QATAR UNIVERSITY

COLLEGE OF HEALTH SCIENCES

THE USE OF DATA-DRIVEN QUALITY STRATEGY TO IMPROVE THE PROCESS OF PATIENT IDENTIFICATION AND PRE-TRANSFUSION SPECIMEN COLLECTION DOCUMENTATION AT SIDRA MEDICINE

BY

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ABSTRACT

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Title: The Use of Data-driven Quality Strategy to Improve the Processes of Patient Identification and Pre-transfusion Specimen Collection Documentation at Sidra Medicine

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Background: Regardless of healthcare technology advancements and widespread use of barcode identification technology, patient identification errors still occur. Several studies and benchmark programs have shown that patient misidentification is the leading cause of transfusion-associated reactions and fatalities. Therefore, it is recommended to use barcode technology to reduce and possibly eliminate avoidable blood transfusion errors. However, none of the available studies so far has investigated the compliance with using barcode technology to identify patients and specimens during the process of specimen collection for transfusion. **Aims**: This project aims are (1) Identify the prevalence of noncompliance in barcode scanning assisted patient identification at the pre-analytical phase during specimen collection at Sidra Medicine; and (2) Evaluate the causes of barcode scanning noncompliance; and finally (3) Develop quality improvement action plans that could reduce noncompliance events. **Materials and Methods**: The frequency of blood typing specimen collection noncompliance events between January 1, 2019 and December 31, 2019 were retrieved from the Laboratory Information System (LIS) module of Transfusion Medicine Laboratory report. Quantitative and qualitative analyses of data included stratification of collections by role and collection event, and finding possible sources of errors were

performed. Accordingly, process improvement plans specific to each department involved in specimen collection were established. **Results**: Collection compliance rates of a total of 6387 blood typing specimens were evaluated. Full barcode scanning identification of both patient and specimen was utilized in only 33.6% of total collections during the baseline study period. The remaining two thirds of collections were override events, in which no barcode scanning at all represented 31.3%, and the sample accession label was scanned but not the patient armband in 32.3% of total collections. In addition, there were significant differences between phlebotomists and nurses with more phlebotomists performing the full scanning and specimen label scanning only, while more nurses obtained specimens without scanning either identification of patient or specimen ($p<.001$). **Conclusion**: Our study highlights poor utilization of barcode scanning to verify patient and specimen identification during specimen collection. We launched a quality improvement project that identified the causes contributing to non-compliance practices, and formulated improvement strategies.

DEDICATION

I dedicate this accomplishment to my beloved parents, sisters and family members who have always inspired me to achieve higher education and thrive in professional and academic life.

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CHAPTER 1: INTRODUCTION

Sidra Medicine is a tertiary healthcare provider in Qatar offering service to women and children. Sidra Medicine is accredited by The Joint Commission International, and acquired College of American Pathologists accreditation for the clinical laboratories. Barcode-based identification system is an integral part of delivering high levels of patient care and managing patient safety at Sidra. Hence, continuous improvement initiatives should be implanted to study the practice of patient identification.

Research Questions:

a) What is the prevalence of patient and specimen identification non-compliance during specimen collection?
b) What are the causes and root-causes of non-compliance?
c) How to improve patient and specimen identification process during specimen collection at Sidra Medicine?

Research Objectives:

a) Identify prevalence of barcode scanning assisted patient identification noncompliance at the pre-analytical phase during specimen collection
b) Evaluate the causes of barcode scanning noncompliance
c) Outline quality improvement action plans to reduce noncompliance events
d) Assess the implementation of action plans by statistical comparative measures

CHAPTER 2: LITERATURE REVIEW

Patient safety during blood transfusion has received considerable attention due to its adverse effects on mortality as a result of transfusion errors. Medical errors occur in distinct areas of healthcare practice such as patient misidentification, transfusion of blood, product labeling, and the dispensing and distribution of medication and blood products. Therefore, operational processes that ensure correct identification takes place during blood transfusions have been recommended. Reduction of errors using different system approaches have been advocated over the years as one of the methodologies to simplify the process and reduce reliance on human entry. As a result, the use of computer technology has increasingly transformed blood administration, empowering health systems to develop necessary infrastructure that support proper functioning of patient identification for blood transfusion processes. Barcode technology is a growing technology for streamlining blood transfusion processes that provides a primary criteria through which healthcare systems can significantly reduce human errors, enhance patient identity, and enforce accurate administration of medication and blood components.

2.1 Historical Patient Identification Procedures and the Clerical Errors History

Increasing concern about blood transfusion is derived from the need to reduce avoidable transfusion errors in patient identification [1]. In the US, fatal misidentification errors during transfusions occur in 1 in 600,000 to 1 in 800,000 transfusions, with the error incidence in the UK is 335 for every 5.5 million of red cells transfused [1]. According to Ohsaka et al, the risk of non-infectious complications related to transfusion care is at least 100 times greater than that of acquiring hepatitis C or HIV and other blood-related viral infections [2]. A study conducted at the Institute

of Medicine, in the US, in 1999 revealed that hospital mortality resulting from medication errors were 98,000 patients annually, underlining a major public health concern related to transfusion safety [3]. On the other hand, data from World Health Organization (WHO) indicates that there is 1 out of 300 probability of a patient to be harmed due to medical errors, with the Food and Drug Administration (FDA) estimating that half of these medical errors are caused by misidentifications [4]. Although not all errors are preventable, around 95% harmful blood and medication identification errors can be avoided to mitigate the rate of infections and other harmful adverse effects [5]. To support the need for patient identification during blood transfusion, Sandhu et al. revealed that 11% of all transfusion deaths in the US are caused by mislabeling of blood components by phlebotomists and improper identifications [6]. As a result, safety of blood transfusion is a growing priority for different health systems.

The historical path to patient identification systems during blood transfusion has oscillated between manual and technological methodologies, with advancements developing effective and innovative approaches to blood transfusion safety concerns. According to Bolger & Moss the prioritization of blood transfusion safety in the UK led to the formation of the Serious Hazards of Transfusion (SHOT) in 1996 to monitor the adverse effects and events of blood transfusion [7]. On the other hand, the Institute of Medicine assessed that the cost of healthcare is around $3 billion, with over $1 million allocated as avoidable costs during blood transfusion. Consequently, the Joint Commission has enacted improved accuracy of patient identification on hospitals accreditation programs to prioritize patient safety [8]. The history of automated systems for patient identification originates from the failings of the manual production

processes. Increasing production volumes and the complex work flow in blood transfusions necessitated quick asset movement through the blood lifecycle that challenged the conventional laboratory setup for blood transfusion [8]. The need to permit seamless workflow and desirable reading experience necessitated technologically-based support that corresponded with automation. For example, University of Iowa Hospitals and Clinics (UTHC) in an attempt to reduce reliance on human data entry and hence the error-prone to manual double-checking of blood product processes initiated automated patient identification manuals [9]. On the other hand, Uy et al, , and using a survey from the health Information and Management System Society (HIMSS) from 5,400 non-federal US hospitals, delineated that manual patient identification caused majority of patient identification errors, with insufficiency in blood labeling [3]. With approximately 30% of transfusion service errors taking place during pre-issuing, there was an increasing need to address the selection of blood samples, transposition of labels, transcription of errors and selection of pre-transfusion testing [2]. As a result, appropriate specification of patient identification increased the adaptation of automation of transfusion services, necessitating development of electronic systems during the pre and post-transfusion processes.

Understanding patient identification in transfusion medicine and the growth of automation services requires advance assessment of variation of errors in the practice. According to Kaufman et al , errors leading to wrong transfusions can occur at any step of blood collection and transfusion [10]. Incidences of errors during blood collection are highly prevalent validating that repetitive tasks pose consistency problems to human or manual transmission. Insufficient patient data collection is directly attributed to wrong treatment, patient dissatisfaction, and high hospital costs; existing literature

provides no accepted taxonomy for identifying errors during blood transfusion [6]. However, a multidisciplinary approach offers systematic links at different specimen collection and analysis points that can be used to address transfusion errors. Apart from the collection errors in the transfusion service, the role of professionals in handling and treating blood samples and specimen may give rise to clerical errors that affect the conformity percentage of the patient identification. Failure to undertake frequent identity during critical procedures affected the distribution of accurate blood identification procedure [11]. On the other hand, Ohsaka et al., while measuring the pre-transfusion procedure at the bedside of Japanese patients, found out that mistransfusion attributable to clerical errors compromised the safety and administration of blood protocols [2]. Blood banks are in continuous operation on 24 hours basis, any minor clerical error can cause fatal harm, making demands for automated systems valid [12]. As a result, a system approach that simplifies the transfusion service and obviates the incidences of errors has the potential to substantially increase the safety, accuracy and productivity of patient transfusion procedure.

2.2 Emergence of Electronic Systems – Scanners, Barcode, and Wristbands

Electronic systems in transfusion medicine follows the mandate to improve patient safety as a priority area in reducing blood transfusion morbidity cases. The Health Information Technology for Clinical Health (HITECH) promotes the development of real-time monitoring health informatics to improve efficiency and safety of clinical procedures [12]. The Transfusion Medicine Service (TMS) provides a range of multiple regulations to enforce and regulate automated blood bank applications that govern blood collection, matching, delivery and self-administration [12]. With a validated improvement in specimen identification, the role of technology

tools in transfusion has facilitated availability and movement of different electronic tools applicable in patient identification and blood labeling, reducing the prevalence of clerical errors and improving the accuracy and utilization of laboratory services [12]. With reporting policies and administrative guidelines supporting accurate identification to foster quality improvement in transfusion medicine, electronic systems are poised at bridging the identification gaps of manual systems and improving the adaptability and acceptance of technology by hospitals and clinicians [13]. Therefore, implementation of automated identification systems is a sequential process to bridge the identification complexities in the conventional blood bank procedures.

Different automated systems have been developed as practical means to reduce misidentification problem in healthcare. Barcode technology is one of the most visible patient identification tools integrating automation [14]. According to Sharma et al., barcode scanners use a technology that provide on-demand customized labels that transform and validate pre and post-blood collection and processing activities [12]. Barcode technology is infused into patient identification using products such as scanners, wristbands, portable printers and computer-based scanners [15]. The objective of transfusion medicine is availing the right blood to the right patient and ensuring compliance and verification of functions along the blood supply chain [12]. Barcode technology has the propensity to match patient's identification data before and after administration of blood-related activities. Barcoding practices are effective intervention to reduce human error due to the flexibility in linking specimen labels with identified patients. Electronic barcoding provides an identification protocol through the entire testing process from ordering, specimen collection, analysis, and reporting, giving them a high prospective accuracy in patient identification [15]. Apart from the

product-based barcode options, automation of the transfusion service can take the form of point-of-care systems. According to Snyder, barcode technology provides an effective methodology for tracking and labeling capabilities throughout the transfusion process through its myriad of options such as scanners, wristbands and barcodes [15]. The implementation of this technology offers quality improvements in safety, privacy and accuracy of transfusion activities by reducing human errors and improving patient identification [15]. In regard to healthcare productivity, automation of the transfusion process using barcode technology increases clinicians and patient's satisfaction rates [15].

