The Cost of Pre-Analytical Errors in the Context of Inpatient Complete Blood Count Testing at Sunnybrook Health Sciences Centre

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science
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Abstract

The majority of laboratory testing errors originate in the pre-analytical phase. While the causes and frequencies of pre-analytical errors are well characterized, there are few studies investigating the cost of these errors. The objective of this research was to build a model to quantify the cost of pre-analytical errors occurring during inpatient complete blood count (CBC) testing at Sunnybrook Health Sciences Centre (Sunnybrook). The resultant cost model accounts for the costs of materials, resources, and personnel-time consumed in the CBC testing process. In 2011, pre-analytical errors in inpatient CBC testing cost Sunnybrook $43,462, and represented a loss of 775 employee hours due to laboratory test repetition and error-related activities. This cost model represents the minimum cost of a pre-analytical error, as costs extraneous to the laboratory were beyond the study scope. Future studies investigating downstream effects of pre-analytical errors and the costs associated with them should be conducted.
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List of Abbreviations

**ABG**: Arterial Blood Gas
**CAP**: College of American Pathologists
**CBC**: Complete Blood Count
**CPR**: Cost per Reportable
**CVIS**: Collection list Verification – Interface by Specimen
**EPM**: Errors per million
**EBP**: Evidence-Based Practice
**EDTA**: Ethylenediaminetetraacetic Acid
**FMEA**: Failure Mode Effects Analysis
**IBCT**: Incorrect Blood Component Transfused
**IOM**: Institute of Medicine
**LIS**: Laboratory Information System
**MCHC**: Mean Corpuscular Hemoglobin Concentration
**MCV**: Mean Cell Volume
**NICU**: Neonatal Intensive Care Unit
**OER**: Order Entry Review
**P<sub>a</sub>O<sub>2</sub>**: Arterial blood oxygen tension
**PCV**: Packed Cell Volume
**PDCA**: Plan-Do-Check-Act
**PPID**: Positive Patient Identification
**PTS**: Pneumatic Tube System
**QI**: Quality Improvement
**RBC**: Red Blood Cell
**RCA**: Root Cause Analysis
**REI**: Interface Requisition Entry
**RFID**: Radio Frequency Identification
**SOP**: Standard Operating Procedure
**Sunnybrook**: Sunnybrook Health Sciences Centre
**TMC**: Transfusion Medicine Clinic
**TTP**: Total Testing Process
Chapter 1

1 Introduction

1.1 Errors in Medicine

The clinical laboratory plays a critical role in the delivery of care to hospital patients. It is estimated that 60-70% of all major clinical decisions, such as therapy, admission, or discharge, are influenced by the clinical laboratory.\(^1\) Accordingly, failures in laboratory testing can have significant and potentially dangerous effects on patients. The magnitude and the severity of iatrogenic errors in medicine were brought to the attention of both the medical community and the general public by a groundbreaking report called “To Err is Human,” which was published by the Institute of Medicine (IOM) in 2000.\(^2\) This report found that over one million adverse medical events occurred each year in the United States, and that more than 100,000 of these events led to serious harm befalling a patient. It estimated that as many as 98,000 Americans die annually in hospitals as the result of preventable medical errors. While not specifically focused on errors in the clinical laboratory, the report emphasized the importance of error reduction, mainly by presenting this startling cost in the currency of human life and well-being. Lives, however, are not the only cost of such errors; the IOM estimated that medical errors cost U.S. hospitals $17-29 billion each year.\(^2\)

1.2 The Laboratory Testing Process

The laboratory testing process can be divided into three phases: the pre-analytical phase, the analytical phase, and the post-analytical phase. These three phases together are referred to as the “total testing process” (TTP) (Figure 1). Each phase in the TTP can be subdivided into a series
of overlapping and interrelated processes which in turn can be separated into a sequence of process-steps. Each process-step in the TTP represents a unique point at which an error can occur. The pre-analytical phase encompasses all components of the laboratory testing process that take place prior to specimen analysis. This includes test ordering, specimen collection, specimen transport to the laboratory, specimen accessioning in the laboratory, and preparation of the specimen for analysis. The analytical phase involves the actual analysis of the specimen in the clinical laboratory. The post-analytical phase encompasses resulting of specimens and result reporting.

Figure 1. The total testing process for a CBC test at Sunnybrook. The pre-analytical phase has processes that occur both inside and outside of the clinical laboratory. The analytical and post-analytical phases occur entirely inside the clinical laboratory.
1.3 Errors in the Clinical Laboratory

The IOM defines a medical error as “The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.” Medical errors can and do occur in all aspects of healthcare delivery to patients. Of the 98,000 deaths estimated to occur annually by the IOM as a result of preventable medical errors, 17% are attributable to diagnostic errors. Sandars and Esmeil estimated that 26% to 78% of primary-care medical errors are diagnostic errors. In the context of laboratory medicine, these errors can occur at any point in the laboratory testing process from the decision to order a laboratory analysis made by a physician to the actions taken by that physician regarding patient therapy once analysis is complete. The many studies investigating errors in laboratory medicine have yielded similar rates of error distribution for each of the three phases of laboratory testing regardless of differences in study design, methodology, and error monitoring practices. These studies nearly unanimously report that the majority of laboratory errors occur in the pre-analytical phase of testing. The error rates reported in the literature for the various testing phases range from 31.6%-84.5% (pre-analytical), 4.35%-31.6% (analytical), and 9%-30.8% (post-analytical).

1.4 Pre-Analytical Errors in Laboratory Testing

Historically, research and advances in laboratory medicine have been focused on improving accuracy and reducing errors in the analytical phase. One of the first published studies on laboratory errors in 1947 reported an error rate of 16.21%. In the 50 years following that publication, error rates decreased to 0.47%. As the analytical phase has become increasingly reliant on computer and automation technology error rates in that phase have decreased and accordingly the laboratory medicine community has become comfortable with the current state.
of the analytical phase. This sense of security surrounding the analytical phase has allowed for a shift of focus in the study of laboratory testing errors. In the last 15 years, increased attention has been paid to the extra-analytical phases of laboratory testing, especially the pre-analytical phase.

1.5 Pre-Analytical Errors in the Scientific Literature

In 2007, Plebani and Carraro investigated the type and frequency of pre-analytical errors occurring at the University Hospital of Padova (Italy) in the stat laboratory. Over a three-month period, a total of 51,746 laboratory analyses were prospectively monitored from internal medicine, nephrology, surgery, and the Intensive Care Unit. The clinical laboratory at the University Hospital of Padova conducts clinical chemistry, hematology, coagulation, immunology, and molecular biology testing, but the authors did not provide frequencies of the specific types of tests occurring or frequencies of errors for different test types. A total of 160 errors were detected, resulting in an error frequency of 0.309%. It should be noted that error frequencies in this study were determined based on the number of errors/test and not the number of errors/specimen. The most common errors were tube-filling errors (13.1% of errors detected), followed by patient ID errors (8.8%), specimen collection in inappropriate containers (8.1%), and request procedure errors (7.5%). Pre-analytical errors accounted for 61.9% of laboratory errors detected (99/160), with the majority of said errors occurring during specimen collection. Analytical and post-analytical errors accounted for 15% and 23.1% of total errors respectively. All of the specimens considered in this research were stat specimens. The authors stated that specimen collection in their institution was conducted by physicians and nurses on the wards, and not laboratory staff. All test orders at this institution were placed through an electronic test
request system. It was not specified what type of patient identification system was in place (text-based ID wristbands, barcoded ID wristbands, etc.).

Arikan et al.\textsuperscript{17} conducted a study of pre-analytical error frequency at the 1200-bed Ibn-i Sina Hospital in Turkey. This was a one-month long prospective study and involved observations of 8393 day-time specimens and 4678 night shift/weekend specimens submitted for biochemical analysis. The authors found that depending on the test type and the time of day, the rates of specific types of pre-analytical errors ranged from <0.1\% to 23.5\%. A total pre-analytical error frequency for the time period of the study was not listed in the report, nor were rates of analytical or post-analytical errors. It was also unclear from the paper what type of patient identification system was in place at the hospital and what the breakdown of test types performed by the laboratory was. The most common error reported was mistaken patient information entered into the computerized test ordering system. This accounted for 16.3\% of pre-analytical errors during the day shift and 23.5\% of pre-analytical errors during the night shift/weekends.\textsuperscript{17}

A 2001 study by Wiwanitkit\textsuperscript{8} found a pre-analytical error frequency of 0.11\% (1048/935,896 specimens). The distribution of errors across the three laboratory testing phases was 84.5\% pre-analytical, 4.35\% analytical, and 11.13\% post-analytical. This was based on data collected prospectively over a 6-month period at the 2900-bed University-Hospital of Chulalongkorn (Thailand). The clinical laboratory at this hospital was the first Thai laboratory to achieve ISO 9002:1994 certification, and the rate of pre-analytical errors was determined to be a quality indicator for the performance of the laboratory. Error rates were determined based on the number of specimens rather than on the number of tests performed as multiple analyses were performed on some samples. Wiwanitkit\textsuperscript{8} identified 1048 pre-analytical errors prospectively.
Interestingly a subsequent retrospective analysis of the same time period identified 1240 pre-analytical errors. More than 90% of the errors detected in this study were found to originate in the care units and not the laboratory. Inappropriate specimen quality was the most common error (47.04%), followed by incorrect ID of the patient (26.81%). As with many other studies in the literature, the author neglected to specify how patients in his institution were identified or to discuss the frequencies of specific types of lab tests for which errors were detected. It is also unclear what type of ordering system was in place at this hospital (manual versus electronic) and whether it was ward staff or laboratory staff who were responsible for the collection of blood specimens.

In 2008, Salvagno et al. reported a pre-analytical error frequency of 5.5% in their study conducted at the 750-bed University Hospital of Verona (Italy). The frequencies of analytical and post-analytical errors were not provided. This research considered only data from inpatients and was conducted prospectively over a 24-month period. Data were collected on tests from the ER, the ICU, Surgical Departments, Clinical Departments, and Paediatric Departments. The data gathered from each of these departments were analyzed separately. The study investigated both routine and stat testing requests for first-line coagulation testing. The most common error detected was no sample received in the laboratory after a test request was made. This accounted for 49.3% of errors. Hemolysis (19.5%) and specimen clotting (13.7%) were the second- and third-most common errors respectively. The authors noted that specimen collection at this institution was conducted by clinical department personnel and not laboratory staff. Paediatric departments had the highest frequency of pre-analytical errors (10.1%). The error frequencies across the remaining departments ranged from 4.9% to 6.2%. Interestingly, the authors made
no mention of identification errors, leaving the reader to assume that none occurred while the study was being conducted.

1.6 The Pre-Analytical Phase is Inherently Error-Prone

There are several characteristics of the pre-analytical phase that contribute to the high error rates observed. Errors occurring in the pre-analytical phase can often be attributed to human factors; human error is responsible for as many as 98% of pre-analytical errors.8,9 Many pre-analytical tasks such as test requisition, specimen collection, and specimen labeling are completed manually. The vast majority of the pre-analytical phase is not automated, and pre-analytical procedures frequently lack standardized protocols.6 Furthermore, the greater part of the pre-analytical phase takes place outside of the clinical laboratory (Figure 1) and involves multiple individuals across different departments. Subsequently, it is challenging to monitor pre-analytical processes or implement changes to said processes. This challenge is reflected in studies of pre-analytical errors. Carraro and Plebani16 reported that 87% of detected pre-analytical errors occurred extraneously to the laboratory, highlighting the need to consider all aspects of the laboratory testing process in the investigation and improvement of pre-analytical errors.

1.6.1 Errors in Specimen Collection

Specimen collection is perhaps the most human-intensive process in the pre-analytical phase. Narayanan19 identified specimen collection as one of three pre-analytical variables that affect the TTP and the subsequent laboratory results reported to clinicians. Some of the variability in pre-
analytical error frequencies appears to be associated with errors in specimen collection. As
specimen collection errors account for a higher fraction of pre-analytical errors, the total
frequency of pre-analytical errors reported in a study tends to increase. Wiwanitkit\textsuperscript{8} reported
84.5\% pre-analytical errors, 59.16\% of which were specimen collection errors; Nutting \textit{et al.}\textsuperscript{12}
reported 55\% pre-analytical errors, 33.9\% of which were specimen collection errors; Plebani and
Carraro\textsuperscript{10} reported 46\% pre-analytical errors, 25.3\% of which were specimen collection errors.

Despite the variety of reported pre-analytical errors in any given study, different investigations
tend to identify the same set of errors as occurring the most frequently. These most common
errors are: patient identification errors, insufficient specimen volume, specimens collected in the
wrong type of tube, and poor sample quality (i.e. hemolyzed sample, clotted sample,
contaminated sample).\textsuperscript{7,8,10,16-18,20,21} Test-tube labeling, which at Sunnybrook Health Sciences
Centre (Sunnybrook) is completely under the control of the staff member performing specimen
collection, is frequently identified as an error-prone process-step in the pre-analytical phase.\textsuperscript{22}
All of these errors occur during specimen collection.

