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Specimen Accountability Process Change in a Non-Automated Consolidated Microbiology Laboratory

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Specimen Accountability Process Change in a Non-Automated Consolidated
Microbiology Laboratory

By

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A culminating capstone project report submitted to the faculty of Dominican
University of California in partial fulfillment of the requirements for the degree of
Masters in Clinical Laboratory Sciences

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This Capstone Project, written under the direction of the candidate's First Reader/ Project Supervisor and approved by the Program Director, has been presented to and accepted by the Department of Natural Science and Mathematic in partial fulfillment of the requirements for the degree of Masters of Science in Clinical Laboratory Science. The content and research methodologies presented in this work represent the work of the candidate alone.

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ABSTRACT

The pre-analytical phase contributes 60-70% of total error of the total testing process (TTP) (Plebani 2006). The pre-analytical phase can be further divided into two phases; the 'pre-preanalytical' and 'preanalytical' phases, which commonly includes tasks performed outside of the laboratory walls, and tasks performed within the laboratory's walls and control, respectively. Additionally, medical care reimbursement policies in the U.S. along with the need to efficiently produce quality results and reduce the costs to clients, has caused the microbiology lab to move from on-site to more resourcefully abundant consolidate labs (Sautter 2014). Serving many satellite facilities, it is of interest to look at the pre-preanalytical phase to ensure specimen accountability when transported over the distance to the core laboratory.

While automation has assisted in reducing errors in all phases of testing, automation in the pre-analytical microbiology laboratory has been slower due to its inherent variation (Mulatero 2011). In addition, the lack of well-defined quality indicators in the pre-preanalytical phase makes it more difficult to monitor possible errors. Plebani encourages the best way to reduce errors in the pre-preanalytical phase is to work interdepartmentally and monitor compliance to standard operating procedures (SOP).

This study utilizes Plebani's approach to encourage specimen accountability between sending facilities and the core microbiology laboratory. Focusing on the transportation element in the pre-preanalytical phase, common non-compliance issues were identified and used as pre-defined quality indicators to communicate as standardized emails to non-compliant departments over of a course of five months in 2017. By reaching a consensus on adjustment of workflow and duties, quality monitoring data of non-compliance issues had been compiled and communicated to enhance specimen accountability at a consolidated core microbiology lab without the need of automation in the pre-preanalytical phase.

INTRODUCTION

The paradigm of the laboratory testing process has been described as 'brain-to-brain loop' that encompasses the total testing phase (TTP) by Lundberg decades ago in 1981. The nine steps of TTP are ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation, and action; essentially beginning and ending in the mind of physician in order to treat a patient (Lungberg 1981). These steps have been classified into three phases: pre-analytical, analytical, and post-analytical phases. Quality improvement has primarily been focused at the analytical phase, since the wrong result can adversely affect patient outcome. With the contribution of standardized techniques, reagents, automated instrumentation, information technology, and methods in quality control and assurance; error rates in the analytical phase have seen a ten-fold reduction (Plebani 2012).

The main contributor of error rates in the TTP stem from the pre-analytical phase with a low prevalence of them actually leading to adverse patient outcomes (Hawkins 2012). Such errors can delay result turnaround time and patient treatment for routine diagnostics. Decrease in customer satisfaction due to the need of recollection may affect the perception of quality for the laboratory.

The pre-analytical phase can be further divided into two categories; 'pre-preanalytical' and 'preanalytical' (Plebani 2006). 'Pre-analytical' activities inside

the laboratory such as sorting and routing, pour-off aliquoting, pipetting and mislabeling, and improper centrifugation of specimens account for 3%-5% of the total pre-analytical errors (Hawkins 2012). The 'pre-preanalytical' tasks performed by personnel outside of the laboratory contribute the most error in laboratory's TTP quality. Contributing 46%-68% of errors, the 'pre-preanalytical' category includes "inappropriate test request, order entry, patient/specimen misidentification, sample collection from infusion route, sample collection (hemolysis, clotting, insufficient volume, etc.) inappropriate container, handling, storage, and transportation" (Hawkins 2012). Well defined quality indicators (QI) in the analytical phase monitor laboratory test performance and efficiency, however definitions for QI in the pre-analytical phase are not fully established. (Plebani 2012). A definition issued by the International Organization for Standardization in 2008 states that errors need to be evaluated in all phases of TTP, in or out of the laboratory, and centered about patient care. Table 1 lists sixteen quality indicators developed by the IFCC Working Group for the pre-analytical phase based on globally collected data (Sciacovelli 2009). These indices do not assess possible patient effects and translate into improvement in the laboratory; the best approach for pre-analytical error reduction is to monitor adherence to procedures (SOP) and compliance that may vary from institution to institution (Plebani 2012).