As the most common automated patient identification tool, barcode scanner has a high degree of accuracy; therefore, it is an ideal method to reduce medical errors in transfusion medicine. The barcoding system was enforced by the Center for Disease Control and Prevention (CDC) in 2010 as the best practice to reduce the incidences of identification errors and improvement of patient specimen accuracy [6]. With the usage of the barcode scanner increasing from eight to 38 percent between 2007 and 2015, the effectiveness of this automation tool in improving communication and collaboration in transfusion medicine was established [6]. The application advantages of barcode scanners originates from their computational abilities and from the potential to be combined with other passive manual and automated systems [4]. The ability to update and integrate information contained in other automated systems increases the accuracy, continuity, and functionality of medical information, developing interfaces through which specimens can be described and tested in the course of the transfusion process [13]. According to Coustasse et al., linking of patient identification and other patient procedures is enhanced by higher data storage capabilities of barcode scanners that

provide a systematic review of transfusion information to manage and track blood products [16].

Progress in use of automated wristbands in the transfusion process has been made, providing flexible technology for patient identification. According to Latham et al. the wristband intervention has increased usage along monitoring needs of the transfusion process with the acceptability of the automation dependent on the compliance standards of the hospital [11]. Wristbands with the right identification protocol such as name, hospital identification number and other details improved the communication and appropriateness of medication and blood protocol from admission to discharge [17]. According to Tase & Tronchin, the identification process enabled by wristbands is easily understood and implementable increasing its incorporation value by transfusion clinicians [17]. However, there are anecdotal observations on the use of wristbands that change the engagement of the tool in patient identification. According to self-evaluations undertaken by Latham et al, wristbands had high levels of mistrust among patients and clinicians, necessitating continued supervision and training to promote its coverage. [11]. Similarly, Tase & Tronchin found that misidentification of patient still permeated hospitalization using wristbands indicating potential hazards of mislabeling and medication [17]. Absence of overall standards and institutional protocol affected the quality of performance protocols and necessitated active contribution of health professionals and patient's families [17]. As a result, it is essential to improve the compatibility levels of wristbands in the transfusion service to increase their alignment with other technological assessments in patient identification.

The effectiveness of wristbands is derived from its ability to integrate other forms of technology to improve accuracy. Automated wristbands can be integrated with radio frequency identification (RFID) to improve connectivity and ability to use wireless networks to identify patients, avoid delays and poor administration [13]. RFID is the next advanced innovation in patient identification due to its capability in tracking, automating and monitoring location and movement of patients and data [4]. RFID can increase the safety of the transfusion medicine by providing intelligent services to wristbands to accumulate continuous knowledge throughout the blood bank path. A study performed in 4 Italian hospitals found that embedding an RFID transfusion system on wristbands made significant improvements in errors and work reduction times [16]. As a result, there are multiple benefits to blood bank operations when RFID technology is infused to automated wristbands to monitor and track patient and clinician compliance to transfusion safety guidelines. In addition, barcode technology can be assigned to wristbands to link patients to other computerized systems within the laboratory setup [15]. The barcode technology on wristbands aids in verifying data displayed and assessing whether the barcodes on the wristband match the blood specifications of the patient [2]. With eye-readable barcodes for identification, wristbands offer verification protocol to measure the compatibility features of provided patient data, making it an effective checking procedure during pre and post-transfusion services.

2.3 Barcode Implementation Studies

The use of barcode automation technology in transfusion medicine is not only a future requirement in healthcare but also a tested practice with improvement rates recorded after its implementation. In a study by Porcella & Walker , the University of

Iowa Hospitals (UTHC) replaced the manual blood system and automated collection and care of specimens using a barcode system [9]. The methodology change was proposed as a tool for error reduction, increasing productivity, accuracy of patient identification, and specimen matching. An analysis of the system activity before and after the adoption of automation found out that barcoding was 30 times likely to catch identifications errors than the manual system, reflecting a major improvement and relative lesser risk compared to the previous process [9]. A Haemonetics blood tracking system introduced by the National Patient Safety Agency in the UK prompted by the need to ensure the correct blood protocol was implemented. The system reduced the number of incident report errors significantly [7]. Additionally, the experiment revealed that blood transfusions were performed in a timely manner, with active checking of delays by nurses, supported by the barcoded wristbands [7].

A prior study has explored the benefits of using barcode scanning of specimen accession over manual entry of patient information [18]. Duteau implied that the use of scanners improved efficiency in delivering patient care with less involvement of manual steps [18]. Therefore, patient safety practices can be enhanced [18]. Similarly, Murphy discussed applied strategies to overcome patient identification barriers and outcomes [19]. Nurses were satisfied with the use of portable devices to identify patients, and there were reduced [19] . This further implies the benefits of utilizing the electronic systems in improving patient safety and patient care services.

A prospective before-and-after investigation undertaken by Spain et al. in Queensland, Australia found improvements in 90.4% of the subjects measured using an armband barcode scanner [20]. The study intended to measure the frequency of correct key behaviors during blood specimen collection, error analysis and costing of barcode

technology intervention [20]. The specimen integrity improved due to collection of desirable patient identification information and the reduction of clerical deficiencies from the labeled tubes [20]. Studies on the long-term improvement and sustainability of barcode technology in transfusion medicine has been promoted by the need to identify safety r measures in larger hospitals with high patient numbers. Quality improvements from a barcode-based transfusion management (BCTM) system was tested in a 3,000 bed tertiary hospital handling more than 60,000 blood transfusions covered by 2,500 nurses annually [21]. Over a period of six years from 2011 to 2017, it was found that the error rate decreased to 0.001%, with the only incidence among the 68, 324 blood samples was caused by incorrect labeling [21]. The reported results indicate the important of the barcoded system to make quality changes in a large healthcare system and subsequent reduction of transfusion errors.

A study undertaken by the Serious Hazards of Transfusion (SHOT), a health agency in England, revealed that approximately 70% of blood sample errors originated from the bedside, with a large observable improvement detected after monitoring audits [2]. The blood transfusion guidelines in British blood laboratories were also updated to incorporate pre-transfusion barcode automations at the bedside aimed at initiating safe and accurate blood collection and handling protocols [2]. A meta-analysis study reported that errors related to barcode identification methods were rare and generally preventable indicating the beneficial outcomes of reduced workflow [15]. With respect to production, barcode systems have economic benefits for hospitals. Studies reviewing the satisfaction levels of patients and clinicians found that barcoding had reduced workflow processes and enabled targeted performance measurement, shortened patient stays, reduced discomforts and lesser treatment delays [15]. A standardized Laboratory

Medicine Best Practices Initiative (LMBP) study conducted by Sandhu et al. in 2017 on 12 studies published between 1980 and 2015 communication and collaboration between laboratory and clinical staff post barcode implementation [6]. They found that seven studies indicated improvement in communication and collaboration, that apart from reducing error incidences, improved patient satisfaction [6]. As a result, barcode automated interventions decreased treatment delays and costs leading to improved patient satisfaction [6]. Adoption of infusion automation also increased provider satisfaction due to the technical organization and improved tracking of testing protocols that elicit support and positive behavior [22]. As a result, reduction of dissatisfaction of the quality, safety and accuracy of blood transfusion services among patients and clinicians is a justifiable ground for implementation of barcode-related system in transfusion medicine.

To justify the redundancy of paper requisition forms in blood centers, a BCTM system was introduced in a 3000-bed tertiary hospital where it was found out that mean number of near-miss incidents reached zero per quarter for 18 quarters between 2011 to 2017 [21]. The deployment of specific patient identification (ID) barcode wristband and labeling discontinued the paper requisitions provided a cost effective method for laboratory tools to collect blood specimen. In measuring the improvement rates for labeling, a survey in UK hospitals addressing clinicians to label critical blood specimens found excellent agreement between critical blood information and quick response (QR) barcodes [23]. Barcodes enhanced identification of blood samples by de-cluttering the extensive information displayed on transitional label essential in collection and analysis of blood specimens. In a study conducted by Ohsaka et al. in Japan, a barcode-based labeling attached to blood components supplied from the

Japanese Red Cross Blood Center found out that automation improved the compatibility levels of pre-transfusion data providing an active methodology to track, monitor and authenticate patient blood identification details [2]. Improvement rates in transfusion samples labeling have facilitated the emergence of international labeling standards such as the ISBT 128 that enforces the tracking, movement and availability of blood products across hospitals and international borders [12]. To validate the use of barcodes to eliminate errors, Hachesu et al. advocated the use of training to increase the efficiency of transfusion clinicians [24]. A descriptive study conducted by Kaur et al to measure the responses of training in improving capabilities for transfusion medicine found improvement in bedside blood compatibility reflecting accuracy of post-blood assessment activities [25]. With barcode system making improvements in hemovigilance and blood safety, there are expected effects that can be used to improve a monitoring and quality standards of blood centers and hospitals [26]. As a result, these improvements address key quality and safety issues in transfusion medicine and promote the standardization of automated blood applications.

2.4 Sidra Medicine

2.4.1 Accreditation

Sidra Medicine is a specialist hospital providing high level of care to women and children in Qatar. An ambitious vision is stated on the organization's site "Sidra Medicine is a beacon of learning, discovery and exceptional care, ranked among the top academic medical centers in the world" [27]. The hospital is keen to deliver exceptional care to patients delivered with high levels of standards and safety. Sidra Medicine has achieve a number of international accreditations. Sidra Medicine was awarded Gold Seal of Approval, JCI accreditation on February 2019 [28]. In addition,

following a successful initial CAP inspection, clinical laboratories became CAP accredited on May 2019 [29].

2.4.2 Laboratory Information System (LIS)

Sidra Medicine utilizes Cerner software to streamline its clinical workflows. Cerner modules offer extensive services that facilitate management of the hospital's laboratory information system. This includes ordering tests, documenting specimen collection, log in of samples when received in the clinical laboratories, and viewing or reporting results. Cerner software is interfaced with a barcode-based identification system.