1.6.2 Patient Identification Errors in Specimen Collection
Dunn and Moga\textsuperscript{23} reported that 73\% of patient misidentification events occurred in the pre-
analytical phase and that 88\% of pre-analytical events were associated with misidentification of
patients. A College of American Pathologists (CAP) Q-Probes study\textsuperscript{24} comprising of data from
120 institutions (98\% of which were in the United States) found that 55\% of patient
identification errors occurred during primary specimen labeling. This study was conducted
prospectively by each of the institutions involved over an average time period of six weeks.
While the report indicated how many of the hospitals contributing data used barcoded specimen labels in the laboratory, it was unclear how many (if any) of the institutions used an electronic patient identification system to identify their patients. Hospitals using a positive patient identification (PPID) system would likely report a lower number of errors compared to hospitals not using that technology. While the majority of institutions participating had an identification error monitoring system in place for more than one year at the time of study commencement, 12% of institutions had either no system in place or had a system in place for less than one year. It was noted in the paper that the percentage of specimens derived from inpatients ranged from <20% to >80% depending on the institution.24

Patient identification errors can be the result of problems with the ID wristband or inappropriate/absent ID wristband checks made during specimen collection by hospital personnel. At Sunnybrook, the ID wristband is the primary means by which patients are identified. ID wristbands are used to confirm patient identity in the context of surgical procedures, transfusion medicine, medication administration, and clinical laboratory testing. Errors with the ID wristband itself do occur, though relatively rarely. A large CAP Q-probes study of wristband identification errors found ID wristband absence to be the most common error (49.5% of wristband errors), followed by patients wearing multiple different ID wristbands (8.3%) and incomplete data on ID wristbands (7.5%).25 A 2008 study conducted at Sunnybrook found that 0.38% of ID wristbands (3/794) contained partially incorrect information, though no instances of misidentification or absent ID wristbands were found.26 In each case the patient’s birth date was incorrectly listed on the ID wristband. Proctor27 reported that specimen mislabelling was the most prevalent pre-analytical error at Sunnybrook, accounting for 35% of
pre-analytical errors over a 24-month period. The rates of specimen mislabelling and miscollecting are 1000-10,000-fold greater than the risk of viral infection.28

1.6.3 Specimen Integrity Errors

Specimen collection is one of a multitude of processes in the pre-analytical phase where errors can occur. Not surprisingly, specimen handling practices after collection have been shown to affect laboratory testing outcomes. Levels of inflammatory markers as measured in blood specimens were shown in a Danish study to fluctuate depending on how staff had handled the sample in the pre-analytical phase.29 A CAP Q-probes study of chemistry specimen acceptability found that hemolyzed samples were the most common reason for specimen rejection.30 In this study, data were collected prospectively at 453 laboratories (434 and 9 of which were located in the United States and Canada respectively) over a 3-month period or until 300 rejected specimens were observed at a given institution. The specimen rejection rate was found to be 0.35% before analysis in the clinical laboratory.30 In 2008, Proctor27 found that after mislabelling errors, clotted specimens (29%), insufficient quantity (23%), and hemolyzed specimens (6%) were the most common pre-analytical errors detected at Sunnybrook.

In a large-scale study of complete blood count (CBC) specimen acceptability, Jones et al.31 identified clotted specimens as the most common cause for specimen rejection by the laboratory (65% of rejections). The second- and third-most common causes for rejection in this study were insufficient specimen quantity and unacceptable variance (delta check), which accounted for 10.1% and 5.3% of CBC specimen rejections respectively. Jones et al.31 reported that 0.45% of the nearly eight million specimens considered in the study were rejected. This large-scale
investigation was conducted prospectively at 703 institutions, the majority of which (98.3%) were in North America. The adequacy of specimens is of course a critical aspect of laboratory quality control. Both preventative and reactive measures need to be in place to minimize the analysis of inadequate specimens. This helps to decrease the amount of blood taken from a patient, minimize delays in diagnosis and treatment by clinicians, and reduce repetitive laboratory testing.32

1.7 Systems are to Blame for Pre-Analytical Errors

Despite the increased prevalence of pre-analytical errors in aspects of laboratory testing with the highest human involvement, hospital staff must not shoulder unnecessary blame for the occurrence of these errors. The main conclusion from the IOM report “To Err is Human” was that the majority of medical errors are not the fault of individuals or groups.2 The IOM suggests instead that scrutiny be paid to the systems, processes, and conditions in place that cause humans to make errors or that fail to prevent said human errors. Thus, a good health system necessarily must make it harder for staff to make mistakes while simultaneously making it easier for those same staff to complete a task correctly.2 When laboratory systems, rather than laboratory individuals, are held “responsible” for errors, it becomes the responsibility of the overarching healthcare institutions to ensure that the best possible systems are in place to support laboratory personnel and to minimize the risk of error.
1.8 The Effect of Pre-Analytical Errors on Patient Safety

Pre-analytical laboratory errors present unnecessary risks to patient safety. Plebani and Carraro\textsuperscript{10} reported in 1997 that 70\% of pre-analytical errors had no effect on patient care while 23\% of errors resulted in unnecessary procedures. In their 2007 paper, Carraro and Plebani\textsuperscript{16} found that 75.6\% of errors had no effect on patient care while 24.4\% of errors had a negative impact on patient care. Observed negative impacts included the inappropriate admission of a patient to intensive care and two inappropriate transfusion events. Not all errors result in a serious incident like a mistransfusion. Other potentially negative outcomes of a pre-analytical error include incorrect diagnoses by physicians, repeat of specimen collection and testing, and the extension of a patient’s stay in the hospital. Approximately 30\% of errors in the clinical laboratory result in unnecessary repetition of laboratory testing, unnecessary further (and often more invasive) testing, and additional consultations between patients and healthcare teams.\textsuperscript{3} These events lead to decreased patient comfort and increased costs to the healthcare system. Based on anecdotal evidence, a single error in laboratory testing has the potential to result in 15 consultations with physicians and specialists, 77 additional laboratory tests, a CT scan, and inappropriate treatment.\textsuperscript{33}

1.9 The Cost of Pre-Analytical Errors

1.9.1 The Value of a Pre-Analytical Error Cost Model

Despite the substantial volume of literature devoted to identifying, tracking, and reducing pre-analytical errors in clinical laboratories, a literature review found no published studies of the cost incurred by a laboratory when a pre-analytical error occurs. While some studies refer indirectly to the cost of a pre-analytical error in terms of patient comfort or safety, the relationship between
pre-analytical errors and laboratory finances remains unexplored. Plebani\textsuperscript{3} noted that redundant laboratory testing and error correction represent costs to clinical laboratories, but no attempt was made to quantify that cost. As such, a cost model for a pre-analytical error would help to better characterize this common occurrence and would also provide a tool of great value to the scientific and medical communities. Such a cost model would provide healthcare institutions with information necessary to target the pre-analytical errors that consume the most financial and personnel resources and to identify and implement strategies to prevent these errors. Additionally, while pre-analytical errors have been investigated in laboratories around the world, a literature review suggests there is no published study on pre-analytical errors from a Canadian healthcare institution.

1.10 Research Objectives and Hypotheses

The objective of this research was to build a cost model to estimate the cost of a pre-analytical error at Sunnybrook in the context of inpatient, adult, CBC testing. This test was selected as it is one of the most common analyses performed in the laboratory at Sunnybrook. By directing our attention towards the CBC test we were able to better assess the TTP for that particular laboratory analysis, as well as the costs incurred by Sunnybrook when activities within the TTP deviate from standard operating procedures (SOPs). The decision to focus our investigation on inpatients was due to differences in error rates between inpatient and outpatient populations reported in the scientific literature. Bonini \textit{et al.}\textsuperscript{7} reported a 15-fold difference in pre-analytical error rates between inpatients and outpatients: they found the frequency of pre-analytical errors to be 0.60\% for inpatients and 0.039\% for outpatients. Furthermore, as inpatients represent a
significantly higher cost to hospitals than outpatients, decreasing errors in inpatient testing will provide greater benefit to Sunnybrook.

The cost of a pre-analytical error was assessed from two angles. First, the costs of materials and resources consumed during each process in the CBC total testing process were determined for one CBC (the materials/resources-cost). The materials/resources-cost included tangible materials (latex gloves, for example) as well as intangible resources, such as the cost to own and maintain the instruments which perform CBC analyses. Second, the time spent by hospital personnel performing tasks in the CBC testing process (the personnel-time) was determined through direct observation. The personnel-time was calculated for each process involved in CBC testing across all three testing phases. In addition to standard CBC testing phases and processes, such as specimen collection and accessioning, the personnel-time was also determined for activities that are undertaken only when errors occur CBC testing. These supplemental error-related activities include error investigation, error reporting, and the correction of erroneous testing results. By combining personnel-time data with personnel-wage data, the personnel-cost for each process was calculated.

Data on pre-analytical errors in inpatient CBC testing at Sunnybrook were collected along with “demographic” data on CBC tests performed in our clinical laboratory. These data allowed us to determine, among other things, where in the TTP errors were detected. Despite the fact that all errors pertinent to this research originate pre-analytically, they can be detected during any phase in CBC testing (pre-analytical, analytical, or post-analytical) after they occur. Identifying the point of detection is critical if a CBC error is to be assigned an accurate cost. As described in this research, the cost of a pre-analytical error will be comprised of the cost(s) of the testing
process(es) that need to be repeated as a result of the error, as well as any costs associated with error-reporting and correction. The cost of individual errors will vary depending on when the error was identified since different points of error detection may necessitate the repetition of only some components of the TTP. Accordingly, it was important to determine the personnel-costs and materials/resources-costs separately for each process in the total CBC testing process.

We hypothesized that pre-analytical errors in inpatient CBC testing represent a substantial annual cost to Sunnybrook. Furthermore, we expected to find that hospital personnel invest a great deal of time performing tasks related to redundant testing and error reporting activities. The cost model allowed us to identify the most costly errors occurring during CBC testing. This in turn allowed for the development of strategies to reduce these errors and reallocate rescued resources to other aspects of the hospital or laboratory budget such as quality control, improvement to laboratory operations, or patient safety projects.
Chapter 2

2 Methods

2.1 Background

Research was conducted at Sunnybrook Health Sciences Centre in Toronto, Ontario, Canada between April 2010 and June 2012. Sunnybrook is a large academic centre which sees over one million patient visits per year. Data were collected, compiled, and analyzed by the author. Data were collected between 6:00 am and 5:00 pm Monday-Friday. Data analyses were performed using Excel (Microsoft, 2007, Redmond, Washington, USA) and SPSS (v13.0, 2004, Chicago, IL, USA).

2.2 Specimen Collection

The phlebotomy process was directly observed to determine the steps involved in obtaining an inpatient specimen for CBC testing at Sunnybrook. An experienced phlebotomist was shadowed as she completed numerous specimen collections, and from these observations a process map of the specimen collection process was created. This process map reflects the actual process as it was performed in practice. An SOP was obtained from the department of phlebotomy in order to make comparisons between the suggested process and the process actually performed by phlebotomists. The process map generated from observations was used to create a timing sheet, which allowed for both the entire specimen collection process and individual steps within that process to be timed.
Phlebotomists were shadowed as they collected specimens during the morning phlebotomy rounds beginning at 6:00 am. To maintain phlebotomist anonymity, each phlebotomist was assigned a numeric code to be recorded on the timing sheets in place of their name.

Phlebotomists were timed as they completed each step in the collection process. Times were recorded to the nearest 1/100 second. Eleven phlebotomists were shadowed as they performed specimen collection duties. Each phlebotomist was timed on a minimum of two different days. Each phlebotomist was also timed collecting specimens in two different hospital wards to minimize biases in collection time resulting from patient physiology, anatomy, or familiarity of the phlebotomist with a given patient.

The average time required to collect one CBC specimen was determined for each phlebotomist observed. When phlebotomists collected more than one specimen from a patient in a single venipuncture event, the times required to complete tasks performed for each specimen (tube labeling, specimen draw) were added and then divided by the total number of tubes collected from the patient. This allowed us to assess a time to collect a single specimen. A total mean time for specimen collection was determined by averaging the mean collect time determined for each individual phlebotomist. The average wage for a phlebotomist at Sunnybrook was obtained from management.

All materials consumed during the CBC specimen collection process were determined from direct observation and catalogued. The cost per unit for these materials was obtained from
Sunnybrook’s Department of Materials Management. A materials cost was calculated for the collection of one inpatient CBC specimen.

2.3 Specimen Transportation

Data were obtained from electronic hospital records on all CBC tests carried out between September 2009 and December 2011 inclusive. An algorithm was applied to the data to identify any tests reported in duplicate in the hospital records, and all duplicate test records were discarded. Any information that could identify the ordering physician or the patient, including patient hospital file numbers, test accession numbers, and physician names, were discarded. The CBC test data included the time of specimen collection at the patient’s bedside and the time of specimen accessioning in the laboratory. These times were used to assess specimen transit time from the hospital ward to the clinical laboratory. All transit times were determined to the nearest minute. The aforementioned analyses were performed for all data over the entire time period for which data were available, as well as for each month within that range.

2.4 Specimen Accessioning

Laboratory technicians in the clinical laboratory at Sunnybrook were shadowed as they accessioned specimens arriving at the laboratory for testing. Observations were conducted for each of the three methods of specimen accessioning used in our laboratory: (1) Collection List Verification – Interface by Specimen (CVIS), (2) Order Entry Review (OER), and (3) Interface Requisition Entry (REI). From these direct observations, a process map was created for each order entry method. The completeness of these process maps was verified by comparison with
SOPs obtained from the clinical laboratory. Timing sheets were created from these process maps. Laboratory technicians were observed and timed as they conducted specimen accessioning of inpatient CBC samples. To preserve technician anonymity, each laboratory technician observed was assigned a numeric code to be recorded on all timing sheets in place of their name. Each technician was observed and timed on a minimum of two different days. All times were recorded to the nearest 1/100 second. The average wage for a laboratory technician at Sunnybrook was obtained from management.