Table 1. Quality indicators in the pre-analytic phase developed by IFCC Working Group

| | |
|--|---|
| QI-1: Appropriateness of test request | Number of requests with clinical question (%) |
| QI-2: Appropriateness of test request | Number of appropriate tests with respect to the clinical question (%) |
| QI-3: Examination requisition | Number of requests without physician's identification (%) |
| QI-4: examination requisition | Number of unintelligible requests (%) |
| QI-5: Identification | Number of requests with erroneous patient identification (%) |
| QI-6: Identification | Number of requests with erroneous identification of physician (%) |
| QI-7: Test request | Number of requests with errors concerning test input (%) |
| QI-8: Samples | Number of samples lost/not received (%) |
| QI-9: Samples | Number of samples collected in inappropriate containers (%) |
| QI-10: Samples | Number of samples haemolysed (haematology, chemistry) (%) |
| QI-11: Samples | Number of samples clotted (haematology, chemistry) (%) |
| QI-12: Samples | Number of samples with insufficient volumes (%) |
| QI-13: Samples | Number of samples with inadequate sample-anticoagulant ratio (%) |
| QI-14: Samples | Number of samples damaged in transport (%) |
| QI-15: Samples | Number of improperly labelled samples (%) |
| QI-16: Samples | Number of improperly stored samples (%) |

In 2006, Plebani conducted a study using a methodology from 1996 to examine pre-analytical error rates concluding that the percentage of error had been left unchanged at approximately 60-70%. What did change was the source of the

error type within the pre-analytical phase. Errors involving incorrect collection tube types and requirements declined when staff committed to compliance of standard operating procedures (SOP). Meanwhile, an increase of errors was observed in patient identification despite the introduction of new information systems. Plebani attributes this shift of unsatisfactory compliance to widely-distributed new written procedures; concluding the need to focus on close interdepartmental cooperation and compliance (2007).

Microbiology laboratory consolidation into core laboratories have been more frequent in the U.S. due to funding and medical care reimbursement, and the need to increase efficiency (Sautter 2015). Core microbiology laboratories provide the space required for resources to perform microbiological tests in a central location to serve their affiliate facilities and hospitals in the region.

Examples of these are the TPMG Regional laboratory in Berkeley, California that serves Kaiser Permanente hospitals and facilities, and Sutter Shared Laboratory in Livermore, California that serves it's Sutter customers around the region. Due to the changing landscape of policies concerning healthcare, other areas in pre-analytical phase require attention as well. Specimens travel long distances before undergoing testing, therefore transportation is an element of the pre-preanalytical phase that also must be focused on (Plebani 2012). Transport of specimens can impact the perception of the laboratory when specimens are not accounted for and are unable to be tracked. In addition, the final steps in the pre-preanalytical phase involve many hands-on sorting or routing, prior to allowing

automation to take over the next steps in the overall preanalytical phase of testing.

Error decline has been observed the analytic phase due to standardization and improved quality controls and assurance methods; post-analytical errors have decreased as well thanks to technological advancements in information handling with laboratory information systems (LIS) linked instruments; even true pre-analytical tasks of aliquoting, sorting, and processing have seen improvement in error rates impart by utilization of automation of robotic workstations (Plebani 2012, Da Rin 2009). In addition, personnel undertaking roles in the analytical phase are commonly licensed professionals with a good understanding compliance with SOP. All of the aforementioned have one thing in common being that they are under the laboratory's control. The pre-preanalytical phase is out of the laboratory's control and errors can be reduce with the when using the right technological information tools alongside with active involvement and cooperation of human interactions to monitor compliance (Carraro et al 2012). In the present study, the focus is specimen accountability in a large microbiology core laboratory. Without the ability to use automation in the pre-preanalytical phase, interdepartmental coordination, compliance monitoring, and communication will be the method to compile data to identify quality indicators in large microbiology core laboratory. This data may be valuable for identifying problematic areas that may need further attention to ultimately reduce preanalytical errors.

CORE LABORATORY STUDY

In this present study, the consolidated microbiology laboratory is simply identified as core lab. The multiple facilities that the core lab services are identified as sending facilities. The present study was performed between July through December 2017; data was collected at the end of the study.

Interest in specimen accountability was sparked by an issue that was escalated to the quality department; requiring investigation and immediate resolution to prevent recurrence. The issue the core lab encountered involved a specimen on the core lab's pending list for multiple days. The core lab's LIS container tracking feature indicated that the specimen was in the lab and should have been completed.