2.4.3 Specimen Collection at Sidra Medicine

Specimens are mainly collected by phlebotomists and nursing staff at Sidra Medicine. The process starts with confirming the patient's identity verbally using at least two identifiers – by asking the patient to state their full name and date of birth (DOB). This practice has been implemented as per JCI standards (IPSG.1) [30], since Sidra Medicine is a JCI accredited institute [28]. The collector then opens the specimen collection wizard in PowerChart, a module of Cerner Pathnet, and verifies patient identity on the system. Electronic verification, positive patient identification (PPID), is accomplished by scanning patients ID bands with a barcode reader. This confirms that the correct patient record is accessed in PowerChart. The requisitions are subsequently retrieved and specimen labels are printed; sometimes, collectors pre-print labels before admitting outpatients into phlebotomy rooms. The collector inspects the requisition and/or labels, chooses the proper the container, and collects specimens accordingly. The preprinted labels are attached to the appropriate tubes in the presence of the patient (JCI Requirement) [30]. The collection process completes by scanning each label to

change the order status from ‘Dispatched’ to ‘Collected’. Collector’s identifier (staff ID), collection date, and collection time are documented in the system upon validation of collection. Hence, positive accession identification (PAID) is accomplished.

When specimen collectors bypass positive identification of patient wristband, specimen accession labels or both, the system marks an override event. Thus, Cerner categories specimen collection status into the following:

1. Dispatched: Specimens that have not been collected remain in dispatched status until collection is documented in the system. In addition, collectors cannot be identified.
2. Collected: Specimens that are collected and signed-in electronically.

The events of collection are tabulated in Cerner Container Inquiry under Event List. The specific details include :

I. Positive Patient Identification (PPID)
    i. PPID Collection: This event indicates that patient’s wristband was scanned into the Specimen Collection Wizard.
    ii. PPID Override: This event reflects that specimen collector bypassed scanning of patient’s wristband.

II. Positive Accession Identification (PAID)
    i. PAID Collection: This event specifies that collector used barcode reader to scan specimens’ labels to validate collection.
    ii. PAID Override: This event confirms that specimens’ labels were not scanned against barcode reader but collection was signed manually.

The collected specimens are placed in the pneumatic tube system, and are sent directly to the laboratory. Specimen Reception staff visually check the specimens and send them to their designated laboratories. Thus, there is minimal handling of the specimens from collection to receiving and processing.

2.4.4 Specimen Receiving at Transfusion Medicine Laboratory (TML)

Specimen Reception in Department of Pathology, Sidra Medicine, is responsible for receiving specimens from the different wards across the hospital, and from an external entity, Qatar Foundation Clinic (QF Clinic). Using Cerner Specimen Log-In, phlebotomists scan each accession label into the app against the barcode readers to log in the specimens. The status changes from 'Collected' to 'In Lab'. All specimens are sent to the designated laboratory sections for testing.

Specimens received in 'Dispatched' status lack collector identifiers, collection date and collection time. Instead, the system by default associates the specimen-receiving staff with the collection in Cerner Specimen Log-In. The collection status changes from 'Dispatched' to 'In Lab' upon clicking 'Log In'. This would show that the receiver collected and received the sample at the same date and time.

An exception is formulated by TML to acknowledge receiving their own specimens. Specimen Reception delivers TML samples to the Specimen Receiving Bench, and TML technologist logs in the samples in Cerner Specimen Log-In. This is done to monitor and control Turn Around Time (TAT) of processing blood samples, according to their priorities, from the time of receiving them in TML to the time of reporting the test results.

2.4.5 Types of Tests Processed by Transfusion Medicine Laboratory (TML) in 2019

There are two classifications of orderable tests for TML: primary tests and ancillary tests. Primary tests are blood typing (ABORh), antibody screening, cord blood testing and direct antiglobulin test (DAT). These are predominantly requested by physicians, while ancillary tests are mainly ordered by TML technologists to the previously collected specimens. The ancillary tests, or add-on tests, include antibody identification, antibody titration, and elution. These tests are performed to supplement the positive results of antibody screening and DAT.

Blood typing and antibody screening are ordered together, and sent to the lab in one specimen tube per patient. Typing is performed to determine the blood group of an individual, while the screen is done to detect unexpected antibodies circulating in the patient bloodstream against red blood cells (RBC) [31]. The unexpected antibodies developed from exposure through blood transfusion or pregnancy are termed alloantibodies [32]. Autoimmune conditions attribute to the production of antibodies targeted against an individual's own red cells, autoantibodies [33]. DAT is a test to detect coating of patients red cells by antibodies or for investigations of Hemolytic Disease of the Fetus and Newborn (HDFN) [34] [35]. Hence, DAT is performed on cord blood and venous blood samples . Positive results of antibody screen tests and DATs are coupled with antibody identification tests to determine the detected antibody [35].

2.5 Overview of the Present Study

To date, no study was conducted to check if healthcare providers are using the implemented technology to document specimen collections. At Sidra Medicine, the system has been implemented before hospital activation, and thus, its use should be assessed. By studying the prevalence of improper patient identification and specimen accession identification at Sidra Medicine, and identifying the root cause, we intend to improve patient identification process and ensure compliance by specimen collectors across Sidra Medicine. The study framework is constructed according to the quality improvement Six Sigma initiative, DMAIC. Thus, the outcomes of the project can be applicable in patient identification studies nationally and globally.

CHAPTER 3: MATERIALS AND METHODS

3.1 Ethical Compliance

IRB applications have been submitted to Sidra Medicine IRB and QU-IRB, and have been examined by both boards. SIDRA IRB and QU-IRB have made the determination that this is a quality improvement project that does not require IRB review and approval (Appendix C).

3.2 Research Design

A multimethod approach including the use of quantitative metrics derived from electronic medical records, and informal interviews was utilized. No identifying information of patients or the specimen collectors (staff involved in blood collection) has been captured as it serves no purpose in the study.

3.2.1 Setting

The study has been conducted at Transfusion Medicine Laboratory (TML), Department of Pathology, Division of Hematopathology, Sidra Medicine.

3.2.2 Participants

Data have been retrieved from the collection of all blood specimens for blood typing at Transfusion Medicine Laboratory between January 1, 2019 to December 3, 2019. Test patients (non-real patient records created to validate the system), external quality assessment, and add-on specimens were excluded from the analysis.

3.3 Data Collection

3.3.1 Quantitative Analysis

Several quantitative metrics has been used to identify and evaluate the following, retrospectively:

1. Number of blood typing specimens processed in 2019
2. Number of specimen collectors roles (based on their position)
3. Prevalence of specimens collection status which are categorized as below:
    a. Specimens collected per policy/procedure (both patient ID and specimen accession ID verified electronically)
    b. Specimens with partial compliance (either patient ID or specimen accession ID verified electronically, and the other verified manually)
    c. Specimens collected using override mode (neither patient ID nor specimen accession ID verified electronically but manual verification performed and documented on system)
    d. Specimens received in dispatched status (collection was neither documented electronically nor manually)
4. Number of rejected dispatched specimens by TML

3.3.2 Qualitative Analysis

A qualitative approach of informal interviews and a survey has been developed in this project. Informal interviews were conducted to identify possible barriers and to better understand the workflow of different health care workers involved in performing blood collections. None of the interviews were audio recorded.

3.3.2.1 Informed Consent

Because there is no requirement for survey respondents to identify themselves, since this study falls under the quality improvement category, it will not involve informed consent. Both the interview and the survey are categorized as parts of quality improvement project, based on anonymous and voluntary contribution, to avoid any potential coercion.

3.3.3 Study Framework

The study was carried out using the DMAIC (Define, Measure, Analyze, Improve and Control) approach of Lean Six Sigma retrospectively.

1. Define: Data of ABORh specimens processed by the Transfusion Medicine Laboratory was extracted from Explorer Menu module in Cerner PathNet; Cerner PathNet is Sidra Medicine's laboratory information system. Data was exported and analyzed in Excel to filter out test and external quality assessment specimens after which all patient identifiable information were removed. Collector roles were identified after which all employee specific information were removed.
2. Measure: Prevalence of noncompliance events, by role and by location were calculated.
3. Analyze: Quantitative tools including statistical tools were employed to analyze and interpret the results. In addition, informal interviews and audits were conducted to identify the reasons for patient identification and accession identification noncompliance incidents.
4. Improve: Process improvement plans were developed based on the outcomes obtained and some strategies were implemented.

5. Control: An internal audit was executed to assess and control the analytical phase. This involved examining rejection and processing of dispatched samples received by Transfusion Medicine Laboratory post-implementation of new acceptance criteria.

3.4 Confidentiality

3.4.1 Data Security

The initial extracted data contained patient and staff identifiers. Data was assessed at Sidra Medicine to remove test patients and proficiency testing specimens. Then, all patient identifiers (patient name, Medical Record Number, Date of Birth, and specimen accession number) were deleted permanently as only the collection status of the specimens is required for the study. The staff ID was used to identify the job position/title of each staff then, all staff IDs were removed completely from the data. The final data only contained specimen collection status, specimen collection location (the wards at which the specimens were collected), and the position of the collector.

Because this data is being generated from the Laboratory information system it is already available to others. There is no separate information being obtained. The initial dataset will be kept on a lab restricted shared drive and rapidly de-identified. Data was not coded, yet completely de-identified by deleting the columns of patients and staff identifiers.

3.4.2 Privacy

Since participants are specimens with deleted patient and staff identifiers, patient and staff privacy were maintained. The confidentiality of identifiable

information was ensured at the initial stage of the project before proceeding to analysis of data. Any identifier, patient and staff, was deleted from the data sheet. Patient identifiers served no purpose in this study. As for staff ID, the identifier was removed after indicating the position of the collector. Data analysis was conducted once de-identified data was established.

3.5 Statistical Analysis

Inferential analysis was performed on the results to obtain an understanding of interdependence of specimen collection compliance and role of collector. Specifically, due to the data type, and that collection of samples are mutually exclusive, chi-square test of independence was calculated using Microsoft Excel.

CHAPTER 4: RESULTS

4.1 Tests Performed at Transfusion Medicine Laboratory (TML) in 2019

A total of 14443 primary tests were performed at TML in the calendar year 2019. Steps for inclusion and exclusion criteria and the proportions of the tests processed in TML are illustrated in Figure 2. The majority of these tests are blood typing and antibody screening, with similar proportions of 45.4% (6559) and 45.2% (6525), respectively (Figure 2). The difference in numbers between the two tests is due to some samples received from QF clinic where only blood type is requested. In addition, patients not admitted for blood transfusion, surgery, prenatal screening, oncology services, with no immunocompromised conditions, hemolytic anemias, hemolytic disease of the newborn (HDN) or any type of hemoglobinopathies, do not require antibody screen testing.

An average of 7.8% (1133) of the tests were performed on cord blood samples, and DAT was processed in 1.6% (225) of the total tests.