2.5 Specimen Analysis

The specimen analysis process was directly observed, and SOPs were obtained from the clinical laboratory to verify the accuracy of process observations. A process map detailing the process-steps performed by laboratory technologists during CBC specimen analysis was created. Laboratory testing costs for inpatient CBCs were obtained from the core laboratory administration. This information includes the cost per reportable (CPR), the purchase/rental costs for instruments employed in CBC testing, and maintenance/service costs for each analyzer. These analytical instrument costs were assessed for every analyzer used in CBC testing at Sunnybrook during the years 2008 to 2011. Data detailing annual CBC testing volume for each analyzer were obtained and used, in concert with the instrument costs, to assess the cost to perform one CBC analysis on each analyzer used in CBC testing.
The time required for a laboratory technologist to perform one CBC analysis was determined by analyzing data obtained on CBC testing volume from the month of November, 2011. The month of November 2011 was selected as it was the second-to-most-recent month for which these data were available. December 2011 was not used in this calculation to avoid any deviations from normal monthly testing volume that may have occurred as a result of decreased patient flow during the holiday season. The average hourly salary of a laboratory technician at Sunnybrook was obtained from management to determine the personnel-cost for specimen analysis.

2.6 Error Investigation and Reporting

Laboratory personnel were interviewed about activities involved in the investigation and reporting of pre-analytical laboratory errors in CBC testing. The processes for both error investigation and error reporting were described and the error-reporting process was directly observed so that a map of the process could be created. Laboratory personnel also provided information on the time investment required for both of these activities.

2.7 Pre-Analytical Error Data

Sunnybrook utilizes an electronic system to report and record all errors detected in the hospital (the E-safety reporting system). A list of reported pre-analytical errors was obtained from the E-safety reporting system for the years 2008 to 2011 inclusive. These data indicate the total number of reported pre-analytical errors for inpatient CBC testing as well as information on frequency of specific causes of errors (i.e. clotted specimen, labeling error, et cetera). These
errors were organized by the error codes assigned to them during error-reporting. The error codes can be used to determine where in the TTP the error was detected.
Chapter 3

3 Results

3.1 The Pre-Analytical Phase

3.1.1 Specimen Collection

The inpatient phlebotomy process was directly observed and a process map was created detailing each of the specific tasks performed by phlebotomists when collecting specimens for CBC testing (Figure 2). The specimen collection process is comprised of 29 process-steps that are performed in a specific order. While the process-steps performed remained consistent regardless of which phlebotomist performed the collection, minor variances in the order in which some of the tasks were performed were noted. These variances were most commonly seen in the labeling of specimens and cleanup of phlebotomy supplies after the specimen collection had been completed. It should be noted that while the order of tasks performed varied from one phlebotomist to another, each individual phlebotomist observed nearly always performed the tasks in the same order every time a specimen was collected.

3.1.1.1 Personnel-Time and Personnel-Cost of Specimen Collection

The time required for a phlebotomist to collect one inpatient blood specimen was determined to be 3.6 ± 0.6 minutes (mean ± SE, n = 106). Average specimen collection times for the 11 individual phlebotomists observed varied from 2.9 minutes to 4.8 minutes (Figure 3). The average wage for a phlebotomist at Sunnybrook is $21.42 per hour (E. Proctor, Personal Communication). Based on this salary, the cost of personnel-time for inpatient CBC specimen collection is $1.29 per CBC specimen collected.
Figure 2. Process map detailing the process-steps involved in inpatient specimen collection for CBC testing at Sunnybrook.
During observation of the inpatient phlebotomy specimen collection process, a list of all materials consumed was created. The consumed materials were: latex gloves (2), rubber tourniquet, alcohol swab, needle, vacutainer holder, lavender-top vacutainer, gauze pad (4), and micropore tape. The per-unit cost for each of these items was obtained from Sunnybrook’s materials management department. The total materials-cost for specimen collection was determined to be $1.29 per CBC specimen collected (Table A).
Table A. List of materials consumed during the collection of one inpatient CBC specimen at Sunnybrook.

<table>
<thead>
<tr>
<th>ITEM</th>
<th>COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacutainer - Lavender</td>
<td>$0.10</td>
</tr>
<tr>
<td>Vacutainer Holder</td>
<td>$0.11</td>
</tr>
<tr>
<td>Needle</td>
<td>$0.61</td>
</tr>
<tr>
<td>3M Micropore Tape</td>
<td>$0.01</td>
</tr>
<tr>
<td>Alcohol Swab</td>
<td>$0.01</td>
</tr>
<tr>
<td>Latex Glove (x2)</td>
<td>$0.22</td>
</tr>
<tr>
<td>Tourniquet</td>
<td>$0.19</td>
</tr>
<tr>
<td>Gauze Pad (x4)</td>
<td>$0.04</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1.29</strong></td>
</tr>
</tbody>
</table>

Some materials were not included in the cost analysis of phlebotomy supplies, as they comprised a cost too negligible to warrant reporting (fractions of a cent). These items included pens (each one used for several days by phlebotomists), tube labels, printer ink cartridges (each cartridge printing a large number of labels for both inpatient and outpatient specimens), paper clips, and the sheets of paper on which daily specimen collection lists were printed.

3.1.2 Specimen Transportation

Between September 2009 and December 2011, 678,962 CBC tests were performed at Sunnybrook. Each month, an average of 24,249 CBC tests were performed, and each month an average of 1722 tests had no recorded specimen collection time. Monthly variation in both of
these numbers was minimal, with no clear trends of an increase or decrease in either the number of CBCs performed or the number of tests for which no specimen collection time was recorded. Over the entire time period, 7.1% of tests had no recorded specimen collection time. Without a specimen collection time, specimen transit time could not be determined. Considering the 92.9% of tests for which transit time was calculable, it was determined that the mean time from specimen collection to specimen accessioning in the laboratory was 68.5 minutes. The mean specimen transit time varied from month to month, with a trend of decreasing transit time from September 2009 to December 2011 (Figure 4).

Figure 4. Mean time difference between specimen collection and specimen accessioning for CBC testing from September 2009 to December 2011. The mean time from specimen collection in the ward to accessioning in the clinical laboratory shows a decreasing trend over the time period during which the tests were performed. The break in the trend line corresponds with the start of a continuous quality improvement program focused on decreasing specimen transit time (See section 4.1.2 of text).

September 2009 to December 2011 (Figure 4). Personnel-costs and materials-costs were not estimated for the specimen transportation process. During weekday working hours, specimens
collected in most hospital wards are placed in specimen collection bins. The specimens are then picked up and transported to the clinical laboratory by porters. Porters pick up multiple specimens from multiple wards in the hospital in one “run.” The personnel-cost for one CBC specimen would vary from run to run, and the cost was assumed to be negligible given the high volume of specimens being transported by each porter at a given time. A subset of specimens collected at Sunnybrook is transported via pneumatic tube system (PTS) to the clinical laboratory. Materials costs for the transport processes, both manual courier and PTS, were also deemed negligible. Latex gloves, pens, and pickup baskets would all be used for dozens (or in the case of baskets thousands) of specimens and the cost per specimen would be minute (fractions of one cent).

3.1.3 Specimen Accessioning
Upon arrival at the laboratory, each specimen is accessioned by a laboratory technician. There are three methods by which a specimen can be entered into the laboratory’s computer system: CVIS, OER, and REI. Laboratory technicians were observed accessioning specimens by each of the three order entry methods. The CVIS, OER, and REI accessioning processes have 10, 10, and 11 process-steps respectively (Figure 5). The majority of CBC specimens that arrive in our clinical laboratory are accessioned by CVIS, where specimen tubes arrive at the laboratory already labeled. This is the case for specimens from inpatients, outpatients, and outside clients. At Sunnybrook, 76% of inpatient specimens are CVIS specimens (Figure 6).
Figure 5. Process maps detailing the process-steps for each of the three different methods of specimen accessioning used in the clinical laboratory at Sunnybrook. A. Process map for specimen accessioning by CVIS. B. Process map for specimen accessioning by OER. C. Process map for specimen accessioning by REI.
3.1.3.1 **Personnel-Time and Personnel-Cost of Accessioning**

Ten different laboratory technicians were shadowed and timed as they accessioned CBC specimens. The mean time required for a CBC specimen to be accessioned was found to be 6.35 ± 2.37 seconds (mean ± SD, n=372) using CVIS (Figure 7). The average salary for a laboratory technician at Sunnybrook is $25.69/hour (E. Proctor, Personal Communication). Based on the average time required to accession a specimen by CVIS, the personnel-cost for the specimen accessioning process was determined to be $0.04/CBC specimen accessioned.

3.1.3.2 **Materials/Resources-Cost of Specimen Accessioning**

A materials-cost was not assessed for the specimen accessioning process. The only consumed materials in this process were latex/nitrile gloves, test tube labels, pens, and printer cartridges.
Given the large number of specimens accessioned and the low cost of these items, the per-specimen costs were deemed negligible.

![Mean time required for each laboratory technician observed to accession one CBC specimen by CVIS. Error bars show ± 2x standard error of the mean.]

**Figure 7.**

### 3.2 The Analytical Phase

The analytical phase is overseen by laboratory technologists. The analytical process consists of numerous process-steps. The actual length of the analytical process varies from specimen to specimen (Figure 8) and is affected by factors such as specimen integrity and the readiness of the analyzer for testing. This process can range from 9-14 process-steps in length. If additional investigations are required, the process becomes even longer. When CBC testing results are
Figure 8. Process map detailing the process-steps involved in the analysis of a CBC specimen at Sunnybrook. If the CBC analysis reveals a critical result, the laboratory technologist continues to the critical results process (see Figure 9).
Figure 9. Process map detailing the process-steps involved in the analysis of a CBC specimen with a critical result at Sunnybrook. If the result at the end of specimen analysis (see Figure 8) is critical, this process is initiated by a laboratory technologist in the clinical laboratory.
critical, an additional sequence of three to seven process-steps must be completed by the laboratory technologist completing analysis (Figure 9).

3.2.1 **Personnel-Time and Personnel-Cost of the Analytical Phase**

Using data compiled on all CBC tests performed in the month of November 2011, it was determined that between 8:00 am and 4:00 pm, Monday to Friday, 14,546 CBC tests were performed. This translated to 661 CBC tests per day, or 82 CBC tests per hour. At any given point between 8:00 am and 4:00 pm during weekdays there are two laboratory technologists at the CBC workstation, and thus it was determined that each technologist performs an average of 41 CBC tests per hour. The personnel-time for laboratory technologists performing CBC analysis was determined to be 1.46 minutes per CBC test. The average salary for a laboratory technologist at Sunnybrook is $37.31/hour (E. Proctor, Personal Communication). The personnel-cost for CBC analysis at Sunnybrook is $0.91 per CBC test.

3.2.2 **Materials/Resources-Cost of the Analytical Phase**

Inpatient CBC testing was performed by three analyzers in 2011: Cell Dyne Sapphire 1 (CDSAPH1), Cell Dyne Sapphire 2 (CDSAPH2), and Cell Dyne Sapphire 3 (CDSAPH3). For each analyzer, the following data were obtained from management: Annual cost of rental/ownership, annual cost of analyzer service agreement, and the number of CBC tests performed annually by the analyzer (E. Proctor, Personal Communication). This data is summarized in Table B. In the case where analyzers were purchased by Sunnybrook, the capital expenditure was amortized over 7 years, and the annual “cost” of that analyzer was determined
based on that amortization. The seven-year amortization period is standard for CBC analyzers at Sunnybrook.

Table B. Summary of data collected for each analyzer performing CBC testing in the clinical laboratory at Sunnybrook for the year 2011.

<table>
<thead>
<tr>
<th></th>
<th>CDSAPH1</th>
<th>CDSAPH2</th>
<th>CDSAPH3</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERVICE</td>
<td>$16,000.00</td>
<td>$16,000.00</td>
<td>$16,000.00</td>
</tr>
<tr>
<td>OWNERSHIP/RENTAL</td>
<td>$19,285.71</td>
<td>$10,000.00</td>
<td>$21,076.00</td>
</tr>
<tr>
<td>ANNUAL REPORTABLES (CBCs)</td>
<td>59810</td>
<td>86695</td>
<td>113186</td>
</tr>
</tbody>
</table>

Annual service and ownership/rental costs were added together, and then divided by the number of tests performed in a given year to determine the analyzer cost per CBC performed. The CPR is a per-test cost that includes all reagents, consumables, and commercial controls required to perform a CBC analysis. The CPR for CBC testing at Sunnybrook is $0.35 per CBC. The CPR was added to the analyzer cost per CBC to determine the total materials/resources-cost of one CBC analysis on each of the CBC analyzers in our clinical laboratory (Table C).

Table C. Summary of materials/resources-costs per CBC for each analyzer performing CBC analyses in the clinical laboratory at Sunnybrook in 2011.

<table>
<thead>
<tr>
<th></th>
<th>CDSAPH1</th>
<th>CDSAPH2</th>
<th>CDSAPH3</th>
</tr>
</thead>
<tbody>
<tr>
<td>OWNERSHIP/RENTAL AND SERVICE COSTS PER CBC</td>
<td>$0.59</td>
<td>$0.30</td>
<td>$0.33</td>
</tr>
<tr>
<td>COST PER REPORTABLE</td>
<td>$0.35</td>
<td>$0.35</td>
<td>$0.35</td>
</tr>
<tr>
<td>TOTAL COST PER CBC</td>
<td>$0.94</td>
<td>$0.65</td>
<td>$0.68</td>
</tr>
</tbody>
</table>
Each analyzer performs a different number of CBC analyses in a given year. To account for this, the fraction of annual CBC tests performed on each analyzer was calculated. Using weighted averages (% of CBC tests run on a given analyzer multiplied by the cost of one CBC test on that analyzer) we determined the average cost to run one CBC test at Sunnybrook in 2011 was $0.72.