The lab assistant that supposedly logged in the specimen was held accountable for the specimen not reaching the test bench. The common practice for a sending facility to send a batch of specimens to the core lab is to build a Specimen Transfer List (STL), serving as packing list to account for specimens included in the biohazard bags. Creation of a STL automatically changes the status of those specimens from 'collected' to 'in-transit' status in the LIS. A third-party courier service is utilized to deliver shipments from multiple sending facilities to the core lab. Upon delivery lab personnel sort the biohazard bags, with specimens and

STL contained within them, manually into their respective bins according to type of test. Next, the assigned lab assistant for that test bench may gather their specimens and proceed to log in the specimens by list number. Logging in by list number generated by the LIS will log in all specimens on the STL. Status of the specimens is automatically updated to reflect that it has been received at the core lab and the test is pending. This is the point of fallacy in the process. Logging in by list number does not guarantee that specimens on the STL are truly the specimens in the bag, causing the lab assistant to be liable for the specimen.

The missing specimen sparked concerns about who should be accountable for specimens when the sending specimen SOP is not complied with. Sending facilities are to comply with SOP to build an STL when sending specimens to the core lab. Instances have been observed when specimens are received at the core lab in 'dispatched' or 'collected' status, clearly without a STL. Types of status updates in the LIS are 'dispatched', 'collected', 'in-transit', 'pending', and 'completed'; in that order. Each status serves as means to determine tests pending from day to day at each step of the testing process, from ordering to completion of results. 'Dispatched' status notifies healthcare personnel of pending collection, 'collected' status informs the local lab that the specimen should be arriving to the lab, and 'in-transit' indicates to the core lab that a specimen should be arriving within a certain time window. If a specimen is 'in-transit' exceeding 48 hours, a "no specimen received" (NSR) email is sent to the

sending facility. The specimen may be lost, not picked up, pending further instruction, and may require a recollect or recall of the patient. Non-compliance practices have led to time wasted searching for specimens that have already reached its destination.

Prior to this study frequency of STL non-compliance practice was uncertain. Specimens received without a STL at the core lab would be logged in and undergo processing. The concerning issue arises when specimens are truly lost and LIS tracking information indicates otherwise. Blame can be placed on either sending facility or core lab. Failure to comply with SOP leaves little evidence to where the specimen truly is. The purposes of complying with SOP and produce STL are to assist sending facilities to reconcile their pending lists, as well alert the core lab of possible transportation errors; it is the method to track specimens inter-departmentally.

At the consolidate microbiology core laboratory where this study was performed, specimens are received from 70 hospitals and facilities. Specimen accountability is critical when dealing with high volume clinical core laboratories. Automation and enhanced information management can help reduce errors, but currently automation integration is slow due in part to the inherent variability involved in microbiology laboratories (Plebani 2006, Mulatero 2011). Automation of specimen receiving was out of the scope. Immediate changes had to be implemented to prevent issues of missing specimens and monitor non-compliant

practices. The aim of the this study is to 1) develop and implement a non-automation solution to prevent missing specimens and, and 2) capture frequency in which non-compliant practices occur from sending facilities that can help assist with future solutions in a phase of TTP that already lacks well-define quality indicators.

MATERIALS & METHODS

The change proposed was implemented over a five month period and reflects issues encountered only during the night shift at the core lab.

To increase accountability and provide quicker communication of problematic specimens, a managerial approach was utilized to modify current preanalytical work processes and duties to aid in identifying non-compliance QI. Current work processes prior to this study is depicted in Figure 1 with the 'pre-preanalytical' processes colored in orange spanning three areas: the sending facility, the courier, and the core lab. The in-lab 'preanalytical' phase of specimen processing for testing is boxed in green.