The chart (Figure 2) represents approximately 99.0% (14443) of the data from the original data report (14595). The remaining data of about 1.04% (152) tests were excluded from analysis, as indicated in Figure 1. This is because the original data set, with a total of 14595 tests, included tests performed on proficiency testing samples and test patients (non-real patients). Particularly, the proficiency testing surveys are received from CAP, to which the results are submitted. This compromised 0.38 % (56) of the total tests processed throughout 2019. Among the excluded data, 0.66% (96) of the tests were from test patients in efforts to validate a system, workflow or any Cerner function in TML.

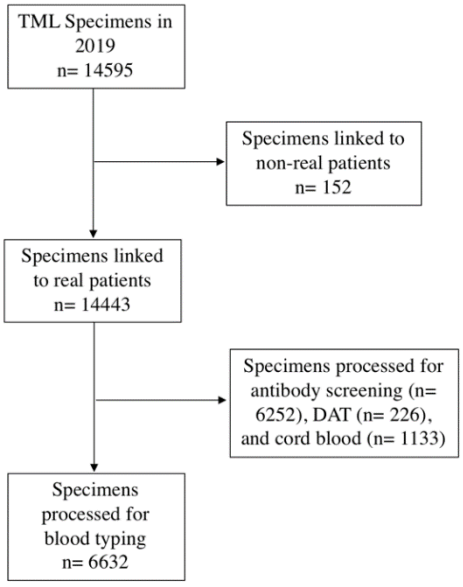

Figure 1. Flowchart showing selection of specimens in the study. Specimens linked to non-real patients represent the sum of proficiency testing specimens and test patients specimes.

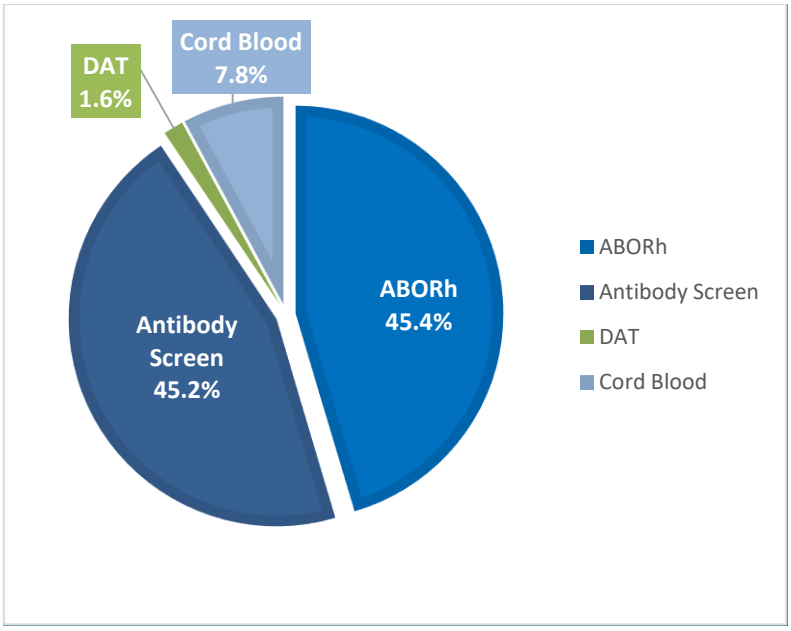

Figure 2. Proportions of blood tests performed at Transfusion Medicine Laboratory in 2019.

4.2 Pilot Audit Overview

The initial phase of this study involved a pilot audit to get an overview on the frequency of noncompliance events during specimen collection in the month of January 2019. The noncompliance events were defined as any barcode scanning override of either patient ID or specimen accession labels in Specimen Collection Wizard, and the failure to document specimen collection electronically or manually. We included blood typing (ABO Rh) data only in the analysis to avoid duplication of results. As stated previously, antibody screening is typically ordered with blood typing per patient. Moreover, cord blood testing is an initial determination of the newborn's blood group but not the confirmatory test, while DAT testing on cord samples is performed to diagnose HDFN [35]. Hence, data sets from antibody screen, DAT and cord blood testing were removed, in addition to all tests from proficiency testing samples and test patients (Figure 1).

4.2.1 Classification of Collection Events

In the pilot study (January 1, 2019 to January 31, 2019), a total of 481 blood specimens were received and processed by TML for blood typing. Collection events were specified according to the use of Specimen Collection Wizard and electronic verifications of PPID and PAID (Table 1).

Table 1. Classification of Collection Events

Use of Specimen Collection Wizard	Event Type	Verification Performance*	
		PPID	PAID
Used	Full Scan	Yes	Yes
	Patient Scan Only	Yes	No
	Tube Scan Only	No	Yes
	No Scan	No	No
Not Used	Received in Dispatched Status		

*Verification performance denoted the use of the barcode scanner to validate identifications

4.2.2 Categorization of Collections by Roles

With reference to Table 2, ABO Rh samples were largely obtained by phlebotomists (60.3%), followed by nurses from different departments (35.8%), adding up to an average of 96.0% of total January collections. There were 5/481 (1.0%) collections extracted by staff with unknown roles (Table 2). Their user ID are known but their profiles could not be found in the Employee Directory and their positions from Cerner database could not be retrieved. Thus, their roles could not be identified.

Table 2. Numbers of ABORh specimen collections per role in January 2019

Job classification/Role	Numbers of Samples Collected	%
Phlebotomist	290	60.3
Nurse	172	35.8
Anesthetist	3	0.62
Anesthesia Technologist	1	0.21
Other	1	0.21
Unknown Role[i]	5	1.0
Unknown Collector[ii]	9	1.87

i. Unknown role: user ID known but profile missing
ii. Unknown collector: no trace of collector ID – specific to samples received in dispatch status

Specimen Collection Wizard was not utilized in only 9/481 (1.87%) collections (Figure 3). The remaining collections, exceeding 98%, were obtained using the wizard, in which the majority involved override events of either one identification verification or both. Hence, 66/481 (13.7%) were collected per procedure/policy where both patient wristband and specimen accession were barcode scanned.

Interestingly, nurses were the largest group overriding both PPID and PAID (60.6%, 131), relative to 35.6% (171) of no scan collections by phlebotomists (Figure 3). Opposite relative proportions were apparent in more phlebotomists performing more of the full scan and sample accession scanning only in comparison to nurses (78.8% vs 19.7%, and 88.5% vs 11.0%, respectively; Figure 3).

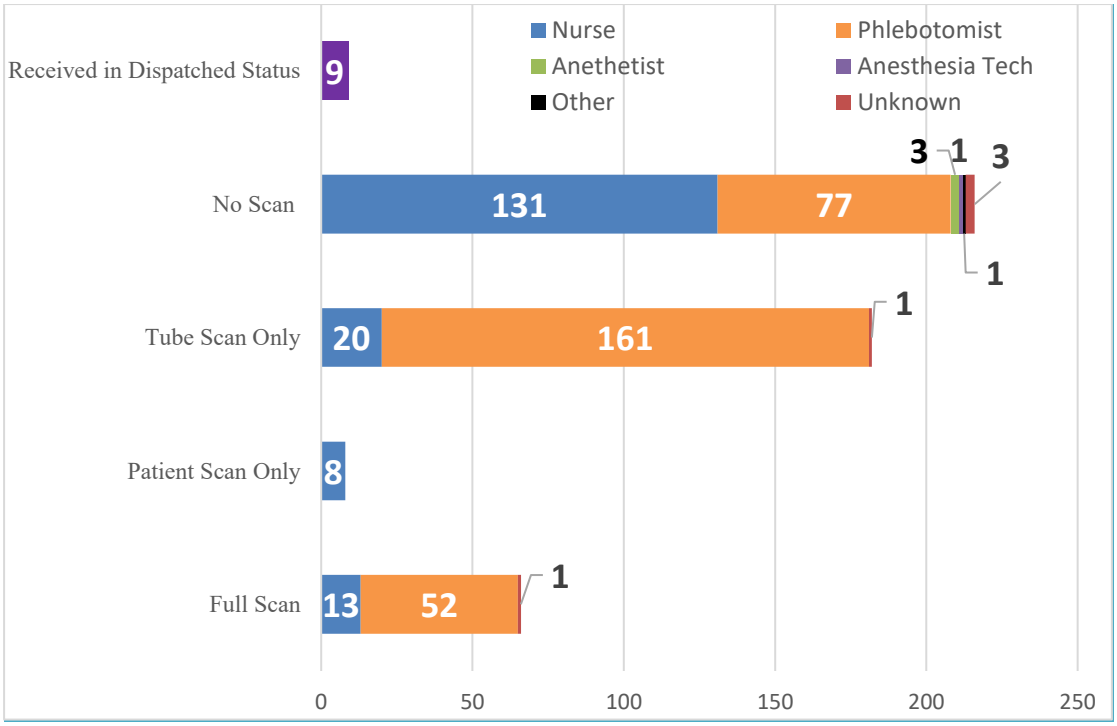

Figure 3. Specimen collection events by roles. The figure illustrates breakdown of collection events by collectors roles of January 2019. Numbers in columns indicate frequency of the event. Colors differentiate the collectors roles.

4.3 Analysis of Complete Audit

4.3.1 Overview

The audit period was extended to include all blood typing specimens collected in 2019 calendar year in an effort to monitor compliance throughout the year and plan improvement strategies accordingly. Data analysis was carried out using data extracted from the modified report.

4.3.2 Summary of Results

There were 6632 ABORh specimens in the year reviewed. Of these, 73 were test patients or external quality assessment specimens, leaving 6559 patient specimens tested. Analysis of results revealed that the role of the collector for 172/6559 (2.6%)

specimens were unknown (Figure 4a). Results were further analyzed after removing data of specimens collected by staff of unknown roles. Thus, the total number of datasets evaluated were 6387.

The rates of collections per role were proportionately similar before and after removing unknown roles (Figure 4).