3.3 Error Investigation and Reporting

Error investigation and error reporting are performed by laboratory technologists. The error investigation process is unique to the error detected, and accordingly a process map was not developed. Error reporting consists of filling out an electronic incident report in Sunnybrook’s E-safety reporting system. A CBC error report can be completed in one of two ways: “quick” report or full report. Both processes consist of a total of 25 process-steps (Figure 10). Upon completion of an error investigation and report, the report is delivered to the laboratory supervisor who must complete any follow up investigations required and approve the final report.

3.3.1 Personnel-Time and Personnel-Cost of Error-Related Activities

Error investigation requires 10-60 minutes of personnel-time, with an estimated average personnel-time of 30 minutes per CBC error (J. King, Personal Communication). At an average salary of $37.31 per hour, the personnel-cost for error investigation was determined to be $18.66 per CBC error investigation. Error reporting, which entails filling out an online report in the E-Safety reporting system, requires an estimated average personnel-time of 5 minutes per CBC error report (J. King, Personal Communication). The personnel-cost for error reporting was
Figure 10. Process map detailing the process-steps involved in the reporting of a pre-analytical CBC error at Sunnybrook. The first four process steps are always consistent, but the following 21 process-steps vary depending on whether the report is a “quick” report or a full report. The process-steps for filling out a quick report are shown in light blue (top) and the process-steps for filling out a full report are shown in dark blue (bottom).
determined to be $3.11 per CBC error report. Final error investigation and report approval by a laboratory supervisor takes 5-90 minutes to complete, depending on the complexity of the error and the depth of the investigation required. This requires an estimated average time of 15 minutes per error investigation and report approval (J. King, Personal Communication). At an average salary of $46.76 per hour (E. Proctor, Personal Communication) the cost of personnel-time for this final approval stage was determined to be $11.69 per CBC error.

3.4 Pre-Analytical Errors at Sunnybrook

Data were obtained on the frequency and type of laboratory errors that occur in adult, inpatient CBC testing at Sunnybrook. Error data from the years 2008 to 2011 were taken from our hospital’s E-safety reporting system and analyzed. The total number of pre-analytical errors increased each year from 2008 to 2011 (Figure 11). Over the same time period, annual inpatient

![Figure 11](image-url)  
**Figure 11.** Annual frequency of pre-analytical errors reported during adult, inpatient CBC testing at Sunnybrook for the years 2008 to 2011.
CBC testing volume rose from 124,805 to 139,163. This 12% increase in inpatient testing volume was paralleled by a rise in outpatient testing volume from 2008 to 2011. Total annual CBC testing volume in Sunnybrook’s clinical laboratory increased from 222,440 to 259,697 – a 17% increase. From 2008 to 2011, the percentage of CBC tests performed on inpatients versus outpatients has remained essentially unchanged (Figure 12). Despite increasing annual testing volume, the annual pre-analytical error frequency for inpatient CBC testing also increased from 0.57% in 2008 to 0.86% in 2011 (Figure 13). The frequency of pre-analytical errors in inpatient CBC testing was significantly higher in 2011 (1198 of 139,163 tests) than it was in 2008 (712 of 124,805 tests, $X^2 = 77.23$, $p < 0.0001$).
In addition to the number of pre-analytical errors reported, the types of pre-analytical errors that occurred in inpatient CBC testing were compared for each year (Figure 14). For most error types, annual frequency changed little from year to year. The annual number of clotted specimens (CLT, RICLT), duplicate test requests (DUP), correlation failures with previous result (MCVC), insufficient specimen quantities (NSQ), and order entry errors (OEE) increased from 2008 to 2011. Labeling errors (LBLM, LBLU, and RISM) remained remarkably steady in frequency from 2008 to 2011. Table D defines the error codes for each type of pre-analytical error reported.

Figure 13. Comparison of annual inpatient test volume with annual pre-analytical error frequency for inpatient CBC testing at Sunnybrook for the years 2008-2011.
In determining the cost of a pre-analytical error in CBC testing, it was necessary to assess where in the TTP reported errors were detected. Our cost model takes into account the cost of error investigation and error reporting for each CBC error. In addition to these costs, the total cost for each CBC process that must be repeated is considered in the error cost. For example, the cost of an error detected during specimen accessioning would be the sum total of the specimen collection process cost, the specimen accessioning process cost, and error investigation and reporting costs. The cost of an error detected after the completion of specimen analysis would equal the sum total of specimen collection, accessioning, and analysis process costs as well as the cost of error investigation and reporting.

### Figure 14
Annual frequency of different types of pre-analytical errors reported during adult, inpatient CBC testing at Sunnybrook for the years 2008 to 2011. Errors are organized by the error codes designated to them during error-reporting. These error codes are defined in Table D.

### 3.5 Classification of Pre-Analytical Errors

In determining the cost of a pre-analytical error in CBC testing, it was necessary to assess where in the TTP reported errors were detected. Our cost model takes into account the cost of error investigation and error reporting for each CBC error. In addition to these costs, the total cost for each CBC process that must be repeated is considered in the error cost. For example, the cost of an error detected during specimen accessioning would be the sum total of the specimen collection process cost, the specimen accessioning process cost, and error investigation and reporting costs. The cost of an error detected after the completion of specimen analysis would equal the sum total of specimen collection, accessioning, and analysis process costs as well as the cost of error investigation and reporting.
Table D. Definitions of the various error codes assigned to pre-analytical CBC errors when those errors are reported in the E-safety reporting system at Sunnybrook Health Sciences Centre.

<table>
<thead>
<tr>
<th>ERROR CODE</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>BROK</td>
<td>Broken/Spilled in Transit</td>
</tr>
<tr>
<td>CANN</td>
<td>Cancelled</td>
</tr>
<tr>
<td>CLT</td>
<td>Specimen Clotted</td>
</tr>
<tr>
<td>CONT</td>
<td>Specimen is contaminated and unsuitable for testing</td>
</tr>
<tr>
<td>DEL</td>
<td>Request cancelled</td>
</tr>
<tr>
<td>DUP</td>
<td>Specimen not processed. Specimen collected in the last 24 hrs has been processed</td>
</tr>
<tr>
<td>DUPL</td>
<td>Duplicate request</td>
</tr>
<tr>
<td>HEM</td>
<td>Specimen is hemolyzed. Test not done</td>
</tr>
<tr>
<td>IMSP</td>
<td>Wrong tube/specimen type submitted</td>
</tr>
<tr>
<td>LBLM</td>
<td>Specimen unsatisfactory: mislabelled</td>
</tr>
<tr>
<td>LBLU</td>
<td>Specimen unsatisfactory: unlabelled</td>
</tr>
<tr>
<td>LEKR</td>
<td>Specimen leaking. Please repeat</td>
</tr>
<tr>
<td>MCVC</td>
<td>Correlation failure with previous result. Request redraw CBC</td>
</tr>
<tr>
<td>MOEE</td>
<td>Order entry error. The appropriate test has been ordered</td>
</tr>
<tr>
<td>NDSLE</td>
<td>Test not done on this specimen. Lab error</td>
</tr>
<tr>
<td>NSQ</td>
<td>Not sufficient quantity</td>
</tr>
<tr>
<td>NSR</td>
<td>No specimen received</td>
</tr>
<tr>
<td>OEE</td>
<td>Order entry error</td>
</tr>
<tr>
<td>OLD</td>
<td>Stability limit exceeded when received</td>
</tr>
<tr>
<td>RICLT</td>
<td>Results invalid: specimen clotted</td>
</tr>
<tr>
<td>RINSR</td>
<td>Results inconclusive. New specimen requested</td>
</tr>
<tr>
<td>RISM</td>
<td>Results invalid: specimen mislabelled</td>
</tr>
<tr>
<td>SIRR</td>
<td>Query specimen integrity/request redraw</td>
</tr>
</tbody>
</table>
A classification system for pre-analytical errors was developed. Errors were assigned a Class on the basis of the processes that were repeated in order to correct that error and generate an accurate, reportable test result. This classification system, and the cost of one CBC error for each error Class, is outlined in Table E. The cost of one error in each Class is comprised of the costs for each repeated process, considering the cost of materials and resources and the cost of personnel-time. In addition to the cost of repeated testing processes, the costs of error investigation, error reporting, and supervisor approval of error reports are included in the total cost of an error in each of the four Classes. Using the summarized error data from 2008 to 2011, we designated an error Class to each reported pre-analytical error in inpatient CBC testing (Table F). The frequencies of pre-analytical errors of each Class are shown in Table G. By combining the frequency of errors in each Class with the known cost of errors of each Class, the annual cost of pre-analytical errors in inpatient CBC testing was calculated (Table H). This cost has increased each year from 2008 to 2011.

Table E. For each CBC pre-analytical error Class, the testing processes repeated and the cost of one error in that Class are listed.

<table>
<thead>
<tr>
<th>ERROR CLASS</th>
<th>CBC TESTING PROCESSES REPEATED</th>
<th>COST PER ERROR</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No testing processes repeated</td>
<td>$33.45</td>
</tr>
<tr>
<td>II</td>
<td>Specimen Collection, Specimen Accessioning</td>
<td>$36.07</td>
</tr>
<tr>
<td>III</td>
<td>Specimen Collection, Specimen Accessioning, Specimen Analysis in 50% of errors</td>
<td>$36.89</td>
</tr>
<tr>
<td>IV</td>
<td>Specimen Collection, Specimen Accessioning, Specimen Analysis</td>
<td>$37.70</td>
</tr>
</tbody>
</table>

For each CBC pre-analytical error Class, the testing processes repeated and the cost of one error in that Class are listed.
Table F. Error Class designations for each error code. The annual number of pre-analytical errors in inpatient CBC testing at Sunnybrook are listed for each type of error. Error codes are defined in Table D.

<table>
<thead>
<tr>
<th>CLASS</th>
<th>ERROR CODE</th>
<th>ANNUAL FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2008</td>
</tr>
<tr>
<td>Class I</td>
<td>NSR</td>
<td>60</td>
</tr>
<tr>
<td>Class II</td>
<td>BROK</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>CLT</td>
<td>184</td>
</tr>
<tr>
<td></td>
<td>DUP</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>DUPL</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>IMSP</td>
<td>43</td>
</tr>
<tr>
<td></td>
<td>LEKR</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>NDSLE</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>NSQ</td>
<td>82</td>
</tr>
<tr>
<td></td>
<td>OEE</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>OLD</td>
<td>13</td>
</tr>
<tr>
<td>Class III</td>
<td>CANC</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>CANN</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>DEL</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>LBLM</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>LBLU</td>
<td>29</td>
</tr>
<tr>
<td>Class IV</td>
<td>CONT</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>HEM</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>MCVC</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>MOEE</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>RICLT</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>RINSR</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>RISM</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>SIRR</td>
<td>21</td>
</tr>
</tbody>
</table>
Table G. Annual frequencies of pre-analytical errors in inpatient CBC testing in each Class at Sunnybrook for the years 2008-2011.

<table>
<thead>
<tr>
<th>YEAR</th>
<th>CLASS I</th>
<th>CLASS II</th>
<th>CLASS III</th>
<th>CLASS IV</th>
<th>ANNUAL TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>60</td>
<td>412</td>
<td>119</td>
<td>121</td>
<td>712</td>
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<tr>
<td>2009</td>
<td>68</td>
<td>651</td>
<td>118</td>
<td>157</td>
<td>994</td>
</tr>
<tr>
<td>2010</td>
<td>66</td>
<td>658</td>
<td>125</td>
<td>185</td>
<td>1034</td>
</tr>
<tr>
<td>2011</td>
<td>54</td>
<td>847</td>
<td>114</td>
<td>183</td>
<td>1198</td>
</tr>
</tbody>
</table>

Table H. Annual costs of each Class of pre-analytical error in inpatient CBC testing at Sunnybrook for the years 2008-2011.

<table>
<thead>
<tr>
<th>YEAR</th>
<th>CLASS I</th>
<th>CLASS II</th>
<th>CLASS III</th>
<th>CLASS IV</th>
<th>ANNUAL TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>$2,007.00</td>
<td>$14,860.84</td>
<td>$4,389.32</td>
<td>$4,561.70</td>
<td>$25,818.86</td>
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<tr>
<td>2009</td>
<td>$2,274.60</td>
<td>$23,481.57</td>
<td>$4,352.43</td>
<td>$5,918.90</td>
<td>$36,027.50</td>
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<tr>
<td>2010</td>
<td>$2,207.70</td>
<td>$23,734.06</td>
<td>$4,610.63</td>
<td>$6,974.50</td>
<td>$37,526.89</td>
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<tr>
<td>2011</td>
<td>$1,806.30</td>
<td>$30,551.29</td>
<td>$4,204.89</td>
<td>$6,899.10</td>
<td>$43,461.58</td>
</tr>
</tbody>
</table>
Chapter 4

4 Discussion

4.1 The Pre-Analytical Phase

4.1.1 Specimen Collection

The specimen collection phase is a linear process comprised of 29 process-steps. It is completed entirely by phlebotomists, with the only automated portion being the initial batch printing of labels that occurs in the phlebotomy office prior to phlebotomist travel to hospital wards. Each specimen collected requires an average personnel-time investment of just under four minutes per CBC specimen at a cost of $1.29/specimen collected. When personnel-time is considered in terms of annual error frequencies, the magnitude of productivity lost due to the repetition of erroneous CBC testing becomes apparent. Of 1198 inpatient pre-analytical CBC testing errors in 2011, 1144 necessitated the repeat of specimen collection. This translates to a waste of 68.6 phlebotomist hours per year.