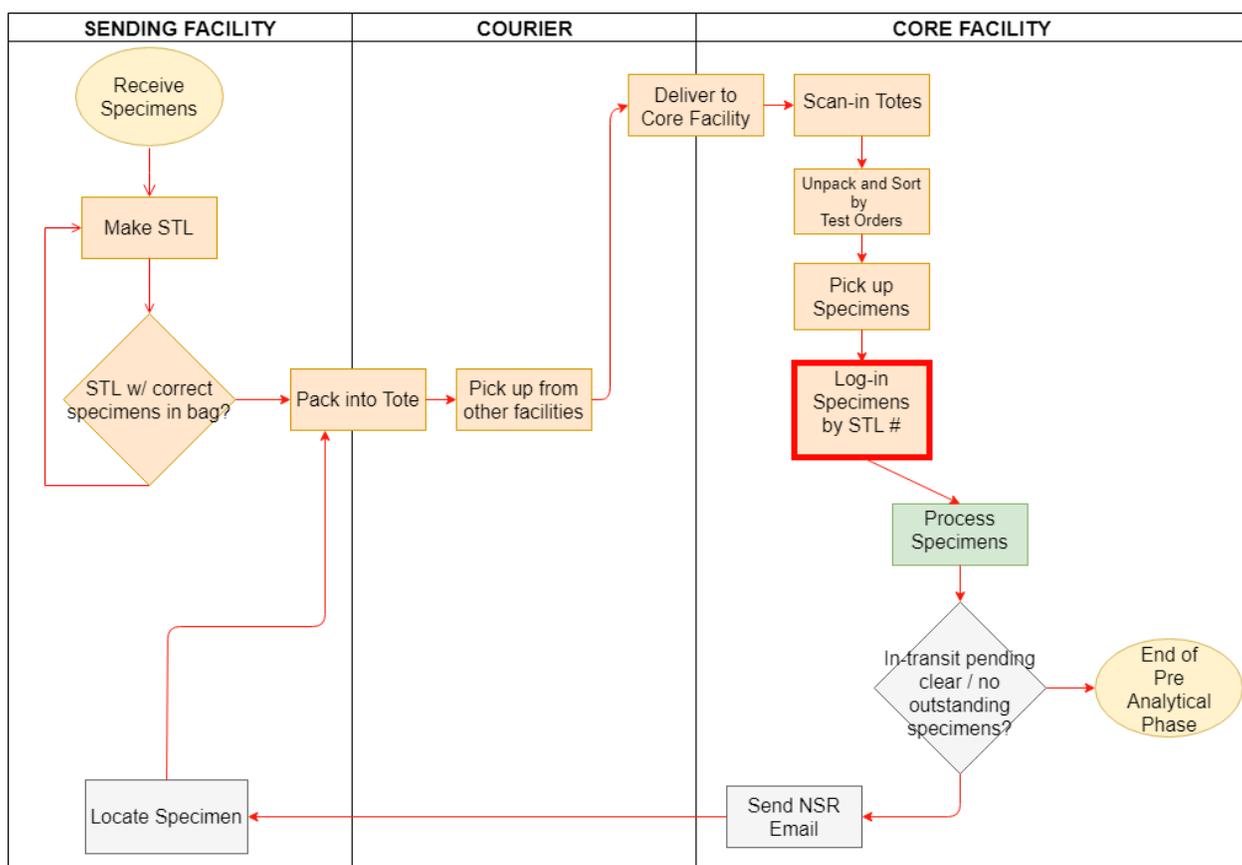


Figure 1. Process map prior to study depicting current processes of sending specimens to the core lab.

Mitigating issues and capturing data for non-compliance from sending facilities required the addition of supplemental tasks. The major processes added were: 1) manually checking all specimens against their respective STL, 2) triaging specimens received in biohazard bags without STL, or vice versa, and 3) identifying STL that had multiple tests types ordered considered as 'mixed STL'. The addition of the processes can be seen in Figure 2 which includes a method process to capture non-compliance events within the work shift to communicate

promptly any discrepancies; thereby improving accountability and releasing liability of missing specimens at the core lab.