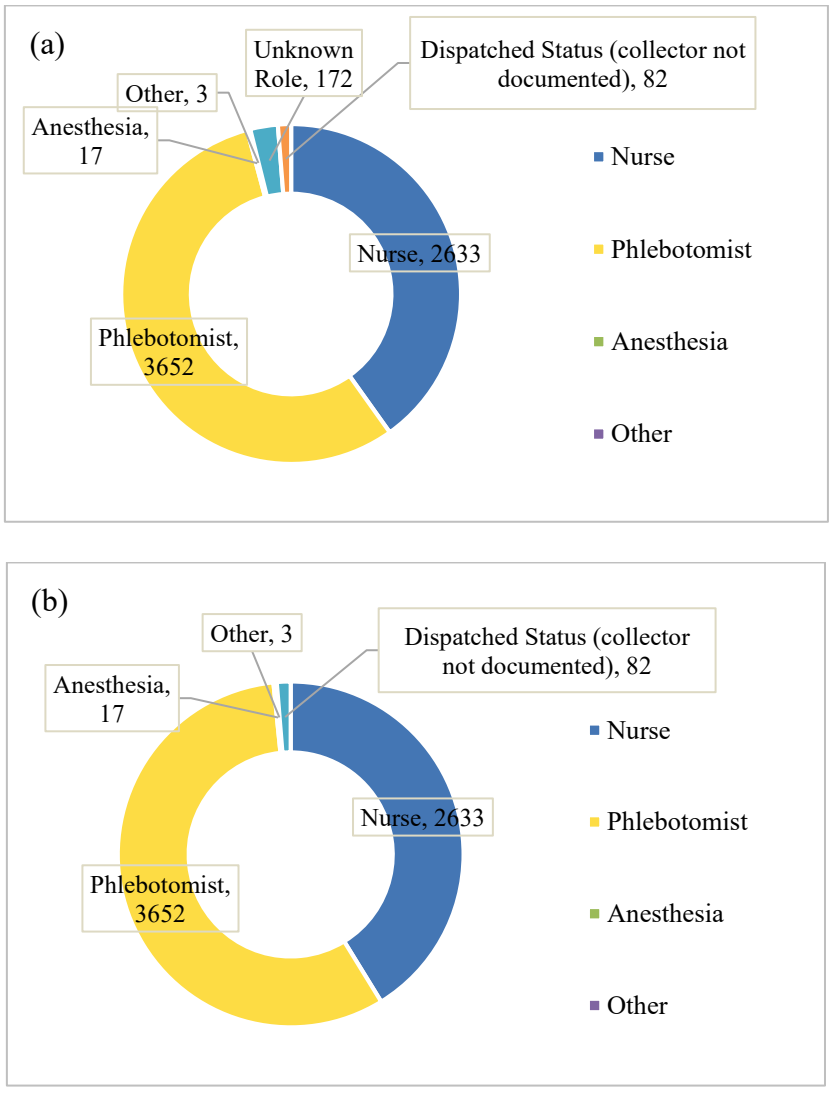

Figure 4. Comparison of collections per role (a) with unknown roles data (b) without unknow roles data.

4.3.3 Stratification of collections by event type and roles

With reference to Figure 4b, Nurses collected 41.2% (2633) of the specimens while phlebotomists collected 57.2% (3652). Anesthetists and anesthesia technologists documented only 0.26% (17) of samples, while collections by other roles account for 0.05% (3) of total collections. Specimens collected in dispatched status (collectors not documented) represented 1.28% (82).

Collection status/events of all samples (6387) were specified, and their proportions among total collections were measured (Table 3). As indicated in Table 3, only 33.6% of specimens collected utilized the full barcode scanning identification of the patient and specimen. Close to a third (31.3%) had no barcode scanning at all and in another third (32.3%) the accession label of the sample was scanned but not the patient armband (Table 3).

Overall, there were variations between nurses and phlebotomists in verification of patient identify and documentation of collections during blood typing specimen collection. Table 3 demonstrates more phlebotomists were completing collections with full scanning (44.8% vs 19.6%), and accession labels scanning only (41.4% vs 20.9%). However, nurses failed considerably to scan both patient ID and accession labels overriding the two verification steps (57.1% vs 13.0%) (Table 3).

Table 3. Comparison between Rates of Specimen Collection by Nurses and Phlebotomist relative to the Collection Events*

Collection Event	Collector Role	
	Nurse (n=2633)	Phlebotomist (n=3652)
Full scan (33.6%)**	515 (19.6%)***	1635 (44.8%)
Patient scan only (1.53%)	66 (2.51%)	32 (0.88%)
Tube scan only (32.3%)	550 (20.9%)	1510 (41.4%)
No scan (31.3%)	1502 (57.1%)	475 (13.0%)

*Collection events significantly differed between nurses and phlebotomists ($\chi 2$ (3) = 1448.99, p<.001)
**values in parentheses represent percentage relative to total number of collections in 2019
***values in parentheses represent percentage relative to the total number of collections per specific role

The relative proportions of compliance by nurses and phlebotomists throughout 2019 were individually examined. Numbers of collections obtained by nurses following identification protocols slowly increased from 7.56% in January 2019 to 37.0% in December 2019 (Figure 5a). Phlebotomists performance, otherwise, showed a substantial increase in specimen collections with both patient and sample accession identifications verified (from 17.9% in January 2019 to 94.3% in December 2019; Figure 5b).

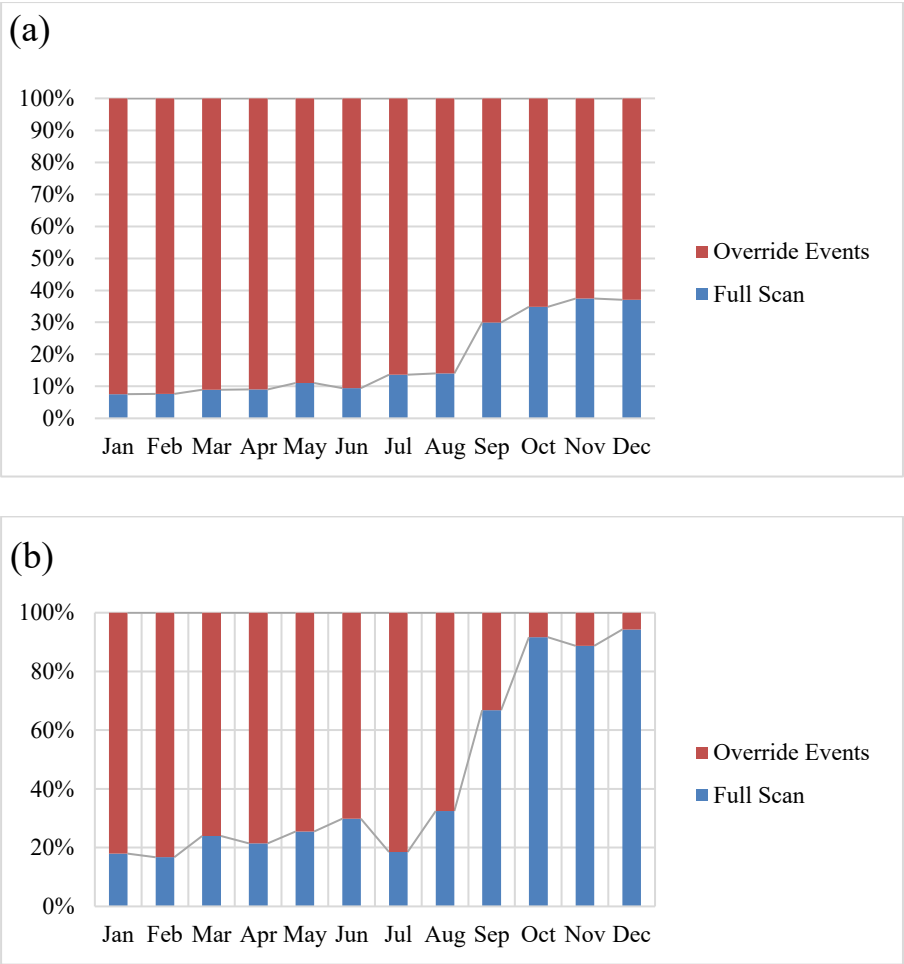

Figure 5. Relative proportions of compliance within (a) nurses (b) phlebotomists. Override events included the sum of collections with no scanning of either patient and specimen identifications or both.

4.3.4 Stratification of dispatched collections by event type and roles

There were 1.28% of specimens which arrived in the laboratory with no collection documentation (Figure 4b). Blood typing test of all samples (82) were run by the medical technologists. Data extracted from the report does not include rejected/cancelled samples. Dispatched samples were sent to the laboratory with different priorities and from multiple locations within the hospital wards. Routine samples constituted approximately 90% of collection priority (Figure 6a), while

majority of the samples came from outpatients of QF Clinic and in-patients in postpartum wards (Figure 6b).

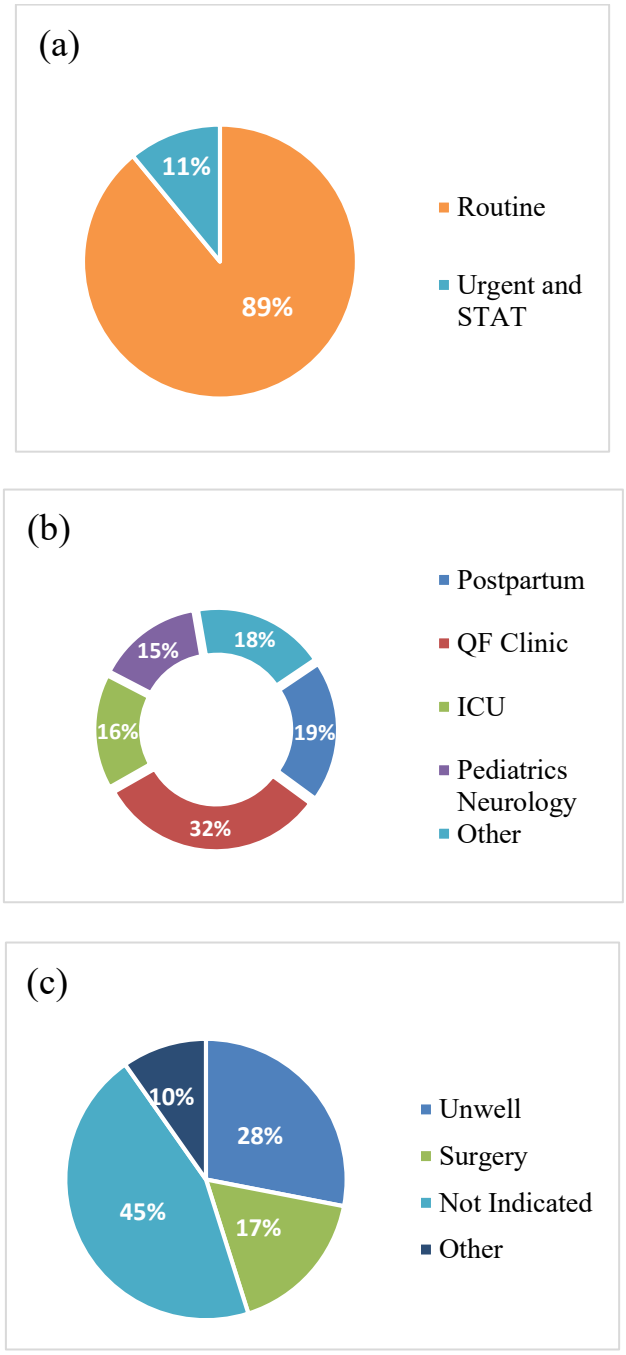

Figure 6. Breakdown of dispatched samples received by (a) sample priority (b) patient care location (c) admission diagnosis.