At Sunnybrook the majority of inpatient blood specimens are collected by trained phlebotomists. In some hospital wards nursing staff collect blood for laboratory testing. Specimens are drawn by nursing staff in the critical care unit, the emergency department, and the cardiovascular intensive care unit. Outpatient specimens are collected by phlebotomists at Sunnybrook.

Qualitative observations of the process reveal that while all phlebotomists perform the same process-steps during specimen collection, the order in which they are performed sometimes
varies between phlebotomists. This deviation from the outlined procedure always occurs during the labeling of specimens once venipuncture is completed. Some phlebotomists label tubes immediately upon terminating venipuncture at the patient’s bedside. Others perform labeling tasks outside of the patient’s room at the phlebotomy cart in the hospital ward corridor. Unless the specimen being collected is the last specimen collected from the ward, labels from other patients are present and sometimes loose on the phlebotomy cart. While the majority of labels from uncollected specimens remain attached to one another in a long strip, there are instances where individual labels are left on the cart. Loose labels usually result from the temporary abandonment of phlebotomy on a specific patient by a phlebotomist. This occurs if the patient is using the restroom, being administered medication by a nurse, or being seen by physicians upon phlebotomist arrival at the bedside. Given the superficially identical appearance of all specimen labels, this poses an inherent risk to patient safety and creates the opportunity for a labeling error to occur. Labeling was also observed to take place during phlebotomist transit from the bedside to the phlebotomy cart. In these cases it is often interrupted by other process-steps such as the disposal of phlebotomy supplies and hand sanitization. Phlebotomists who label specimens in transit likely do so to save time but consequently perform this important specimen identification task with less than full attention.

The materials-cost of an inpatient specimen collection is $1.29. The supplies required for specimen collection are standard and little variation in supplies consumed was observed to occur. The materials-cost would increase if extra units of any supply were required. The most common causes of extra supply consumption were glove tears, difficulty accessing a suitable vein, and faulty specimen collection tubes (e.g. loss of vacuum).
In a 1995 CAP Q-Probes study, Jones et al.\textsuperscript{31} investigated causes of specimen rejection and who collected specimens that were subsequently rejected in the laboratory. While laboratory personnel collected >75\% of all specimens, they collected only half of the total rejected specimens.\textsuperscript{31} Non-laboratory, non-phlebotomy personnel (nurses, physicians, residents, medical students) collected roughly 10\% of all specimens but collected >25\% of rejected specimens. Jones et al.\textsuperscript{31} recommended that specimen collection duties become the sole responsibility of a dedicated phlebotomy team, unless the non-laboratory personnel responsible for the rejected specimens could be identified. If identification was possible, the authors suggested that education be directed to these individuals in the hopes of decreasing rejection rates. Certain causes for specimen rejection were noticeably more prevalent in non-laboratory, non-phlebotomy personnel as compared to laboratory phlebotomy personnel. These included patient identification errors (laboratory phlebotomy personnel frequency: 3\%, non-laboratory, non-phlebotomy personnel: 7.3\%) and specimens contaminated by intravenous solution (laboratory phlebotomy personnel: 0.8\%, non-laboratory, non-phlebotomy personnel 3.4\%). The study found that teaching institutions had a higher rate of rejected specimens, but that bed-size and personnel variables played a more important role in the rejection of CBC specimens.\textsuperscript{31} Lippi et al.\textsuperscript{21} reported that 95\% of pre-analytical errors originate in patient care activities performed by non-laboratory personnel.
4.1.2 Specimen Transportation

Specimen transit times at Sunnybrook showed a decreasing trend from September 2009 to December 2011 (see Figure 4). The decreased specimen transit time is thought to be due to continuous quality improvements in specimen transportation. In March of 2010, the portering department at Sunnybrook participated in a quality improvement (QI) program called Kaizen, aimed at decreasing specimen transit times by improving process efficiency. The decrease in monthly average specimen transit time observed from March to June 2010 is likely attributable to the commencement of this program and the resulting changes implemented. It should be noted that the data used to calculate specimen transit times from the bedside to the laboratory bench included times from transport by both manual courier and pneumatic tube. Specimens delivered to the laboratory via the PTS would have a substantially lower transit time than the average specimen making its way through the hospital. For a CBC specimen at Sunnybrook, the average time elapsed between specimen collection at the bedside and specimen accessioning in the laboratory is 68.5 minutes. This time is not exact; during observations of specimen collection it was noted that some phlebotomists estimate the collection time to the nearest five-minute time – a specimen collected at 7:32 am may have a recorded specimen collection time of 7:30 am. It was found that 7.1% of specimens collected between September 2009 and December 2011 had no specimen collection time recorded on the specimen label.

4.1.2.1 Pre-Analytical Errors in Specimen Transportation

Pre-analytical errors in the specimen transportation process are infrequent at Sunnybrook – less than 1/250,000 inpatient CBC tests. Between 2008 and 2011, a total of four specimens were broken/damaged in transit (three specimens in 2009, one specimen in 2011). There is only one
error code (BROK) referring exclusively to errors in specimen transportation (Table D), though errors classified under other codes such as RINSR, SIRR, or OLD could also be due to conditions specimens are subjected to during transportation. The majority of specimens at Sunnybrook are transported by manual courier from the point of collection to the clinical laboratory. Sunnybrook utilizes a PTS for the transportation of specimens from some hospital areas to the clinical laboratory. Specimens collected in the Odette Cancer Centre, the operating room, the critical care unit, the cardiovascular intensive care unit, the neonatal intensive care unit (NICU), the burn unit, the maternal newborn unit, the same day surgery unit, the Schulich Heart Centre, and the special collection centre travel via pneumatic tube to the laboratory for analysis.

During transport through a PTS, specimens experience rapid acceleration and deceleration during “takeoff” and “landing” in addition to radial gravitational forces while navigating sharp corners along the tube system’s course. While the effects of intense physical forces on biological specimens are largely unknown, studies have shown that measurable changes to blood cell structure, blood analytes, and blood gases can occur as the result of pneumatic tube transportation.

In 2011, Peter et al. examined 50-paired arterial blood gas (ABG) specimens after one specimen from each pair was transported to the laboratory via pneumatic tube and the other by manual courier. They found clinically significant differences for $P_{a}O_{2}$ (arterial blood oxygen tension) measurements between specimens transported by the two different methods. After transport by pneumatic tube, analysis of specimens with lower $P_{a}O_{2}$ values (<160 mm Hg)
resulted in an overestimation of $P_aO_2$, while analysis of specimens with higher $P_aO_2$ values (>160 mm Hg) resulted in an underestimation of $P_aO_2$.\textsuperscript{36}

Streichert \textit{et al.}\textsuperscript{37} conducted a similar study with 30-paired blood specimens but, unlike the study by Peter \textit{et al.}, included data loggers with each specimen sent through the PTS. These data loggers measured temperature, pressure, humidity, and 3-axis acceleration. While temperature, pressure, and humidity measurements did not vary significantly between manually- and pneumatically-transported specimens, substantial differences in 3-axis acceleration were observed. Clinically significant differences in potassium, phosphate, aspartate transaminase, and lactate dehydrogenase measurements were observed between specimens transported by the two different methods. These changes were correlated with transport speed: lower pneumatic tube speeds resulted in smaller differences in test results between manually- and pneumatically-transported specimens.\textsuperscript{37}

Bolliger \textit{et al.}\textsuperscript{38} found that specimens transported by PTS showed reduced \textit{in vitro} platelet activity compared to control specimens, resulting in a reduced potential for aggregation as measured by impedance aggregometry. The authors noted that the differences between the control and experimental specimens were low but clinically relevant. This creates the potential for inappropriate clinical decision-making due to platelet function in pneumatically-transported specimens. Contrary to the findings of Bolliger \textit{et al}, Braun \textit{et al.}\textsuperscript{39} found no evidence of altered platelet aggregation results after transport by pneumatic tube. The authors noted, however, the
importance of minimized acceleration and deceleration during transport through the PTS, especially at bends in the course and arrival at the terminal stop in the laboratory.

Other studies have also drawn the conclusion that low-carrier-velocity travel (3.6 m/s), proper specimen padding, and controlled acceleration/deceleration can eliminate significant changes in ABG values for specimens transported by pneumatic tube. Astles et al. found that cooling specimens and reducing pneumatic transport speed by 50% decreased measured \( P_{a}O_{2} \) changes in specimens. It has also been suggested that changes in 3-axis acceleration and air pressure during pneumatic transportation of specimens can damage red blood cells (RBCs) and induce hemolysis. Based on measurements from their study, Streichert et al. determined acceptable magnitudes and exposure times for 3-axis acceleration for blood specimens. Validation studies conducted at a second hospital showed that when the cumulative accelerations of a PTS are kept below a critical limit, there is no significant increase or decrease in the incidence of hemolysis in pneumatically-transported specimens, regardless of the specifics of the PTS design.

At Sunnybrook, pre-analytical errors including hemolysis, clotted specimens, inconclusive results, specimen integrity problems, and correlation failures with previous results (error codes HEM, RICLT/CLT, RINSR, SIRR, and MCVC respectively) could all theoretically result from pneumatic transport issues according to the scientific literature. Together these 5 errors accounted for 46% of inpatient pre-analytical errors in CBC testing and represented a cost of $20K in 2011. Streichert et al. found that when PTSs transported specimens at speeds less
than 1.5 m/s, the magnitude of changes to specimens were decreased. They also noted that at 1.5 m/s only aspartate transaminase and lactate dehydrogenase measurements differed significantly in PTS-transported specimens as compared to manually transported specimens. Streichert et al. concluded that high acceleration alone is not enough to increase cell destruction in specimens transported pneumatically; the incidence of hemolysis in these specimens is more likely caused by rapid and large changes in acceleration, which can occur when specimens travel through sharp corners at high speeds. The speed of Sunnybrook’s PTS has an estimated range of 3.1-4.6 m/s (Mark Eley, Adanac Systems, Personal Communication). While it is impossible to estimate the frequency of pneumatic transport-induced errors at Sunnybrook without a study specifically designed to identify them, the possibility of their occurrence must be acknowledged as a source of error and hence cost. The evaluation of these errors is beyond the scope of the current study but could warrant further investigation in the future.

4.1.3 Specimen Accessioning

The specimen accessioning processes is a straightforward, linear process. It is the last process in the pre-analytical phase and the only pre-analytical process that occurs inside the clinical laboratory. While accessioning can happen by any of three ordering methods (CVIS, OER, REI), CVIS is by far the most common method by which inpatient specimens are accessioned in our clinical laboratory. More than 75% of all specimens received are accessioned by CVIS.

Errors in accessioning are rare. This is likely due to the ease of the system in which laboratory technicians perform accessioning and to the simple nature of the task. Specimen accessioning
must occur for each specimen arriving at the laboratory, regardless of the condition of that specimen. In order for a test to be cancelled, or for an error to be reported, the specimen must first be entered into the laboratory’s specimen management computer system. As such, specimen accessioning is always included in the cost of a pre-analytical error where specimen collection must be repeated. The cost of specimen accessioning is low, and consequently the repetition of this process, while increasing the overall cost of an error, does not represent a great loss to the laboratory in terms of personnel-time (6 seconds per specimen) or personnel-cost ($0.04 per specimen).

4.2 The Analytical Phase

The analytical phase is nearly completely automated, though it is overseen by laboratory technologists who work to complete specimen analysis at an average rate of 41 specimens per hour. The personnel-time for the analytical phase can vary greatly from specimen to specimen for a variety of reasons. Critical results necessitate the inclusion of a second set of analytical process-steps (Figure 9) that increase both the personnel-time and -cost of the analytical phase. Furthermore, specimens with results that are not critical sometimes require further analytical work, such as dilutions, centrifugation, and the creation of slides for analysis. Given the case-by-case nature of these tasks and the unpredictability of their occurrences they were not factored into our cost model. When one or more of these additional analytical processes must be completed for a specimen, the cost of a pre-analytical error would be increased.
4.3 Error Investigation and Reporting

Error investigation and reporting represent the most costly aspects of a pre-analytical error occurring in inpatient CBC testing at Sunnybrook. Together these processes represent an estimated 35 minutes of personnel-time and a personnel-cost of $21.77 per CBC error. Supervisor approval of error reports requires an additional 15 minutes of personnel-time at a cost of $11.69. Depending on the complexity of the error investigation the supervisor may require as much as 90 minutes to complete approval, which would significantly increase the cost of the error. Labeling errors generally require the most extensive and time-consuming investigations by the laboratory supervisor. A 90-minute investigation and report approval process would increase the cost of such an error to $96.15. Error-related tasks account for 89%-100% of the cost of a pre-analytical CBC error depending on the Class to which the error is designated. In addition to being the most expensive aspect of a pre-analytical error, investigation and reporting must occur for every error that is detected regardless of whether or not other steps in the process need to be repeated. The only practical way these costs can be reduced is by decreasing the number of errors that occur.

4.4 Pre-Analytical Errors at Sunnybrook

4.4.1 Frequency of Inpatient Pre-Analytical Errors

From 2008 to 2011, both the annual number of pre-analytical errors reported for inpatient CBC testing and the total inpatient CBC testing volume at Sunnybrook increased. As test volume increased, so did the frequency of reported pre-analytical errors in the clinical laboratory, increasing significantly from 0.57% in 2008 to 0.86% in 2011. It is known that the longer a reporting system is in place for errors, the more errors that system will capture as the staff using
it become more familiar with it and more aware of errors. The E-safety reporting system at Sunnybrook is a no-fault error-reporting system that was implemented in the summer of 2007 for hospital-wide use. An institution’s error rate depends in part on how methodical laboratory and clinical personnel are in error detection activities. Hospitals with the greatest commitment to error detection sometimes seem to have higher error rates than other, less-focused facilities.