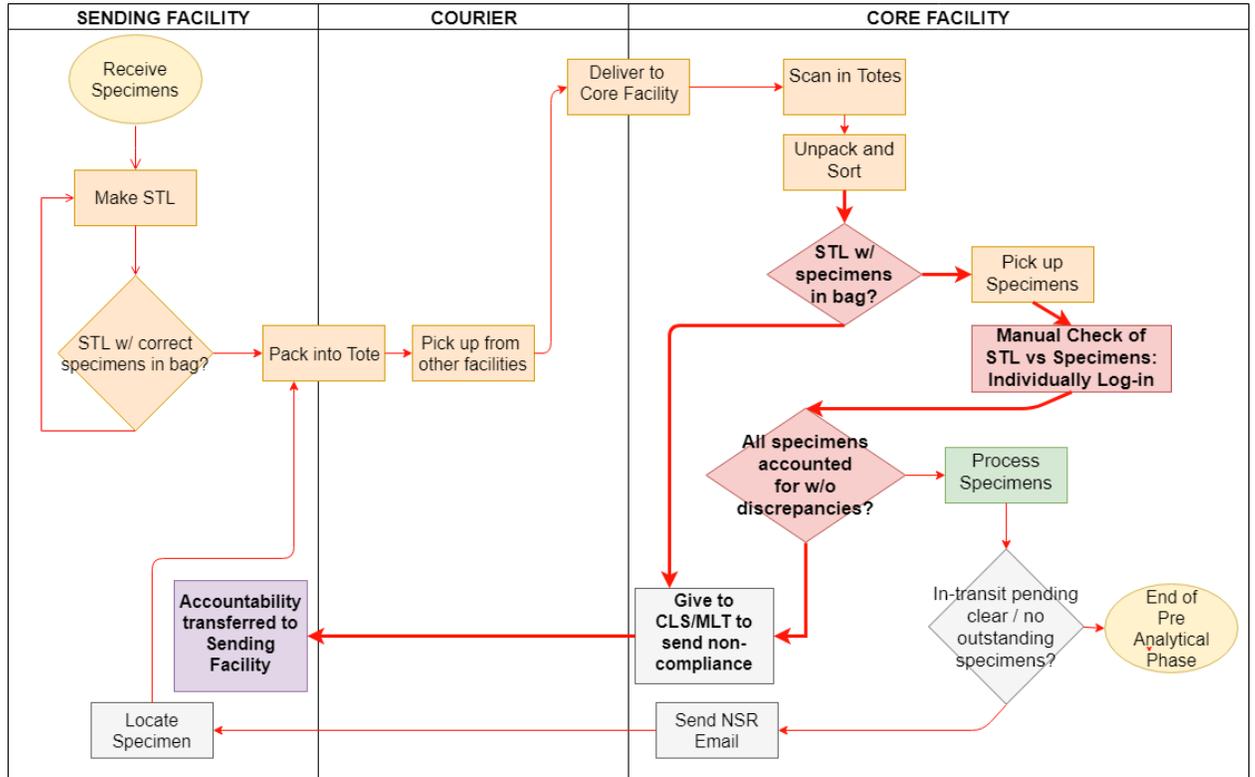


Figure 2. Process map after adjustments made to capture non-compliance practices when specimens are received at the core laboratory.

Additional tasks required adjustment of existing work duties to ensure lab assistants were not overworked, maintaining the health and the ability to complete daily duties of the laboratory as a whole. Implementing change for sample handling that has many manual processing steps involved mapping out the process, measuring performance or compliance, showing results, simulation, simplifying and redesigning, and gaining consensus (Da Rin 2009). Lab

assistants played a vital role in adjusting tasks since they are familiar with the intensity and workload of assigned duties. Task adjustments were made in July and August 2017 and tested. Follow up meetings for input was conducted for two months until reaching a consensus what on new tasks each position were responsible for.

Per procedure, sending facilities are to create a STL before sending out specimens, accurately pack specimens with corresponding patients on the STL, pack STL within the biohazard bags, and consistently make STL for only one test type. Mixed tests STL require additional handling at the core lab which increase the possibility of losing specimens. Any of these 4 issues encountered were placed in a problem bin that was centrally located near where the lab assistants performed manual sorting of specimens. The CLS/MLT who was in charge of sending emails to sending facilities monitored the problem bin and sent communication to the sending facilities, accordingly.

Utilizing standardized email templates to communicate with sending facilities provided a means of monitoring non-compliance. Table 2 was the rubric developed to monitor these non-compliance issues and serve as quality indicators (QI) for the study. Collection of such data was useful for identifying the most problematic areas that required attention. The four situation types were chosen to be the most valuable scenarios to monitor concerning specimen accountability issues encountered at the core lab and non-compliance of the

sending facilities; providing possible solutions in the pre-preanalytical phase which lack well-defined quality indicators.

Table 2. Rubric for Standardize Email of Non-compliance and definition of quality indicators

| Email Template Type | Description | Implications |
|---|--|---|
| NSR | Contents in bag missing 1 or more specimens omit from STL | True error; missing specimen identified within shift hours; effect on patient care |
| | Delayed specimen found on nightly pending list ¹ | Possible shared specimen, not collected, incorrect order, not picked up by courier, misrouted |
| Collected/Dispatched Status | No STL made; Specimen shipped without accountability from local laboratory | Non-compliance w/o immediate effects on patient care |
| STL/Specimen Separate or Mismatched STL | Possible no STL made;no accountability from local laboratory | Non-compliance w/o immediate effects on patient care |
| Mixed Test STL | Increases handling and sorting when received at Regional Laboratory; inefficiency and increase chance of losing specimen | Non-compliance w/o immediate effects on patient care |

¹24 hours after collection time, or 8 hours after collection time for Group A Strep and influenza tests

This method of surveillance and communication was applied to gather data on the complexity of the preanalytical phase and its initial steps prior to testing, and the importance of adhering to SOPs (Carraro 2012).