4.4 Potential Causes of Barcode Scanning Noncompliance

A risk assessment of noncompliance to specimen collection protocols are described below in a fishbone diagram (Figure 7).

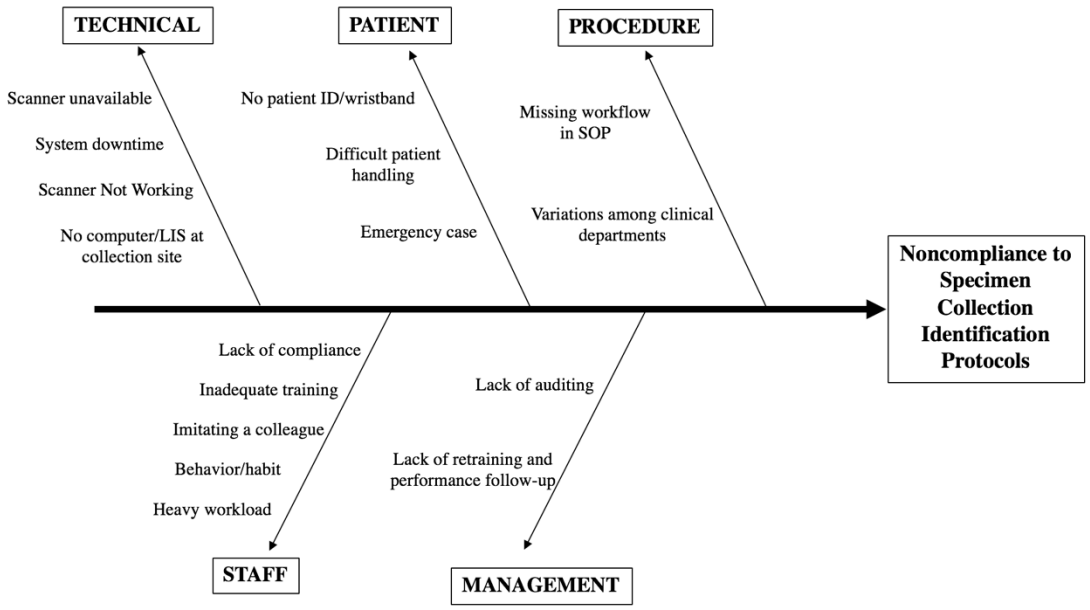

Figure 7. Possible causes for noncompliance to specimen collection identification protocols. The fishbone diagram indicates 5 major categories of causes resulting in noncompliance. 2-5 examples are listed per category.

4.5 Improvement Strategy Plan

4.5.1 Pre-analytical Phase

A survey was designed to identify root causes of identification noncompliance during specimen collection, and will be sent to staff involved in specimen collections during the first half of 2020 (Appendix B). Survey results analysis will be shared with the corresponding clinical groups to target the contributory factors, and to establish improvement plans accordingly.

4.5.1.1 Survey Content

The survey (attached in Appendix B) will collect details on the causes that contribute to non-use of barcode scanning during patient identification and specimen collection documentation. The survey is an electronic, internet based survey, with 11 questions about respondent's position, training in blood collection process, number of collections and the factors influencing the override of the electronic identification. This is not a validated questionnaire but was designed after initial audit of workflow and interview with staff knowledgeable about the process and possible barriers. A link to the survey will be emailed to all staff involved in blood collection.

4.5.1.2 Informed Consent

The survey will not involve informed consent as discussed in Chapter 3 (section 3.3.2.1).

4.5.2 Analytical Phase

As directed by TML Medical Director at Sidra Medicine, TML would reject all samples received in dispatched status regardless of priority, unless the tube was signed manually (with initials of collector and time of collection). No exceptions will be made to any

classification of patient health condition, age of patient, and status of patient (VIP patient) when their samples arrive to TML without electronic or manual acknowledgement of collection.

Clinical wards would be informed of sample rejection, followed by submitting a report to the events surveillance/reporting system. This decision was effective on April 17, 2019, and communicated to TML medical technologists through email and during morning huddles. TML specimen receiving procedure was amended to reflect the new rejection criteria.

Additionally, a new cancellation code was added to Cerner's drop-down list of cancel reason as of September 5, 2019. This code, 'LAB-Collection not documented', would be used when cancelling samples received in dispatched status, instead of using the code 'other' and writing a comment to reflect the reason.

Moreover, an ongoing audit (monthly-basis) of processing blood typing samples sent in dispatched status was established, as part of an internal audit of TML's quality management system.

4.6 Processing of Dispatched Samples in TML (Post-implementation Audit)

An internal audit was conducted to investigate adherence of TML medical technologists to the new specimen rejection rule on dispatched samples. Cancelled specimens data are extracted from a different report as TAT report includes data of processed samples only. Thus, rejected dispatched samples by TML were not reflected in previous

sections. No samples received in dispatched status were rejected prior to the decision implemented on April 17, 2019.

As indicated in Table 4, all dispatched samples received in April were processed; none was cancelled. One sample per month, in May, and July till December, was rejected, except in June where 2 dispatched samples were cancelled (Table 4).

Table 4. Proportions of Cancelled Dispatched Samples in TML since April 17, 2019

Month	Numbers of cancelled samples	Total number of received samples [i]	%
April	0	4	0.0
May	1	10	10.0
June	2	9	22.2
July	1	6	16.7
August	1	4	25.0
September	1	10	10.0
October	1	4	25.0
November	1	7	14.3
December	1	8	12.5

i.Total number of received samples is the sum of processed dispatched samples (Appendix A) and rejected dispatched samples (right column)

Cancel codes (cancel reason) and comments of all rejected dispatched samples were assessed, and results are summarized below (Table 5).

Table 5. Cancel Codes Selected and Comments added to Rejected Dispatched Samples

Month	Numbers of cancelled samples	Cancel reason	Cancel comment
May	1	LAB-other	Dispatched
June	2	LAB-other	Dispatched
July	1	LAB-other	Dispatched
August	1	LAB-other	Dispatched
September	1	LAB-Collection not documented	No comment
October	1	LAB-Collection not documented	Senior informed nurse (No ID of contact person was recorded)
November	1	LAB-Collection not documented	No comment
December	1	LAB-other	Informed personnel ID noted

CHAPTER 5: DISCUSSION

Automated systems in transfusion medicine have found prominence as the general healthcare sector increases its intake of technological advancements. With high morbidity and morbidity prevalence associated with unsafe blood practices, transition from manual blood collection and handling practices to automated tools provided viable solutions to the problem.

Sidra Medicine is an advanced hospital in Qatar accredited by a number of global agencies including JCI and its clinical laboratories are accredited by CAP. As such, Sidra Medicine has integrated Cerner software and barcode-based identification system to achieve and maintain high accuracy of patient identification standards. Therefore, metrics to evaluate the practice of electronic patient identification during specimen collection are needed.

In efforts to comply with patient safety requirements, we have assessed the prevalence of the use of barcode scanning to positively identify patient and specimen labels during collection of blood typing samples. The implications of these findings are discussed below. In addition, we highlighted possible factors that contributed to barcode scanning noncompliance, and initiated improvement plans to reduce noncompliance events.

Transfusion Medicine Laboratory at Sidra primarily performs blood typing, antibody screening, DAT and cord blood testing. Blood typing and antibody screening are usually ordered as a combined order to one specimen tube. This constitutes a pre-

transfusion specimen for most of the cases since the patients are predominantly pregnant women, and children with critical conditions. Both orders accounted for 90.6% of all tests performed in TML during 2019 (Figure 2). In addition, DAT samples were the least collected and processed at TML (1.6%), followed by cord blood testing (7.8%) (Figure 2). DAT is a case-by-case test ordered for patients with suspected antibodies-bound red cells circulating in their bodies. Thus, the proportion of processing DAT as compared to blood typing and antibody screening is much lower. Cord blood typing at Sidra is directly proportional to the number of live births. There were 152 samples associated to non-real patients records encompassing test patients (96) and proficiency testing (56) (Figure 1). Being a CAP-accredited laboratory, TML receives and processes proficiency testing samples on a regular basis. The results are submitted to CAP to determine the performance of the specific tests.

While previous studies have focused on evaluating the numbers of mislabeled specimens pre and post implementation of an electronic system [36] [37] [38] [39], we identified a novel mechanism to audit the use of barcode scanning during specimen collection to authenticate identification of patient and specimen labels.

First, we performed a pilot study to understand the frequency of override events after detecting several samples in dispatched status. In order to facilitate quantification and analysis of collection events, we classified them based on the use of technology to verify patient identification and accession label identification (Table 1). For instance, if specimen collector scanned patient wristband and sample accession label into the Specimen Collection Wizard, we define the event as full scan (Table 1).

The study enclosed 481 blood typing samples performed in January 2019, of which 13.7% only were fully scanned (both patient identification and specimen collection were scanned into the collection wizard) (Figure 3). With reference to Table 2, more than 95% of total January collections were obtained by phlebotomy and nursing staff. A total of 4 samples were drawn by anesthetists and anesthesia technologist (Table 2). Anesthesia staff tend to collect pre-transfusion samples before or during surgeries depending on surgical intervention and/or risk of bleeding.

The results indicated a high level of noncompliance to patient identification and specimen accession identification during specimen collection among all identified collectors roles. Thus, this necessitated the need to investigate the prevalence of the use of barcode-based identification system during specimen collection.

Clustering data into collections by specific roles and locations was feasible. A generated TAT report in the system, was modified to capture collection events and integrate staff ID of the collector. The main challenges encountered during the pilot audit were:

1. Analysis of results

Analysis was time consuming due to the use of simple excel functions to evaluate the results. Moreover, the role of each specimen collector was obtained from Employee Directory per sample in the dataset. Hence, the roles were manually transcribed into the dataset. Similarly, the collection event of each sample was examined individually through Container Inquiry module, and added into the dataset.

2. Some staff roles could not be identified using staff ID.

Several outcomes, summarized below, were gained after completion of the pilot audit:

1. Audit results were unsatisfactory leading to extending the audit time frame.
2. The turn-around-time (TAT) report within Cerner PathNet, from which the data was extracted, would be modified to include the user Identification of the staff who documented the specimen collection and whether the patient identification was barcode scanned (PPID Collection) or overridden (PPID Override) and whether the sample accession number was scanned (PAID collection) or not (PAID Override).
3. Unknown staff roles would be omitted from 2019 data analysis. Most likely the unknown roles are linked to staff who left Sidra before data analysis. Thus, their profiles were not found in either Employee Directory or Cerner database.