Expressed in errors per million (epm), the frequency of pre-analytical errors in inpatient CBC testing at Sunnybrook has increased from 5705 epm in 2008 (1/175 CBC specimens) to 8609 epm in 2011 (1/116 CBC specimens). Plebani and Carraro reported a pre-analytical error frequency of 19,985 epm in 1997 (1/50 laboratory specimens). Their follow-up study in 2007 showed a decreased frequency of 5653 epm (1/176 laboratory specimens). While the frequency of errors reported by Plebani and Carro in 1997 was significantly higher than observed at Sunnybrook in 2011 ($X^2 = 84.07$, $p < 0.0001$), the error frequency they reported in 2007 was significantly lower than observed at Sunnybrook in 2011 ($X^2 = 17.01$, $p < 0.001$). Plebani and Carraro attributed the reduction of observed errors to two main factors. First, they credited a substantial decrease in the frequency of specimens collected from an intravenous line to increased commitment and training of phlebotomists. These errors accounted for 20.6% of TTP errors in 1997 and only 1.9% of errors in 2007. Second, the hospital installed a computerized physician order entry (CPOE) system during the ten years between their original and follow-up studies. This system eliminated some errors, including wrong patient name or care unit and the performance of unrequested laboratory analyses. CPOE systems have been shown to reduce serious medication issues by 60%–80% when physicians enter all orders through that system. These systems can be programmed to check for patient allergies to medications, order
completeness, and whether or not a prescribed dose of medication is within guidelines for use.\textsuperscript{45,46} While Sunnybrook does not currently use CPOE, the hospital is working towards the implementation of this technology.

Wiwanitkit\textsuperscript{8} reported a pre-analytical error frequency (inpatients only) of 1426 epm (1/701 laboratory specimens). This frequency is significantly lower than the frequency at Sunnybrook in 2011 (Sunnybrook: 1198 of 139,163 CBC specimens, Wiwanitkit: 426 of 298,769 laboratory specimens, $X^2 = 1328.41$, $p < 0.0001$). Lippi \textit{et al.}\textsuperscript{21} reported a pre-analytical error frequency (inpatients only) of 8233 epm (1/122 laboratory specimens), which is not significantly different from Sunnybrook’s 2011 pre-analytical error frequency (Sunnybrook: 1198 of 139,163 CBC specimens, Lippi \textit{et al.}: 2891 of 351,153 laboratory specimens, $X^2 = 2.38$, $p = 0.1226$).

4.4.2 Types of Pre-Analytical Errors Reported at Sunnybrook

The most common pre-analytical error reported at Sunnybrook for inpatient CBC testing is clotted specimens (error code CLT), which accounted for 36\% of errors in 2011. While the majority of error types observed at Sunnybrook showed a decrease from year to year, the number of clotted specimens increased from 2008 to 2011. The majority of clotted specimens at Sunnybrook (402/430 in 2011) were rejected prior to specimen analysis. In some cases, the sample is analyzed and subsequently rejected during specimen resulting. Clotted blood specimens, if analyzed, can falsely underreport RBC concentrations. If analyzed, specimens containing blood clots can also result in inappropriate sampling by analyzers, or can clog the instrument’s aspirating pipette.\textsuperscript{47}
The second most common pre-analytical error reported was insufficient specimen quantity (error code NSQ), which also increased between 2008 and 2011. Inappropriately low specimen volume accounted for 18.6% of errors in 2011 compared to 11.5% of errors in 2008. Low-volume specimens have an inappropriately high concentration of EDTA (ethylenediaminetetraacetic acid), the preservative agent present in the lavender-top tubes used for CBC specimen collection. Excess EDTA can result in a dilution artifact in analysis. Thus, the solution is hypertonic, and too much EDTA in a specimen can cause RBC shrinkage. Because shrunken RBCs have a decreased volume, this can lead to a potentially significant reduction in reported packed cell volume (PCV) upon analysis. The shrinkage of RBCs can also lead to erroneously low mean cell volume (MCV) and hematocrit concentration, which in turn can result in a false increase in mean corpuscular hemoglobin concentration (MCHC).

Jones et al. investigated the acceptability of CBC specimens in 703 institutions. A specimen rejection rate of 0.45% was reported in 7,894,882 specimens. They observed the most common cause for specimen rejection to be clotted specimens (65% of rejections), followed by insufficient specimen quantity (10.1% of rejections). Similarly, clotted specimens and insufficient specimen quantity were the two most common pre-analytical errors Sunnybrook in 2011, accounting for 36% and 18.6% of errors respectively.
4.4.2.1 Errors in Patient Identification

Patient identification errors account for 10% of pre-analytical errors in inpatient CBC testing at Sunnybrook. Proctor\(^2\) found that 793 specimens had been mislabeled at Sunnybrook between 2004 and 2006. Of these 793 events, 298 (38%) had incident reports filed by laboratory technologists. Proctor showed that the majority of these mislabelling errors as occurred in the Intensive Care Unit, the Critical Care Unit, and the Emergency Department. In each of these departments, specimens are collected primarily by clinical staff and not by our dedicated phlebotomy team. Bonini \(et\ al\).\(^7\) reported that the misidentification of specimens is the leading cause of errors in the clinical laboratory. In a 1995 CAP Q-Probes study of CBC specimen acceptability, Jones \(et\ al\).\(^3\) found that the frequency of identification errors, the fourth most common cause for rejection, was 5.1%. In a separate CAP Q-probes study involving 120 institutions, Valenstein \(et\ al\).\(^2\) reported that 85.5% of identification errors were detected prior to the release of laboratory results. The study considered all laboratory analyses conducted at participating institutions. The overall rate of identification errors in laboratory testing at Sunnybrook was 900 ppm, although this could be due to better-than-average error reporting at Sunnybrook.

Valenstein \(et\ al\).\(^2\) generated a percentile scale for the overall rate of identification errors, which they used to rank all institutions that participated in the study. All of the rates were expressed per million tests, with higher percentiles indicating better performance by a laboratory. The overall rate of identification errors at Sunnybrook places the hospital in the bottom 20\(^{th}\)-25\(^{th}\) percentile of the Valenstein \(et\ al\). scale.
According to Valenstein *et al.*, the percentage of inpatient specimens, the inclusion of a test accession number with inpatient specimen labels, and the use of barcoded specimen labels were not associated with post-verification error rate or the percentage of errors detected pre-verification. The study concluded that the number of identification errors detected in a given institutions’ laboratory was highly correlated with the number of billable tests. Institutions which had an identification error tracking program in place at the time of study commencement had significantly lower post-verification error rates. Of the 120 institutions involved in this study, 118 were located in the United States. At Sunnybrook, while the number of inpatient CBC tests performed annually increased from 2008-2011, the number of identification errors remained relatively steady, ranging from 121 to 126 per year.

One assumption made by Valenstein *et al.* was that for every identification error that is detected, several errors are not. Errors are likely more common than indicated by studies in the literature because situations exist where results are released to the wrong patient after an ID error but no harm occurs as the result of the misidentification. Physicians and nurses are very likely to report nonsensical laboratory results, but when a result is within normal range or similar to previous test results for that patient an error can easily go undetected and never be reported. The study reported a total of 345 adverse events, most of which “significantly” inconvenienced patients without causing permanent harm. Unfortunately, the study makes no mention of how patients are identified in the hospitals that participated in data collection. It is unknown how many, if any, use PPID technology to identify patients and aid in specimen collection, and
whether or not the presence of this technology resulted in lower identification error rates. Identification errors that are detected by primary-care staff before any harm befalls a patient may not be deemed worthy of an error report. In other cases, staff detecting the error may elect not to report it lest they be blamed for its occurrence.

The inability to capture every identification error that occurs is not restricted to the clinical laboratory. In transfusion medicine, it is estimated that only one-third of mistransfusions are actually detected. Misidentification errors in the context of transfusion medicine have been extensively investigated. The same is not true for patient identification errors in other healthcare settings including the clinical laboratory. Unlike errors in blood transfusion or medication administration, laboratory testing errors result from complex series of events and can take days, weeks, or even years to be revealed. Identification errors in the clinical laboratory are difficult to assess. Challenges in the detection of laboratory-related identification errors present an obstacle to error reduction and process improvement. Consequently, the rate of identification errors in the clinical laboratory is approximately 1% – double the rate of similar errors in transfusion medicine. Misidentification errors in transfusion medicine can lead to IBCTs (incorrect blood component transfused). This is relevant to our clinical laboratory as some specimens collected for CBC testing are also used by the Blood and Tissue Bank. If one of these shared specimens was improperly identified and used to prepare a blood transfusion, there is a risk that a patient could be transfused a blood component matched to another patient. IBCTs resulting in hemolytic transfusion reactions are the leading cause of preventable transfusion-related injuries.
4.5 The Cost of Pre-Analytical Errors in Inpatient CBC Testing

4.5.1 Annual Error Costs at Sunnybrook

Based on the model developed in this project, the cost of pre-analytical errors in inpatient CBC testing at Sunnybrook was $43,462 in 2011. The annual cost of these errors has increased each year since 2008, the earliest year for which we have reliable data on error frequency. While the frequency of most types of pre-analytical errors at Sunnybrook remained relatively steady between 2008 and 2011, the increased prevalence of clotted specimens and specimens of insufficient volume result in additional errors and increased cost. The increases in these error types are reflected in the annual cost of Class II errors at Sunnybrook, which nearly doubled. The cost of Class IV pre-analytical errors, which require the repetition of all processes in CBC testing and are the most expensive errors, increased by 50% from 2008 to 2011 (see Table H). The increased total annual cost is likely attributable, in part, to an increase in the fraction of pre-analytical errors detected. The error-reporting system used at Sunnybrook was implemented in the latter half of 2007, and as personnel became more familiar with the system and more comfortable reporting errors a greater proportion of errors was likely captured. In 2011, a total of 1198 pre-analytical errors were reported in inpatient CBC testing. These errors account for 22% of the total errors reported in the clinical laboratory at Sunnybrook (G. Budrevics, Personal Communication). Assuming that the cost of a CBC error is similar to the cost of other laboratory errors and that the distribution of inpatient CBC errors across the four
error Classes we have identified here is representative of all laboratory errors in 2011, the cost of all pre-analytical errors in our laboratory was estimated to be $197,555 in 2011.

### 4.5.2 Personnel-Costs are Greater than Materials/Resources-Costs

When all the processes involved in CBC testing are examined, the cost of personnel-time is consistently, and sometimes substantially, higher than the cost of materials and resources consumed during testing processes. In specimen collection, the personnel-cost and the materials/resources-cost are identical: $1.29 per CBC specimen collected. Specimen transportation had no cost assigned to either category, as the cost of personnel-time and materials/resources were considered to be negligible. The personnel-cost for specimen accessioning is $0.04 per CBC specimen, and the materials/resources-cost for this process is negligible. Specimen analysis has a personnel-cost of $0.90 per specimen, compared to a materials/resources cost of $0.72 per specimen. The materials/resources-cost for error investigation and reporting (including supervisor approval) is negligible, but the cost of personnel-time for these processes together is $35.68. Depending on the Class of error, personnel-time accounts for 95%-100% of the total cost of the pre-analytical error. Error investigation and reporting activities alone account for 89%-100% of total pre-analytical error costs.

Given the high cost of personnel-time relative to total error costs it seems prudent to focus cost reduction efforts on personnel, specifically the time spent by personnel conducting laboratory testing activities. Reducing the time spent by staff conducting both initial testing and error
investigation and reporting would have significant effects on the total annual cost of pre-analytical errors at Sunnybrook. By decreasing the time investment of staff in testing activities, not only do errors become less costly, but the initial time invested in those tasks will be decreased, further increasing the efficiency at which Sunnybrook personnel are working. This could be accomplished by modifying the processes to make them more streamlined or by larger changes such as the implementation of a PPID system. A PPID system with handheld devices for use in specimen collection would reduce the amount of manual labour required of phlebotomists, resulting in a decreased personnel-time for specimen collection.

4.5.3 **Costs Associated with Different Error Types**

From 2008 to 2011, clotted CBC specimens, the most common error in inpatient CBC testing, cost more than $48K. Errors of insufficient specimen quantity, patient identification, and order entry cost $21K, $19K, and $8K respectively. These costs are associated only with the CBC – one of many dozens of test types performed in our laboratory. By identifying the costs associated with specific error types it will be easier to evaluate the cost of an improvement initiative. The annual cost of clotted specimen errors increased from $7,165 in 2008 to $15,556 in 2011. The annual cost of labeling errors remained essentially unchanged over the past four years. Neither of these error types decreased in frequency; clotted specimens were twice as common in 2011 than as in 2008. For either of these error types, the cost model described here allows Sunnybrook to compare the price of improvement initiatives with the annual cost of the status quo.
4.5.4 **Costs to the Patient**

Aside from the financial ramifications of pre-analytical errors, there are costs to patients that must be considered. A laboratory error can prolong a patient’s treatment, extend a patient’s hospital stay, and increase the time a patient spends waiting for the results of a laboratory test. When a pre-analytical error necessitates the repetition of specimen collection, the patient is subjected to a second phlebotomy procedure. Any of these outcomes can result in the patient experiencing unnecessary physical and/or emotional discomfort. It is possible for patients to experience financial costs as the result of pre-analytical errors as well. An extended hospital stay may necessitate additional time off work, additional child-care expenses, and additional transportation expenses for friends or family visiting the patient in the hospital.