Data collected based on the pre-defined QI was retrieved at the end of the fifth month, December 2017. Volume of the four types of e-mails were tallied from the sent-box of the e-mail client. Any response back from the sending facility regarding the issue was noted.

RESULTS

Over the course of five months between July 2017 to December 2017, data was collected by using standardized emails. Standardized emails allowed for ease of grouping and quantifying the quality indicators as types of non-compliance monitored. Four types of non-compliance was monitored, 1) No specimen received (NSR) emails, 2) STL/Specimens separate from specimens, 3) Mixed STL, and 4) Collected/Dispatched status.

Over the 5 months, 687 emails were communicated to sending facilities. Table 3 below summarizes emails sent monthly based on the quality indicator categorizations for non-compliance monitoring.

Table 3. Total number of non-compliance emails sent between July to December 2017.

| Month | NSR ₁ | Separated ₂ | Mixed ₃ | No STL ₄ |
|-----------|------------------|------------------------|--------------------|---------------------|
| July | 53 | 4 | 7 | 3 |
| August | 62 | 27 | 20 | 44 |
| September | 61 | 20 | 18 | 35 |
| October | 64 | 24 | 7 | 37 |
| November | 43 | 10 | 11 | 32 |
| December | 62 | 5 | 11 | 27 |
| Totals | 345 | 90 | 74 | 178 |

1) No specimen received (NSR) emails, 2) STL/Specimens separate from specimens, 3) Mixed STL, and 4) Collected/Dispatched status, No STL made

The NSR-type of non-compliance had the highest occurrence with 345 emails sent over the course of the study. Of the four types of non-compliance quality indicators, NSR issues and specimens sent without a STL produced were observed to be 50% and 26%, respectively. Figure 3 visually represents the highest frequency of non-compliance issues to least frequent issues. Specimens not received to the core lab in a timely manner occurred more frequently and was further investigated.

Pareto: Frequency of Non-compliance Encounters from Sending Facilities

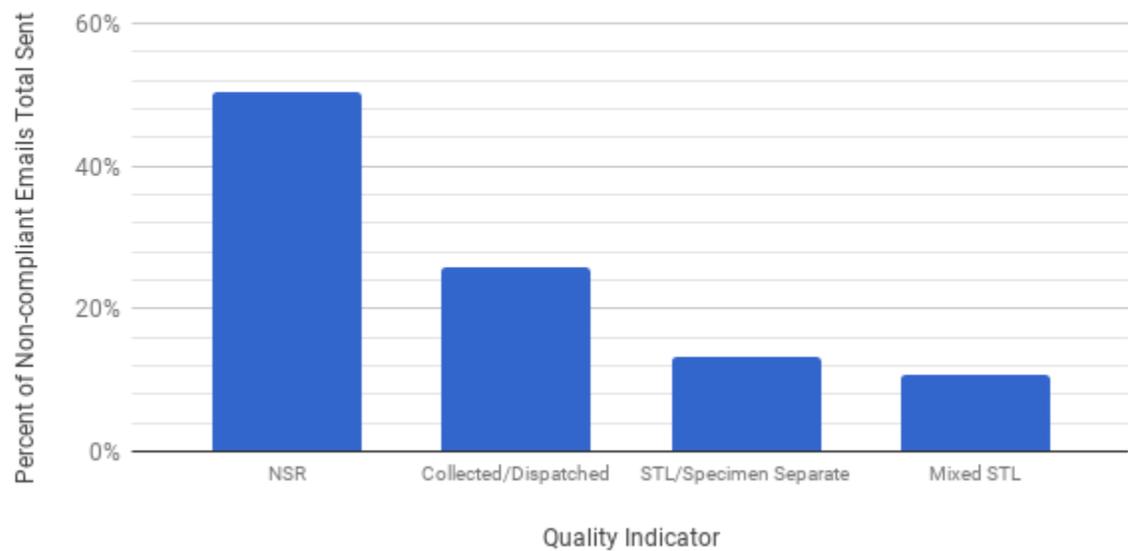


Figure 3. Pareto chart of frequency of types of non-compliance emails sent from July to December 2017. NSR = 50%, Collected = 26%, STL/Specimens Separate = 13%, Mixed STL = 11%.

