensure correct data transfer. We identified this problem with the usage of the specimen number in the HMIS and hence shifted to using the LIS with the customization of the specimen number per our requirements, synchronizing it to the current date on a daily basis.

Discussion

The complex web of events in this case report involved a preanalytical error causing specimen misidentification and data thus being incorrectly transferred, resulting in a transcriptional error despite this error being partially identified and corrected before the release of the laboratory results. The correction done in data entry

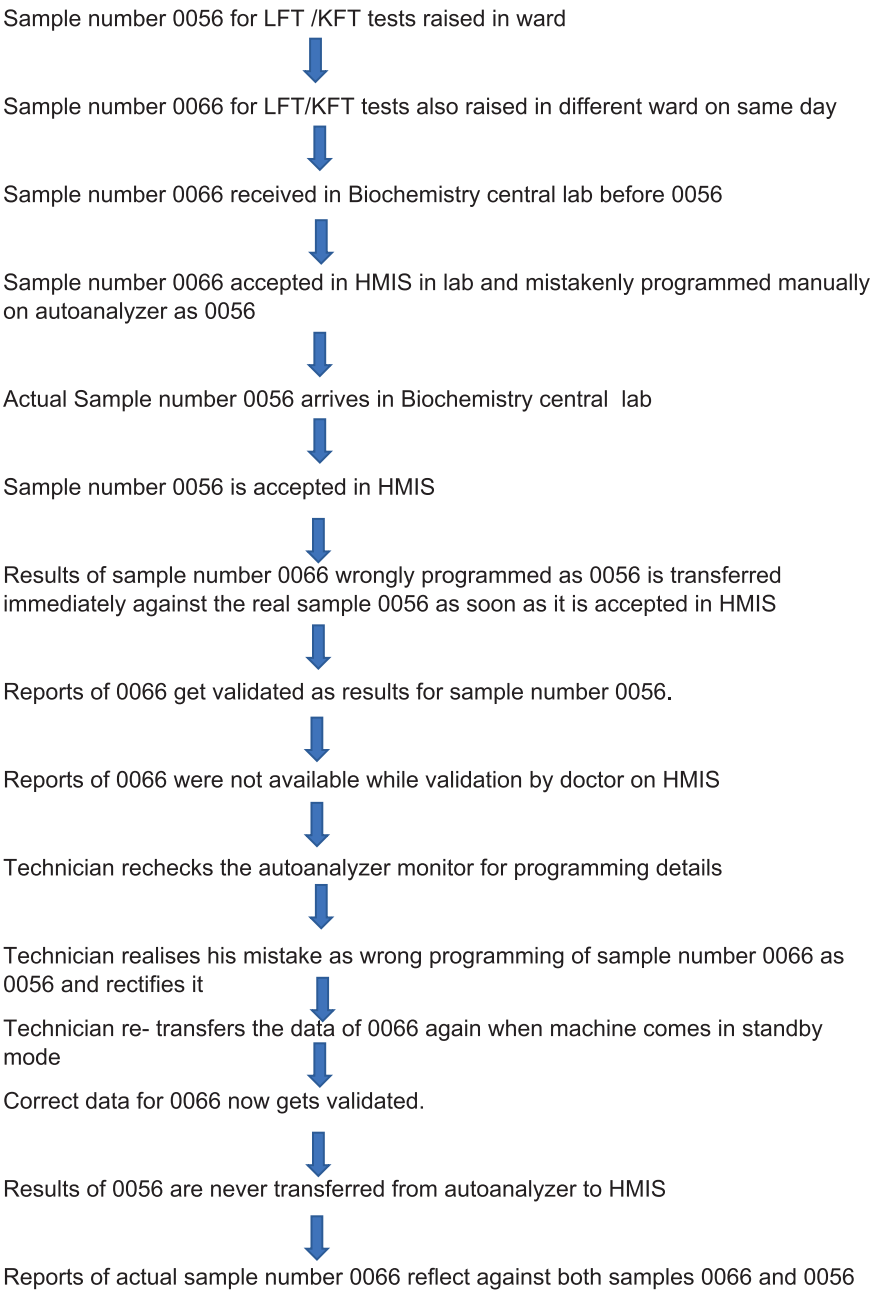

Figure 2

Diagrammatic representation of sequence of events leading to incorrect reporting. HMIS, hospital management information system; KFT, kidney function test; LFT, liver function test.