4.5.5 **Lost Personnel Productivity due to Pre-Analytical Errors**

In addition to the cost of pre-analytical errors, one must consider the personnel-time required to correct them. When an error occurs, a phlebotomist or nurse must repeat specimen collection. Ward staff and laboratory staff spend time investigating how the error occurred instead of caring for patients on their service. The time spent by staff righting these wrongs represents a two-fold loss: the cost of their time, and the time itself. When pre-analytical errors occur, the hospital is in essence paying its staff to put their regular responsibilities to patients on hold and instead to correct each other’s mistakes.

In their study of CBC specimen acceptability, Jones *et al.*\(^3\) used CAP workload units to estimate productivity lost due to extra work required when specimens are rejected. At a minimum, an
estimated 15.75 paid minutes were wasted per rejection, and at a maximum, 36.75 paid minutes were wasted per rejection. These numbers, according to our evidence, underestimate the time wasted by Sunnybrook personnel investigating errors and repeating CBC testing so that an accurate, reportable result can be released. Considering all of the personnel-time for the different processes involved in inpatient testing, one pre-analytical CBC error at Sunnybrook results in an estimated loss of 45-55 paid minutes depending on the Class of that error. This lost productivity takes into account only the time of laboratory personnel, and does not include time spent by ward personnel communicating with the laboratory about the occurrence and cause of a detected error. Furthermore, any subsequent investigations that take place on a ward after an error has been detected would add additional time to the total lost productivity. In 2011, Sunnybrook laboratory personnel (including phlebotomists) spent at least 775 hours performing tasks related to inpatient CBC testing errors. This is equivalent to five months of full-time work by one staff member.

4.6 Future Directions

4.6.1 Expansion of the Cost Model to Other Laboratory Tests

The Department of Clinical Pathology at Sunnybrook, which includes Biochemistry, Hematology, and the Blood and Tissue Bank, performs 70% of laboratory tests across all laboratory services in the hospital. The remaining 30% of laboratory tests fall under the jurisdiction of the microbiology, anatomic pathology, and transfusion medicine departments. The CBC test is one of dozens of test types offered in our department. Different laboratory tests show variation in the frequency of inappropriate testing: 11%-70% for hematology and biochemistry tests, 5%-95% for microbiology and urine screens, and 17.4%-55% for cardiac enzymes and thyroid tests. According to these estimates, errors in laboratory testing are no less
common in other testing departments. Laboratory testing services external to hematology would also benefit from a cost model allowing them to quantify costs associated with pre-analytical errors.

Our cost model is specific to the CBC test but could be expanded to other tests relatively easily. This is especially true for tests using blood as the specimen. Phlebotomy, accessioning, and error-reporting costs would not change. Differences would lay in the cost of specimen analysis and the personnel-costs associated with the analytical phase. Minor differences in supply costs would exist but since the greatest component by far of a CBC pre-analytical error is accounted for by the error investigating and reporting costs, we expect that the model would be applicable to other test types. Small increases or decreases in the cost of testing reagents or personnel-time invested in analysis would be relatively insignificant compared to the large cost of detecting and correcting errors.

4.6.2 Expansion of the Cost Model to Other Patient Populations

4.6.2.1 CBC Testing in Outpatient Populations

The research reported here looks only at errors in an inpatient population. The inpatient population was chosen because they represent a higher cost to a hospital than outpatients and because the literature suggests that there is a difference in error rates between the two patient populations. This difference in error rates between inpatients and outpatients has been attributed to different skill levels of trained phlebotomy compared nurses, and to greater test volume for inpatients. Wiwanitkit found no difference in error rates between inpatients and
outpatients, though he did not specify whether phlebotomy at the University-Hospital of Chulalongkorn was under control of the laboratory. At Sunnybrook, dedicated phlebotomists perform both inpatient and outpatient specimen collection. Furthermore, inpatient and outpatient CBC test volumes are nearly identical (see Figure 12). Given the similarity in testing volume and, more importantly, that the same personnel perform inpatient and outpatient specimen collection and analysis, it is likely that pre-analytical error rates would be similar to those observed for inpatients. If this is true, the outpatient population at Sunnybrook could represent a cost of $43K per year in pre-analytical errors. Because outpatients tend to be healthier than inpatients, specimen collection times may be lower as a result of easier access to suitable veins for phlebotomy as compared to inpatients. As previously noted, since 89%-100% of the cost of a pre-analytical error is accounted for by error reporting activities, a decreased specimen collection time would have a minimal effect on the total cost. A study investigating the cost of outpatient pre-analytical errors could consider the costs to outpatients in addition to the costs experienced by the hospital and laboratory. Travel to and from the specimen collection site and lost productivity resulting from time spent giving a second specimen are two examples of costs an outpatient may incur due to a pre-analytical error.

### 4.6.2.2 CBC Testing in Neonatal Patients

This cost model may also be useful in the context of CBCs performed in the NICU. Patient identification is more challenging with neonates than with adults and identification errors are more likely to occur in this setting. Features commonly used to help care-providers identify adult patients – such as gender, hair colour, size, and age – are not necessarily apparent in neonates. In the NICU, the ID wristband is the only means by which patients can be identified.
by clinical staff since newborns are unable to actively participate in the patient identification process. Suresh et al. reported that 11% of errors detected in a Vermont NICU involved patient misidentification. A six-month study in a British NICU attributed 25% of medication errors to errors in patient identification.

4.6.3 Making a Case for the Implementation of PPID at Sunnybrook

4.6.3.1 Benefits of PPID

The use of PPID in healthcare is increasing globally. Its growing prevalence is due largely to its applications in numerous aspects of healthcare delivery and patient safety within a hospital, including transfusion medicine, patient flow, medication/drug dispensation, prescription order entry, surgical procedures, and specimen analysis in the clinical laboratory. In a study by Kileen et al., identification error rates in an emergency department decreased from 2.56/1000 specimens to 0.49/1000 specimens after the implementation of a barcode PPID system. Similar reductions in error frequencies after PPID system installation were reported in publications by other research groups for adult patients and in a pediatric hospital.

In recent years there has been increasing pressure on hospitals to implement PPID due to its proven ability to reduce errors in numerous aspects of patient care. This pressure comes from a variety of sources including patient safety groups, industry, hospital networks, and professional medical/healthcare societies. Barcode and radio frequency identification (RFID) technologies are two of the most common varieties of PPID with widespread use. A handheld scanner is used to read patient information from a barcode or radio chip on a patient’s ID wristband, allowing for
efficient verification of patient identification and treatment information. These scanners also allow healthcare professionals to record information faster and with greater accuracy than traditional handwritten procedures. Scanners can verify laboratory tests ordered for a patient and print a label for the specimen container as the specimen is collected at the patient’s bedside, streamlining the specimen collection process. It also makes it easier for personnel performing specimen collection to follow SOPs and perform process-steps in the specific order in which they are meant to be performed. PPID handheld scanners have built in checklists requiring phlebotomists to indicate when they have performed certain tasks, such as confirmation of the patient’s identity, before allowing them to proceed with specimen collection. PPID at Sunnybrook could discourage specimen labeling outside of the patient’s room if labels for specimen tubes were printed directly from the handheld device. Furthermore, because PPID systems are linked with a hospital’s laboratory information system (LIS), they aid in the process of analysis and the reporting of test results. The use of PPID handheld devices in specimen collection would make illegible specimen labels obsolete, and the automated process would ensure that patient and specimen information (such as collection time) were accurately and instantaneously recorded in the hospital’s LIS.

While error reduction (and the subsequent improvement in patient safety) afforded by a PPID system alone is attractive, the savings generated by this technology are also important to consider. A PPID system combined with a CPOE system that covers the TTP would result in the near complete elimination of patient ID errors, specimen labeling errors, tube-type errors, and ordering/order-entry errors. These error types alone cost Sunnybrook $37,143 from 2008 to 2011. Inpatient CBC testing errors accounted for just less than 25% of all identified laboratory
errors between 2008 and 2011 (3938/17,000 errors). If we assume that the distribution of CBC errors across the four error Classes we have identified in this research is representative of non-CBC laboratory errors, the cost of patient ID, order entry, labeling, and tube-type errors in the clinical laboratory cost Sunnybrook $160,341 from 2008 to 2011.

4.6.3.2 PPID at Sunnybrook

A business case investigating the cost of implementing a hospital-wide barcode P PID system at Sunnybrook was completed by a P PID task force in 2010. This case study estimated a cost of $2 million for the implementation of P PID for lab specimens and $293K annually in ongoing costs related to laboratory testing. While these costs of implementation and upkeep are significantly higher than the estimated savings afforded to the hospital by P PID in the context of laboratory testing, the laboratory is not the only hospital service that would see rescued financial resources as the result of P PID implementation. Furthermore, we expect that our cost model estimates only the absolute minimum cost of a pre-analytical error. The reduction of these errors would likely result in greater financial savings than we have predicted here.

A barcode P PID system is currently in limited use at Sunnybrook in the Transfusion Medicine Clinic (TMC), the NICU, and the C2 hospital ward. In 2009, following full implementation of P PID in C2 and the TMC, there were zero errors related to misidentified blood specimens collected for group and screen testing and zero transfusion errors due to blood or patient misidentification in these services. Across the rest of the organization there were 156 identified errors related to misidentified blood specimens collected for group and screen testing
in 2009, and likely even more that went undetected.\textsuperscript{49,50,53} In the NICU, the number of wrong baby feeds decreased to zero two years after PPID implementation compared to 11 incidents before PPID.\textsuperscript{69} Sunnybrook is the only Canadian healthcare institution submitting data to the Transfusion Error Surveillance system that uses PPID. At Sunnybrook, there is one error per 78 transfusion medicine samples collected. The national average is one error per 28 transfusion medicine samples collected.\textsuperscript{69}

4.6.3.3 Limitations of PPID

Despite the widely accepted benefits of PPID systems, they are not without their limitations. In an 18-month study of PPID technology at Sunnybrook, Callum \textit{et al.}\textsuperscript{70} reported several limitations in the PPID system being tested in two units. These included difficulty scanning supplier labels on blood products with handheld scanners, damage to handheld screens resulting from repeated use, a lack of uptake by 20\% of RNs, and discrepancies in patient ID between different registration systems. In a separate study of the use of barcode technology systems in a transfusion medicine setting, Anders \textit{et al.}\textsuperscript{71} also identified weaknesses associated with the effectiveness of the system. Examples provided were inadequate error messaging, confusing auditory alerts from handheld devices, poor ergonomic design of scanners, and uninformative directions for staff using the devices. They concluded that from the perspective of usability, blood-checking products were “immature” and would benefit greatly from further improvements.\textsuperscript{71}
Brown et al.\textsuperscript{72} noted that despite significant and sustainable error reduction, the implementation of a PPID system required a large capital expenditure and required extensive staff education. When an adequate number of handheld units are not available, staff become frustrated and create workaround processes. In a study of such workaround processes, staff were observed scanning “surrogate” ID wristbands that were not attached to a patient and bypassing security systems via the input of alternate patient identification into handheld devices.\textsuperscript{73} During PPID-assisted medication administration, RNs were seen scanning multiple ID wristbands and pre-pouring medication for multiple patients in efforts to save time. Patterson \textit{et al.}\textsuperscript{73} noted that staff became over-reliant on barcodes, citing unlabeled medications carrying only a barcode as an example of this over-reliance. They also found that the software system supporting the handheld devices could not be redesigned to avoid or reduce workaround processes.

The over-reliance of staff on barcode-scanners was also reported by McDonald\textsuperscript{74} in a case study of a near-miss in medication administration. One of the risks of the implementation of a PPID system is reduced vigilance by staff who think, “We use barcoded wristbands, so what could go wrong?”\textsuperscript{74} When ID wristbands contain a barcode, other information such as a patient’s name and date of birth are often printed in small fonts that are difficult to read. One potential solution to this is the use of a RFID chip in place of a barcode, which would leave more space available on the ID wristband for printed text. Wristbands using RFID technology do not need to be “seen” by a scanning device; waving the handheld near the patient’s ID wristband is adequate to initiate a handheld-assisted procedure. This is especially useful for patients who are in isolation, where RNs cannot scan a barcode without violating infection control protocols.\textsuperscript{70}
4.6.4 Expansion of the Cost Model to Include “Off-hours” CBC Testing

All data involved in this study were collected during work hours Monday-Friday. We expect that testing errors occurring outside of normal business hours would have increased costs associated with decreased specimen volume in the hospital. A specimen collected in a hospital ward may have a negligible transport cost when it is being couriered in a basket with dozens of other specimens, but in the middle of the night when a courier travels to the ward to collect only that sample and deliver it to the lab the cost of transport would increase and likely not be deemed negligible. In addition to an increased cost of errors, reports in the literature suggest that error rates also rise during off-hours. In their 2006 study, Arikan et al.\textsuperscript{17} investigated differences in error rates at different times of day (day shift versus night/weekend shift). They found significantly higher error rates during the night shift, and cited clerical staff with more experience and increased staff presence in the morning as a probable source of decreased error rates during the day.

4.6.5 Expansion of the Cost Model to Include Costs Extraneous to the Laboratory

This cost model considers only costs within the laboratory and related to laboratory staff. There are costs external to the laboratory that would contribute to the total cost of a pre-analytical error but that are beyond the scope of this study. These costs include tasks related to error investigation and correction in hospital wards and clinical departments. An error detected in the laboratory often leads to an investigation in the ward where it originated, and this consumes the time of clinical and support staff. Investigations on hospital wards occur after the laboratory
investigation, which necessarily includes time spent in a telephone conversation between laboratory and ward staff. A delay caused by the repetition of laboratory testing has the potential to affect a patient’s care schedule within the hospital. This could result in delayed intake, discharge, and clinical or surgical procedures. Such delays might increase a patient’s length of stay in the hospital. This would have effects on scheduling and patient flow in addition to representing further costs to the hospital. A future study investigating and quantifying these costs would provide a more complete estimation of the cost of an inpatient pre-analytical error in CBC testing.