The findings from the pilot study enables designing a better approach of collection and analysis of 2019 data.

Collectively, our findings revealed that specimen collection staff performed poorly in following procedure/policy of documenting collections in the Specimen Collection Wizard throughout 2019. Regardless of increasing proportions of full scan throughout the year reviewed, higher number of noncompliance were evident (Table 3, Figure 5). This accounted for two-thirds of all blood typing collections during 2019. As depicted in Figure 4, similar proportions were maintained before and after removing data of specimens collected by unknown roles from dataset. This is because collections by unknown roles represented only 2.6% of total collections (Figure 4).

Noncompliance to positive patient identification and specimen accession verification, imposes a great risk on patients health. Several studies had shown the

transfusion related-risks associated with patient misidentification [40] [41] [42]. A report prepared by SHOT, reported 908 near miss cases attributable to Wrong Blood in Tube (WBIT) in the years 2016-2018. These errors could have consequently lead to ABO-incompatible transfusion [43]. ABO-incompatibilities have proven to cause detrimental outcomes including transfusion reactions and death [44] [45]. A study by O'Neill et al. indicated significant reduction in incidents of WBIT and mislabeled specimens (by 73.5%; $p \leq .0001$, and by 84.6%; $p \leq .0001$) [46]. The results were attained after successful implementation of strict specimen labelling policy [46]. Thus, more effort needed to improve specimen collection practices, and positive patient identification at Sidra Medicine to eliminate avoidable sources of errors.

In the present study, nurses collected majority of specimens without scanning both patient identification and specimen accession (57.1%), while phlebotomists obtained most specimens with full scanning practice (44.8%) (Table 3). The results of this study indicate that nurses tend to omit steps of specimen collection scanning more than phlebotomists. The data contributes a clearer understanding of non-phlebotomy personnel conducting more preanalytical collection errors relative to phlebotomists, as presented by Rooper et al [47]. The investigators examined prevalence of specimen rejection stratified by acceptance/rejection criteria, patient care areas, and collectors roles; they found that 85% of rejected specimens were collected by nurses while phlebotomists were responsible for collecting 4% of rejected specimens [47]. Collectively, the findings of our study and literature suggest that initiatives are required to target specimen collection procedures in the clinical wards.

Interestingly, rates of full scanning marked increasing proportions relative to all types of override events, over the period of the year reviewed, but were significantly disproportionate between nurses and phlebotomists ($p<.001$) (Table 3, Figure 5). A chi-square test of independence was calculated comparing the frequencies of compliance events among nurses and phlebotomists; the results indicated highly significant difference between the two groups ($p<.001$) (Table 3). Overall, nurses were involved in more than 80% of override incidents of total collections extracted by nursing team (Table 3). Conversely, phlebotomists performed fewer override practices (55.2%) with total compliance (performing full scan) in 44.8% of samples (Table 3).

At the start of the study, phlebotomists were more involved in override events (>50%) compared to full scanning (Figure 5b). The proportions changed dramatically during fourth quarter of 2019, in which full scanning was performed in more than 60% of specimen collections, and exceeding 90% in December (Figure 5b). In comparison, statistics of full scan collections by nurses were fluctuating between 9% and 14% in months of May to August (Figure 5a). Compliance rates by nurses improved slightly over the last 4 months of 2019 with an average of 34.8% (Figure 5a). Although improvement in full scanning by phlebotomist is apparent, efforts in changing behaviors towards the end of 2019 should be studied.

It is notable that there was a decreasing trend in the numbers of override events by the end of 2019 (Figure 5). TML strictly rejected any specimen received with no documentation of collection in the system despite order priority, and was effective mid-April 2019. Nonetheless, a concern circulates on accepting samples with positive patient identification (PPID) overrides, regardless of positive specimen accession

identification (PAID). This is because there is a chance of retrieving wrong patient profile in PowerChart, and with pre-printing of labels, resulting in WBIT. This has been specifically addressed in a study by Nuttel et al. [48], in which more transfusion-related near miss cases were discovered using computerized identification systems. The results were correlated with the findings of a similar study, and implied that preventable/avoidable errors in patient identification are recurrent [48] [49].

Similar and identical first and/or last names are very common among Arab communities. Consequently, more risks are associated with misidentification of patients if two-identifiers standard is not followed [50]. One study, conducted by Henneman et al., examined patient verification during order entries in a prospective approach [51]. The design of the study involved test patients with similar names [51]. Results suggested that all participants (care providers) verified patient identification with patient names only; the medical record number was not checked [51]. Thus, clinical personnel tend to miss the two-identifiers rule. Hence, a similar behavior can occur during specimen collections with PPID override at Sidra. Considering such practices, the use of barcode-based identification system prevents misidentification of patients with similar names as patients are verified by scanning their ID wristbands.

It is difficult to reject samples with PPID override due to high prevalence of specimen received with PPID override (Table 3). For instance, urgent requests for blood transfusions could impede the process of scanning patient wristband during collection of blood typing samples. Thus, probability of receiving such samples would be high. Moreover, Sidra Medicine is a specialized women and pediatrics hospital at which patients with special conditions, such as mental health issues, are treated. Hence, this

imposes challenges on healthcare providers in handling those patients, and increases the need to override PPID.

Clinical laboratories need to invest further in quality measures to improve patient safety across the hospital. However, as long as collector identifiers are not documented, TML will reject the sample regardless of priority or patient condition. Strict adherence to acceptance criteria is required by the American Association of Blood Banks (AABB) [52]. As per the standards, published by AABB, a sample with no traceable collector identification is considered a mislabeled sample, and must be rejected accordingly with no exceptions [52]. In accordance with common standards, patients without blood type history or a valid blood type sample will receive uncrossmatched group O blood in case of emergency [52]. Type-specific blood will be issued once a valid sample, which is electronically documented or manually acknowledged, is received and processed by TML. This practice saves patients from blood grouping errors and potentially ABO incompatibilities when samples are not collected per policy.

We identified possible causes of overriding patient and specimen accession identifications, and summarized them in Figure 7. To some extent, we were able to associate few noncompliance cases with the factors contributing to them. First, anesthesia team collected 0.26% of the specimens without verifying either patient identification or specimen accession (Figure 4, Appendix A). Medical Director of TML, Sidra Medicine, has communicated with leaders of anesthesia team via email, and found some operating rooms lack barcode scanners/readers (Technical). Hence, collections were not documented by bedside. Second, phlebotomists confirmed that no LIS system

and hardware are available at QF Clinic (Technical). This explains the receiving of 18/19 QF Clinic samples in dispatched status. One sample was documented with both PPID and PAID override, as the phlebotomist documented collection upon returning to Specimen Reception in Sidra Medicine.

Additionally, we have reviewed blood collection procedures from Phlebotomy. Even though the SOP clearly detailed use of Specimen Collection Wizard, workflow failed to reflect verification of non-electronic collections by manually signing the tube with collector identifier (Procedure). Additionally, indicated diagnosis for most dispatched samples for blood typing were 'Surgery' and 'Unwell' (Figure 6c). We speculate that failing to use the Specimen Collection Wizard might be due to urgency of blood transfusion requests (Patient). Moreover, we attempted to use the Specimen Collection Wizard against a test patient. An alert was prompted only when specimen accession was not scanned in; hence, this confirms that the wizard does not constrain overriding positive patient identification, and specimen accession identification (Technical).

Furthermore, system downtime is a definite contributor to override collections as Cerner application is not accessible during that time; every step is recorded manually (Technical). In September 2019, Cerner was upgraded, and thus, the upgrade was validated before re-implementation and use. Once the upgrade got confirmed for functionality, all procedures were recorded back into the system, including specimen collection. In addition, it was observed that some nurses claimed they were not aware of the new rejection process (rejection of dispatched samples by TML) (Staff, Management and Procedure). Finally, we noticed that no data-driven audit or

observational assessment was performed by phlebotomy seniors or clinical nurse leaders post hospital activation, other than assessment during competency training (Management).

Moreover, there is no quality control check on how to perform collection of specimens. The physical assessment is done through phlebotomists and nurses annual competency. We have not evaluated their competencies as it should be done annually. The purpose of the study was to get actual figures of noncompliance after receiving many samples at TML that were not appropriately documented in the system. As a result, we examined and identified the frequencies of compliance to the process of specimen collection and documentation using a data-driven approach. Regarding the handling of specimens from collection to receiving, the transport of specimens occurs with very minimal handling due to the use of the pneumatic tube system. Hence, the specimens arrive directly to the laboratory post collection, and Specimen Reception staff sort them and send them to the designated sections. There is an exception of system downtime during which the specimens would be transported by a porter. However, this has been exceedingly rare in the past couple years.

Nonetheless, we anticipate that the survey will help in effectively understanding and deducing root causes of noncompliance. We designed the survey questionnaire based on the results analysis and informal interviews with seniors of phlebotomy, nursing and anesthesia teams. We planned to distribute it by mid-March. However, the COVID 19 crisis has impeded the process. Hence, we were not able to conclude the factors contributing to the noncompliance so far. We are planning to send out the

questionnaire, and analyze the reasons accordingly in a couple of months from May 2020.

No similar studies were conducted internally, as discussed previously in Chapter 2, or locally. With reference to the specimen collection manual of Hamad Medical Corporation, patient identifiers (patient full name and medical record number) are verbally verified upon specimen collection [53]. The process is not similar to Sidra Medicine in that collectors manually acknowledge collection in the system. Hence, we believe Sidra Medicine is the only hospital in Qatar that utilizes barcode-based identification system for scanning patient identification wristbands and specimen labels into the hospital's information system.

Lastly, we examined TML medical technologists compliance in detecting and rejecting dispatched samples upon specimen log-in. The new strict rejection policy of cancelling dispatched samples was effective on April 17, 2019. Because cancelled samples are not recorded in the TAT report, the data was retrieved from a separate report (Laboratory Cancellation Report). Only 15.1% of all dispatched samples, received post effective policy date, was cancelled by TML staff (Table 4). This reflected poor compliance to the new protocol. TML medical technologists are expected to attain high responsibility in assuring patient safety due to the nature of the service they provide. Presumably, staff could have read the email but did not remember to comply with the new process. Hence, staff need to be regularly reminded through emails and during daily morning huddles.