Of the 345 NSR emails communicated to the sending facilities only 64 facilities responded back with explanation of the specimen accountability. The specimens not received were considered as 1) truly missing and identified as near-miss thereby relieved the core lab as accountable, 2) the core lab's mistake of prematurely sending an NSR email when a specimen was later found in the core lab and was not logged in, or 3) an issue relating to courier services or other 'pre-analytical' errors outside of the core lab such as requests to cancel, collection error, missed courier pick up, or misrouted. Figure 4 indicates the core lab was

accountable for more specimens missing in the early stages of the newly implemented work-flow; the following months the core lab had become more accountable for specimens reducing the number of email feedback for specimens that was sent an non-compliance e-mail. Truly missing specimens were identified in 10 incidences in a timely manner during the study and were considered as near-miss events that prevented delayed turnaround times. Accountability issues regarding the sending lab or courier appeared to remain constant without significant improvement. In the month of December there was a spike in emails sent that was attributed to a suspiciously high number missing specimens from one sending facility. This outlier led to discovery of an entire shipment missed by the courier. Although timely communication allowed for quick action to locate the specimens, the specimens were delayed and still was categorized as an accountability issue regarding the sending facilities and courier.

NSR Email Situation Outcome

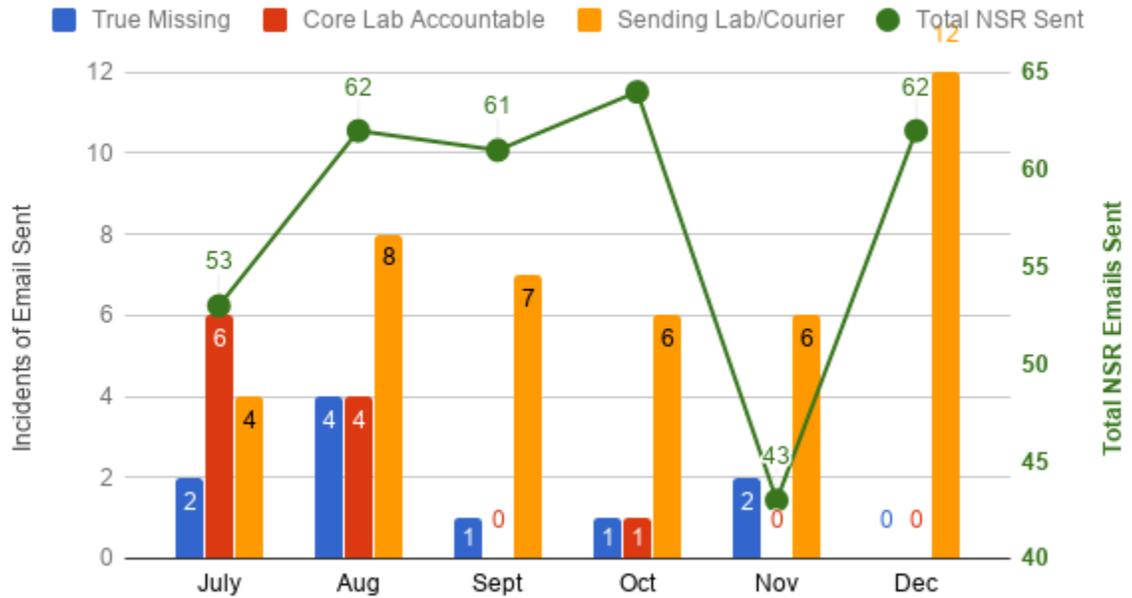


Figure 4. 19% response rate of total NSR emails sent indicating outcome for cause of specimens not received to the core lab.

A total of 345 NSR emails were sent to sending facilities; 64 responses were tracked. With a low response rate of 19%, the frequency of causes of not receiving specimens due that were 1) Sending Lab or courier related, 2) Core Lab accountable and, 3) truly missing specimen, or near-miss with prompt communication were presented in a pareto chart. Figure 5 indicates issues originating from the processes of the sending lab and/or courier comprises 67% of total specimens not received to the core lab.