4.7 Changes that Need to be Made

Each day at Sunnybrook, three pre-analytical errors are detected in inpatient CBC testing alone. This is likely an underrepresentation of the total error frequency for this test, as it is probable that not all errors that occur are detected. It is already known that pre-analytical errors represent a risk to patient safety.\textsuperscript{10,12,16} This research quantifies the cost of those errors at Sunnybrook – $43,462 in 2011. The most commonly occurring errors have been identified, as have the costs associated with them. The next step is to implement changes that will lead to the reduction of these errors and allow for the reallocation of rescued financial and personnel resources into improvements in safety, laboratory operations, and the delivery of care to patients.

Once errors have been targeted for reduction, it is critical to think not only what the desired outcome is, but also how to achieve that outcome in a way that ensures a permanent decrease in error frequency and accordingly a permanent reduction in error-related costs. Studies of short-
and long-term interventions aimed at error reduction have limitations in both effectiveness and efficiency. Kemp et al.\textsuperscript{75} reported the results of a 22-week program aimed at reducing pre-analytical errors in specimen collection in three hospitals in Leeds, United Kingdom. The errors targeted by these interventions were patient identification errors during specimen collection, tube type errors, and specimen volume errors. Two interventions, each lasting two weeks, were performed 10 weeks apart. The first was a series of posters displayed in phlebotomy store rooms and nurse/physician rooms. These posters were accompanied by four visits to hospital wards involving staff interviews and education. The second intervention was a screen saver displayed on ward computers reminding staff of the important information administered during the first intervention. After 22 weeks, there was no significant change in error rates between intervention and control sites.\textsuperscript{75} Long-term interventions, such as a year-long program of education and error monitoring, can reduce error rates.\textsuperscript{76,77} These interventions, however, are costly and logistically challenging, and in a large hospital would not be a feasible program to implement. Furthermore, upon cessation of the intervention there is a chance that error rates would return to pre-intervention levels, rendering the entire activity futile.

4.7.1 **Systems Can Change, Human Nature Cannot**

The medical community, unfortunately, is often trapped in a culture of blame where individuals are held accountable for adverse occurrences such as errors in laboratory testing. According to Reason,\textsuperscript{78} there are two ways in which errors can be addressed: the “person” approach (which is the traditional way of thinking about errors) and the “system” approach. The person approach places blame for an error on staff who commit unsafe acts and violate procedures. The system approach proposes that errors will occur even in the best organizations because humans are
fallible by nature. The person approach views errors as being caused by the forgetfulness, carelessness, and negligence of individuals performing tasks. The system approach views errors as consequences that originate from “upstream” systemic factors. Reason\textsuperscript{78} proposed the idea of “recurrent error traps” in workplaces as being responsible for errors. He suggested that countermeasures to reduce the frequency of errors be designed with the consideration that while human nature cannot be altered, the conditions that those humans work under can be.

Viewing errors as system failures can explain why they tend to happen in recurrent patterns; regardless of who is completing a task, if the same set of circumstances is present that error will occur. Reason\textsuperscript{78} created the “Swiss cheese” model of errors. In a hospital there are many defensive layers set up to reduce the occurrence of errors. Each of these defensive layers has holes in it, like a piece of Swiss cheese. As circumstances change, holes in each slice of cheese open and close. A hole in one slice of cheese will not result in an error occurring, but when holes in several slices of cheese align, the opportunity for an error exists.\textsuperscript{78} In other words, when multiple lines of defense fail simultaneously and in a certain way errors will happen. These holes can result from active or latent failures, the former resulting from lapses in judgment made by staff or unsafe acts and the latter resulting from poorly designed systems that create conditions which allow for errors to occur. While latent failures are more long-lasting and consequently more dangerous, they can be identified before an error occurs.\textsuperscript{78} By eliminating latent errors through improved system design, defenses safeguarding patients will have fewer holes, thus decreasing the risk or errors.
The blame culture is pervasive, and is likely present to some extent in every healthcare institution. A local staff member, while discussing errors in the clinical laboratory, commented that a number of laboratory technicians had repeatedly made the same error, despite discussions with supervisors, public reminders at staff meetings, and other remediation efforts (Personal Observation). This is an example of a situation where education and training are not effective ways to positively influence performance. Instead, we need to scrutinize the systems that our personnel function within and, if necessary, alter them in such a way that it becomes more difficult for staff to deviate from safe, standard practices.

The implementation of a new system is not a simple task, even where the system is designed to simplify the jobs of individual workers. A new system inevitably comes with a cost. Planning, implementation, and staff training are necessary activities that would consume personnel-time. Any equipment or software that needs to be purchased and integrated with the hospital’s current system will also have a cost. While the estimated cost of changing a system may seem prohibitive and create hesitation, spending money on improvements and error prevention are a better use of financial resources than spending that money correcting errors. Old habits can be difficult to break, and new habits take time to form. In addition to adapting to the technology and procedures of a new system, healthcare teams also need to adapt to a new culture of teamwork and a new way of thinking. This culture shift is equally important and equally challenging to the change in working habits. If awareness exists, however, that a system is failing despite repeated and varied attempts to improve its effectiveness, it is the responsibility of management to make changes to that system. This is especially true in a healthcare setting where lives are at stake.
4.7.2 **Tools for Quality Improvement**

Two popular tools for QI are the Six Sigma and Lean systems, both of which have origins in the manufacturing industry. Six Sigma was developed in the 1980s by Motorola. It is based on a 5-stage approach to problem solving: (1) Define, (2) Measure, (3) Analyze, (4) Improve, and (5) Control (DMAIC). When launched by Motorola, the Six Sigma program had a goal of 3.4 defects per million and was based around core philosophies of minimizing variability and predicting and preventing problems. Lean originated in Toyota, and focuses on decreasing waste and removing unnecessary steps from processes. Organizations that choose to adopt either of these tools must be willing to undergo a cultural change in order to maximize benefits of the systems. Six Sigma and Lean both rely on tracking data and measuring progress towards a specific goal via quantitative measurements of QI initiatives. In the healthcare industry, examples of QI measurements include shortened length of stay, simplified billing processes, decreased patient wait-times, fewer X-ray film defects, OR Start time delay, and hand hygiene practices.

Six Sigma and Lean are both models for evidence-based practice (EBP). EBP is an approach to clinical decision making based on problem solving. It combines scientific evidence with experiential evidence in an effort to improve care with respect to a patient, patient population, or system. In addition to Six Sigma and Lean, there are three other QI methodologies that can be used in EBP: PDCA (plan-do-check-act), RCA (root cause analysis), and FMEA (failure mode effects analysis). PDCA, originally developed for QI in business, is modeled after the steps in
the scientific process. RCA was originally developed in the manufacturing industry as a means to study industrial accidents. By examining information gathered during the investigation of an adverse event, underlying causes and system shortfalls are identified and targeted for reduction. RCA, which focuses on systems and processes as opposed to individuals, is widely used by healthcare organizations in the context of medical errors. FMEA was developed by NASA, and is a tool used to prospectively assess risk. FMEA focuses on predicting potential failures within processes and identifying unrecognized hazards in order to prevent adverse events from occurring. Each of these five tools has proven effectiveness in a healthcare setting and is widely adaptable to a variety of situations.

4.7.3 Improvement Strategies Vary in Effectiveness

These tools allow healthcare providers to identify systems and processes to improve in efforts to maximize patient safety. The introduction of new policies is often the first step taken towards improvement when an adverse event is detected. New policies are important for communicating information about the event to practitioners and providing guidelines for safer behaviour. They are, however, frequently ineffective in the long-term because they do not change the underlying conditions that caused the adverse event and they do not physically direct practitioners to perform in a specific way. The most effective solution is physical change, which can be accomplished by forcing functions or by constraining functions.

A forcing function, as defined by Cohen, is “a design feature that makes it impossible to perform a specific erroneous act.” An example of a forcing function is the use of differently-
sized fittings for the lines of different medical gases in the OR. The wrong gas line cannot be connected to equipment delivering the gas to a patient because the couplings of different gas lines are incompatible with one another. A constraint function is “a withholding step in a process that makes it improbable that a specific erroneous act will be performed.” An example of a constraint function is the removal of concentrated potassium chloride from patient care units in order to prevent its accidental administration to patients. If the drug is not present, it cannot be erroneously selected by an RN for delivery. There are additional strategies for improving patient outcomes, which, despite producing results, are not as effective as forcing or constraining functions. In order of effectiveness, these strategies are: (1) Forcing and constraining functions; (2) Automation and computerization; (3) Simplification and standardization; (4) Reminders, checklists, double checks; (5) Rules and policies; (6) Education and provision of information.

More important than the use of effective improvement strategies is the development of a culture where errors and risks can be openly discussed. When an organization diligently reports and analyzes adverse events, its staff become more aware of how processes influence outcomes. This allows them to better understand the ways in which underlying system factors contribute to the occurrence of errors. Organizations in the aviation and nuclear power industries are collectively fixated on the potential for failure and have diligently developed these cultures in the workplace. These organizations are known as “high-reliability organizations.”
4.8 Limitations of the Cost Model

One limitation of our cost model is the potential for an observer bias. While personnel performance was not being evaluated, it is possible that staff adjusted their normal routine to perform tasks in a more timely fashion, or that they deviated from their normal routine in order to follow guidelines and SOPs more closely for the processes they completed. If staff sought to perform their usual tasks faster than normal because they were under observation, this would result in underestimations of the times, and hence costs, subsumed by those activities. As all of the data was collected by me, and all observations made by me, it is possible that I have biases that influenced the observations made or the type of qualitative observations recorded.

Another limitation of the cost model is that all data collection occurred during normal working hours between Monday and Friday. During the work week there are more staff working and laboratory testing occurs at a higher volume. As such, any testing that occurs outside of these normal working hours would likely have a higher cost associated with it. It is likely that errors are occurring during these “off hours” in greater frequency than during normal working hours. If off-hours errors are both more expensive and more common, this cost model underestimates both the cost of a subset of individual errors and the overall annual cost of pre-analytical errors at Sunnybrook. Based on test volume data from the month of November 2011, 43% of CBC analyses at Sunnybrook occur during off-hours.

It should be noted that some pre-analytical errors in CBC testing might be replicated in other specimens collected from the same patient, at the same time, by the same phlebotomist. For
example, if a CBC specimen is contaminated as the result of being drawn through an IV line instead of from a peripheral vein, any other specimens collected for different lab testing at the same time and site would also be contaminated. If this occurs, one CBC error that costs $37.70 could also have 3 other rejected tests to be repeated and 3 other specimens to be collected.

Finally, our cost model considers only costs within the laboratory and related to laboratory staff. Clinical and support staff also spend time correcting and investigating errors when they are detected. A patient’s treatment schedule may need to be altered while an accurate laboratory result is being prepared, which can result in wastage of further personnel-time and hospital resources. If the delay is sufficient to extend a patient’s stay in the hospital, the costs associated with that must also be considered as costs of the error correction. Data on pre-analytical errors in inpatient CBC testing includes errors that occurred in the critical care unit, the cardiovascular intensive care unit, and the operating rooms where specimen collection is performed by RNs. Errors occurring here would have a higher cost since the salary of an RN is greater than the salary of a phlebotomist. The cost model did not take this into consideration. The complexities and case-by-case nature of costs extraneous to the laboratory make them impossible to estimate without a study designed specifically to evaluate them.

4.9 Concluding Thoughts

Pre-analytical errors occur frequently and can have serious and adverse effects on patients. Awareness of this should be enough to set in motion changes to the institutional systems in place. Unfortunately, this is often not the case. The cost estimation for these errors shows
clearly that they have effects beyond the realm of patient safety. Our cost model identifies tangible, financial resources squandered when pre-analytical errors occur. These resources, if rescued, could be reallocated into improvements to patient care and laboratory operations at Sunnybrook.

When compared to the annual hematology budget at Sunnybrook, the cost of inpatient CBC pre-analytical errors seems miniscule – less than one tenth of a percent. It is important, however, to look closely at what these costs stem from and to consider that the costs reported in this research are likely only a portion of the total costs incurred by Sunnybrook when a pre-analytical error occurs. These costs represent failures of the system in place at Sunnybrook to provide physicians with information upon which they base diagnoses, treatment courses, drug prescriptions, and major clinical decisions such as hospital admission or discharge. The errors discussed in this research were detected and likely did not directly or significantly affect the patients’ treatments. While the cost of one error may seem insignificant, consider the cost of that error going unnoticed. The detection and correction of a mislabeling error at Sunnybrook costs $37.70 if detected after specimen analysis. The cost of that error going undetected, however, has the potential to be much higher. A single error in laboratory testing has the potential to result in 15 consultations with physicians and specialists, 77 additional laboratory tests, a CT scan, and inappropriate treatment.³³ Any extension of a patient’s stay in the hospital as a result of these procedures further increases the cost of the error. In an extreme scenario, the hospital could also face legal costs related to morbidity or mortality following inappropriate treatment.
A proactive investment in the detection and reduction of pre-analytical errors is both fiscally and morally responsible. Ultimately, it is irrelevant whether attention is paid to these errors because of the risk they pose to patient safety or because of the $43K loss experienced annually by Sunnybrook as a result of them. What matters is that something is done to reduce their prevalence. The business of a hospital is to help people get better. It is, however, still a business. The reduction of pre-analytical errors will not only allow Sunnybrook to better protect its patients against potentially life-threatening iatrogenic errors, but it will also allow the hospital to use its financial and personnel resources more effectively. Error reduction and system improvements will generate significant savings that can benefit the patients who we care for and who put their well-being in our hands.
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