A new cancel code (LAB-Collection not documented) was added to the LIS in September 2019 to reflect cancellation of samples received in dispatched status. Strict adherence to using the new code facilitates selective data analysis when rejection report is executed or generated. TML technologists used the new code when cancelling the 3 dispatched samples received in September to November, but did not select it when cancelling the sample received in December (Table 5). In addition, the cancel comments are discrepant among the rejected samples from May to December. For instance, no comment was added to 2 cancelled samples, and only 1 contained contact personnel ID (Table 5). Cancel comments should be harmonized among the technologist in order to control the process.

Newly implemented rejection criteria by TML could be a factor of increased improvement rates in specimen collection by phlebotomists. This can be deduced through an independent study to draw an association between numbers of rejected TML specimens and/or numbers of submitted reports to the events reporting system, with regards to increased compliance frequencies of specimen collections. The association could not be properly examined as on average 1 sample was rejected per month; there was no increase in the numbers of samples rejected during 2019.

CHAPTER 6: SUMMARY

6.1 Conclusion

Despite the implementation of barcode-based specimen collection wizard at Sidra Medicine, clinical staff fail to comply with policy/procedure in verifying patient and specimen accession identifications. In addition, medical technologists performed poorly in capturing and rejecting dispatched samples post acceptance criteria amendment. Sidra Medicine is an internationally accredited institution; thus, clinical departments must work collaboratively to assure that high level of patient safety is attained at all stages of patient flow.

6.2 Limitations

We highlighted possible limitations in our study. First, we could not find the specific roles of some collectors using Employee directory and Cerner database. As a result, we omitted about 2.6% of the data from the analysis. Second, we were unable to investigate the factors leading to the remarkable increase in compliance by phlebotomy team during the last quarter of 2019.

6.3 Recommendations

The investigation revealed that there is a clear need to improve patient identification during specimen collection. Support from all management and individual staff is necessary to improve patient safety. Thus, we target our recommendations to the clinical teams, Phlebotomy Department, Clinical Laboratory.

6.3.1 Clinical Teams

CAP recognizes that specimen acceptance and rejection criteria is a laboratory-specific responsibility. However, specimens are not entirely obtained by phlebotomists.

Thus, we recommend that all clinical staff, likely to collect specimens, be competent to specimen collection procedures.

We recommend clinical leaders to investigate gaps in workflow, policy or training of personnel on the use of barcode technology. Hachesu et al identified multiple barriers to the use of the barcode systems, and suggested several recommendation which mainly targeted workflow and training of staff on the use of barcode system [24].

In addition, we recommend performance of data-driven audits and observational audits at random periods. Data-driven audits can be conducted using reports submitted to the events reporting system. In addition, observational audits can improve behavior of specimen collection staff in adhering to the policy or procedure due to Hawthorne Effect [54].

6.3.2 Phlebotomy

We recommend phlebotomy seniors to amend specimen collection SOP to include non-electronic specimen collection procedure. We suggest adding a flowchart to depict the steps of specimen collection. We propose the adoption of specimen collection workflow illustrations from Saint Thomas Health, and non-electronic specimen collection procedure from Vanderbilt University Medical Center [55] [56]. We believe that manual acknowledgement of collections should include collectors staff ID, and not just initials, for accurate traceability. Moreover, we suggest the use of online learning modules to train and/or retrain staff. In addition, phlebotomy seniors should lead educational initiatives to address specimen collections in clinical wards. Finally,

we recommend enforcement of periodic audits on specimen collection, and sharing results with nursing teams.

6.3.3 Clinical Laboratory

We recommend the participation of all laboratory sections in auditing specimens received. In addition, we suggest that all sections alter their rejection criteria to include dispatched specimens, and encourage their staff to utilize the events reporting system to document receiving of dispatched specimens. It has been shown that specimen collection errors reduced with increasing numbers of reports [57]. We also encourage managers, or anyone of superior authority, to request a change of Cerner's Specimen Collection Wizard, to include warning when PPID is overridden, and/or add a drop-down list to justify override practice.

6.4 Future Direction

In light of the limitations identified and the findings of the study, we recommend the following as future studies:

- Use of data for continual improvement projects in TML, Sidra Medicine.
- Interventional studies to compare 2019 results with 2020 results post implementation of a training program.
- Understanding association between pre-analytical errors and events reporting system.
- Identify mechanism to retrieve profiles of unknown collectors roles.
- Assessing use and effectiveness of incidence/events reporting system at Sidra Medicine.

- Nationwide study across all hospitals in Qatar to examine trends of noncompliance during specimen collection.

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Table A. Raw data of frequencies of 2019 ABORh sample collections stratified by months, collection events and collector roles.

Row Labels	January	February	March	April	May	June	July	August	September	October	November	December	Grand Total
Full Scan	**65**	**58**	**91**	**86**	**107**	**110**	**89**	**121**	**286**	**405**	**340**	**392**	**2150**
Nurse	13	13	18	17	25	22	32	31	65	97	88	94	515
Phlebotomist	52	45	73	69	82	88	57	90	221	308	252	298	1635
Patient scan only	**8**	**3**	**8**	**12**	**4**	**3**	**6**	**3**	**8**	**19**	**14**	**10**	**98**
Nurse	8		4	3	1	1	4	3	5	18	9	10	66
Phlebotomist		3	4	9	3	2	2		3	1	5		32
Tube scan only	**181**	**204**	**214**	**179**	**244**	**229**	**271**	**192**	**143**	**70**	**66**	**67**	**2060**
Nurse	20	25	49	40	50	51	57	54	54	50	49	51	550
Phlebotomist	161	179	165	139	194	178	214	138	89	20	17	16	1510
No Scan	**213**	**177**	**195**	**233**	**193**	**190**	**176**	**184**	**111**	**121**	**101**	**103**	**1997**
Anesthesia tech	1											1	2
Anesthetist	3	2	1			3		2		1	2	1	15
Nurse	131	133	131	128	150	160	142	133	93	113	89	99	1502
Other	1		1		1								3
Phlebotomist	77	42	62	105	42	27	34	49	18	7	10	2	475
Received in Dispatched status	**9**	**9**	**11**	**4**	**9**	**7**	**5**	**3**	**9**	**3**	**6**	**7**	**82**
Received in Dispatched status	9	9	11	4	9	7	5	3	9	3	6	7	82
Grand Total	**476**	**451**	**519**	**514**	**557**	**539**	**547**	**503**	**557**	**618**	**527**	**579**	**6387**

APPENDIX B: SURVEY QUESTIONNAIRE

The purpose of this short questionnaire falls within quality improvement strategy of the Transfusion Medicine Laboratory. This survey will assess your practice of the process of patient and sample identification during blood specimen collection.

The survey should be take less than 10 minutes to complete.

We value your feedback, and we appreciate your time and input. As a sign of thanks feel free to include your email at the end of the survey to be entered in a prize draw to win a 75QAR Alshaya gift card. Note your email will ONLY be used for the draw and not to identify your answers. The project lead will have no way of identifying you, and your answers will remain completely anonymous.

Our hope is that the results of this survey will help us identify opportunities to improve the blood collection process, thereby improving patient safety.

Thank you in advance!

1. **Which department do you work in?**
    i. Plaza D - OBTriage/WUC
    ii. Plaza ED - Urgent care & Trauma
    iii. 1A – HOOC
    iv. 1A - Cardiac Cath lab

v. 1A - IR & DI
vi. IB – Ped Infusion
vii. 1B - OR Pediatrics / Womens
viii. 1B - PACU
ix. 1B - DSU
x. 1B/C – Pediatric Endoscopy Department (PED)
xi. OR
xii. 3B - PICU
xiii. 3C & 4C - NICU
xiv. 3D Birth Centre/WSCU
xv. 4B Oncology/BMTU
xvi. 5A - Peds Neuro & Gen Surg
xvii. 5B - Peds Gen Surg/trauma/urology
xviii. 5D - Ante Nat & Gyn
xix. 6A - Peds Special Surg
xx. 6B - Peds Specialty Med
xxi. 6C - Post Partum
xxii. 6D - Post Partum
xxiii. 7A - Nephro & Dialysis
xxiv. OPC
xxv. Other (Please specify)
xxvi.

2. What is your job title?

i. Nurse or Midwife
ii. Phlebotomists

iii. Other (Please specify)

3. **How long have you worked at Sidra?**
    a. 3 months or less
    b. 3-6 months
    c. 6-12 months
    d. More than one year
    e.
4. **Have you received training on how to document collection and correctly label a lab specimen at Sidra?**
    a. No
    b. Yes (If yes, please specify the type of training that you receive)
        i. PowerChart training during induction
        ii. Supervised by a colleague at the bedside
        iii. Other (Please specify)

5. **How often do you collect specimens in your day to day practice?**
    a. Always (at least once per shift)
    b. Frequently (at least once every couple of shifts)
    c. Often (at least once per week)
    d. Rarely (I encounter this maybe once per month)
    e. Never (I haven't done this yet at Sidra)
    f.
6. **How often is the patient wearing their ID band during specimen collection?**
    a. Always

b. Frequently

c. Often

d. Rarely

e. Never

f.

7. **How often do you override barcode scanning of the patient ID band during sample collection?**

    a. Always (with every collection)

    b. Frequently (every 2 or 3 collections)

    c. Often (every 3-10 collections)

    d. Rarely (less than 1 in 10 collections)

    e. Never (I haven't done this yet at Sidra)

    f.

8. **Choose and rate the following reasons for overriding barcode scanning of the patient ID in order of importance/frequency.**

        i. No patient ID available

        ii. Scan unable to read Patient ID

        iii. Scanner not available

        iv. Scanner not working

        v. I didn't have appropriate training

        vi. Sample requested as STAT, and didn't have time to scan

        vii. I open the specimen collection and override to see what to collect before the patient is in the room

        viii. I document the collection after patient has left or away from the bedside

ix. Habit, that is how I learned to use the system

x. It is easier and/ or faster and/or better for patients

xi. Other (Please Specify)

xii.

9. How often do you override barcode scanning of the specimen barcode label during specimen collection?

a. Always (with every collection)

b. Frequently (every 2 or 3 collections)

c. Often (every 3-10 collections)

d. Infrequently (less than 1 in 10 collections)

e. Never (I haven't done this yet at Sidra)

10. Choose and rate the following reasons for overriding barcode scanning of the specimen barcode label in order of importance/frequency.

i. Scan unable to read specimen label

ii. Scanner not available

iii. Scanner not working

iv. I didn't have appropriate training

v. Sample requested as STAT, and didn't have time to scan

vi. I document the collection after I send the specimen to the lab

vii. Habit, that is how I learned to use the system

viii. It is easier and/ or faster and/or better for patients

ix. Other (Please Specify)

11. **What would help you to consistently use the barcode scanning features of the specimen collection wizard?**

Please indicate your email address only if you would like to be entered into the 75QAR Alshaya gift card draw.