Pareto: Frequency of Causes for NSR Email

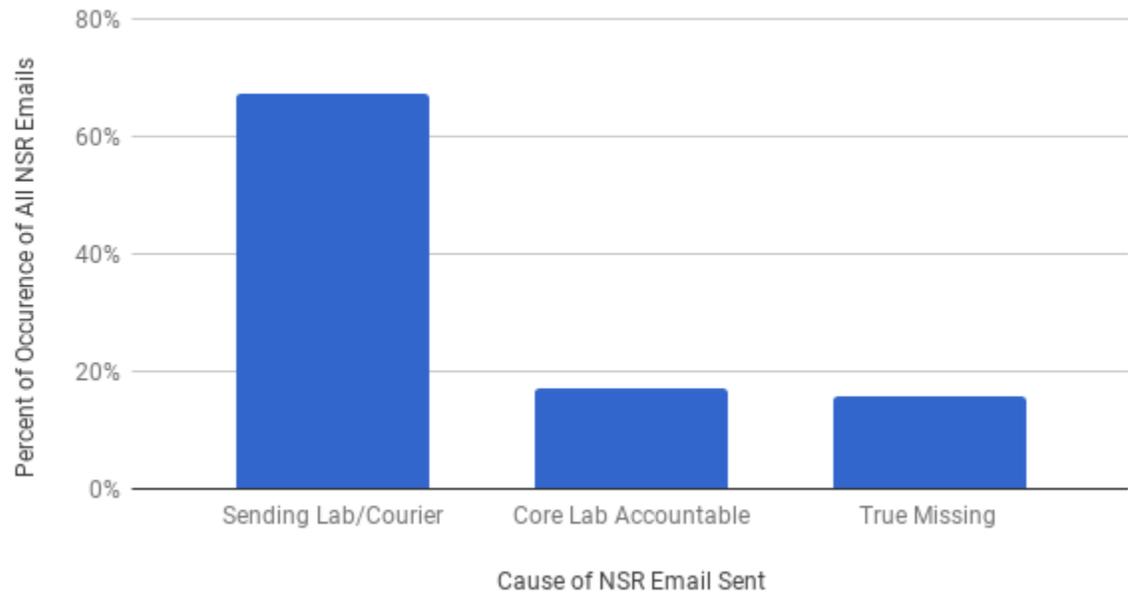


Figure 5. Pareto chart of frequency of causes for NSR email to be sent from July to December 2017.

DISCUSSION

The value of the present five month study, by closely adhering to the changes of communicating non-compliance issues upon each encounter and monitoring workflow, is the ability to evaluate errors and survey non-conforming activities in the 'pre-preanalytical' clinical workflow (Carraro 2012). The complexity of preanalytical errors can be owed in part to the lack of well-define quality indicators. Pre-defining a laboratory's own quality indicators in the preanalytical

phase should be established based on an institutions workflow to increase specimen accountability.

As seen in the Figure 4, the initial implementation of the process changes by adding the manual task of scrutinizing each specimen to its STL did not result in immediate changes in the first two months of July and August. This can be possibly due to workflow changes and the understanding of new SOP steps. With the lack of automation and interdepartmental coordination, poor compliance of written procedures and increase in errors can be observed from overworked staff (Carraro 2007). Adjusting work duties and processes was effective with a consensus of the frontline workers in the lab. In the later months, the core lab's specimen accountability increase as seen by the decrease of in outcome responses that indicated less claims of specimens not received when in fact they were in the core lab's possession. This decrease confirms that the changes implemented at the core lab increased accountability. Meanwhile, the outcomes of missing or late specimens that showed no significant improvement can be traced back to non-compliance or inadequate processes that are sending lab or courier related.

While monitoring quality indicators in the pre-analytical phase does not necessarily translate into quality improvement, it can help identify problematic processes and promote the need for appropriate preparation, understanding, and monitoring of SOP compliance (Plebani 2012). This present study highlighted

issues that needed to be addressed without the assistance of automation.

Monitoring compliance and adjusting work process were beneficial for specimen accountability in the core lab as the study progressed. Future considerations to decrease errors in the TTP should include a team to work with outside sending facilities and healthcare personnel. This study primarily used standardized email templates as a means to communicate and quantitate QI. A response rate of 19% regarding non-compliance issues is too low to indicate any definite probable causes or effects in concerns with the high volume of NSR emails sent out.

Figure 5 indicates that sending facilities compliance and courier related causes of no specimens received to the core lab would be an ideal initial area to focus on in the future. With a dedicated outreach team or group to stress the importance of SOP adherence and a significant increase of response communication to issues may in turn promote decrease in error rates.

Similar to Carraro's findings in 2012, when the core lab closely monitored non-compliance and communicated with outside facilities, it was possible to observe the complexity of the pre-pre-analytical errors and error mitigation due to the performance of external facilities that are out of the laboratories control. In addition, a consensus process should be used to develop procedures from both sending and receiving facilities to further understand the implications of deviating from procedures, and provide a commitment to adhere to those standard operating procedures to further increase the accountability of specimens (Carraro 2012).

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