while programming specimen number 0066 as specimen number 0056 during a recheck being done and subsequent resending of data sorted the reports for specimen number 0066. However, specimen number 0056 was run as the correct number 0056 in the first place but the data could not be transferred because the reporting slot was already occupied by the data for specimen 0066 sent earlier and went unnoticed. This resulted in the monitor of

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the autoanalyzer showing the values of specimen number 0056 as being quite different from the values shown in the HMIS on the second day. With our patient, the incorrect data transfer was the end result of errors involving both the preanalytical and postanalytical phases. A major contributor was the disuse of the APTL during the COVID-19 pandemic leading to the nonavailability of barcoded vacutainers. In addition, our HMIS had a major drawback in the form of specimen numbers being generated daily and not being linked to the date or CR number. The specimen number together with the patient CR number usually gives each specimen a unique identity in the laboratory.

Moreover, the HMIS was not bidirectionally functional, implying that specimen programming needed to be done manually and only data transfer in the form of results was possible from the autoanalyzer to the interfacing computer. This drawback prompted us to switch over to the use of the LIS because it has bidirectional data transfer—ie, the barcode labeled tubes can be read automatically by the autoanalyzer and also transfer the results generated from the machine to an interfacing computer in real time. The bidirectional functionality provides a near-complete assurance of freedom from preanalytical errors in the laboratory with respect to specimen misidentification.

Hence the customization of the HMIS or LIS as per the needs of the end user is mandatory. However, its establishment involves a good deal of effort and interaction with stakeholders. Significant time is needed to understand the functionality of the laboratory involved. The workflow related to the processing of laboratory specimens until reports are made available to the patient concerned varies from laboratory to laboratory despite the basic processes involved remaining the same. LISs have been established to augment communication between patients and healthcare professionals, thereby enabling patients to play a more dynamic role in their own treatment and self-management.[3] Hence it is of utmost importance that the system be flawless.

Monitoring quality indicators in daily work can reduce laboratory errors and risks to patient safety by identifying problems in all phases of laboratory processes and allowing their correction.[4] Apart from the recommended postanalytical quality indicators such as TAT, noting errors during transcription, and notification of critical results, a few other elements that may help identify errors in the postanalytical phase include a random choice of specimens already run for repeat testing without disclosing their identity or the reports obtained in the initial run and cross-checking the results with the ones obtained earlier and matching visually icteric or lipemic specimens with the values obtained for bilirubin or triglycerides in initial runs. Moreover, if 2 different specimens are obtained in different vacutainers from the same patient for routine clinical chemistry and immunoassay tests, a correlation of the values obtained from 2 different platforms for different tests should be requested to check for the integrity of the specimen run.

Finally, we note our delta checks. A delta check is a process of comparing a patient's result with his/her previous result for any analyte over a specified period of time. The difference, or delta, from pre-established rules may indicate a specimen mislabel or another preanalytical, analytical, or postanalytical error.[5] If for any reason the laboratory information software does not have a delta-check procedure for flagging, a good practice would be to check for the results of a specimen from the previous day or the past few days to check for any obvious discrepancy of results: ie, a manual delta check. Because a built-in auto–delta check process within an LIS can produce frequent alarms in hospitals with critically ill patients and delay TAT, our laboratory had not activated our delta check. The postanalytical phase requires more such concerted measures to do a final check before the results are released from the laboratories.

A human crisis like COVID-19 has caused a severe disruption of the healthcare sector globally. However, it has also created unique opportunities enabling researchers and clinicians to revisit healthcare delivery by rationalizing and optimizing the use of available resources.[6]

Takeaway Messages

i. Postanalytical quality indicators should include final measures to monitor the overall testing process before laboratory reports are released.
ii. The use of barcoded specimen containers capable of being read by autoanalyzers is a must to ensure

minimal error in laboratories; there is no alternative for good laboratory practices.

iii. The customization of the HMIS/LIS as per the needs of end users is mandatory.

iv. COVID-19 is a scientific, medical, and social challenge: We need to redefine our priorities in the days to come because SARS-CoV-2 is here to stay. **LM**

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MM and MK researched the literature and conceived the study. MM and AB wrote the first draft of the manuscript, and SK edited the draft. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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