AN INVESTIGATION IN PRE-ANALYTICAL ERROR IN A MEDIUM SIZED PATHOLOGY LABORATORY: FREQUENCY, ORIGIN, TYPE, AND A PROPOSED INTERVENTION

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STATEMENT OF SOURCES

I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or other institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given.

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ABSTRACT

Pre-analytical error in pathology is responsible for as much as 85% of total errors in the testing process. While many studies have examined the frequency of pre-analytical error alone, fewer studies investigate the frequency at which of different types of error occur, or categorise them for comparison across healthcare facilities. Remediation and reduction of error requires a clear understanding of the actual cause and source of error. Therefore an understanding of the type of errors may help inform strategies to reduce these errors and subsequently any impact on patients and the healthcare system. The aims of this study were to identify and characterise the pre-analytical error associated with specimens received into the Pathology Laboratory of the Townsville Hospital; utilising the extensive database of requests and results contained in the laboratory information system (LIS) and once understood, to propose an intervention designed to reduce errors originating from a clinical area with a high error rate.

The results from this study showed that pre-analytical errors are numerous and diverse, however a critical factor in determining the pre-analytical error rate was the ward from which the sample was collected. There currently is no standardised definition for each type of error within laboratory medicine, nor is there a standard unit of measure. Although recommendations for clinical indicators have been proposed, this study considers them to be too laborious and impractical for continuous monitoring and reporting to regulatory bodies. This study found that identifying the overall category of error is an efficient and focussed method for targeting an interventional strategy for the reduction of pre-analytical errors in a clinical area or ward, and that such an intervention can result in substantial savings in healthcare expenditure.

Until there is consensus on the identification and recording of pre-analytical errors, any comparison between studies should be done with caution and interpreted after proper

examination of the study method. In addition, achieving a consensus on the definitions of pre-analytical error in order to monitor the frequency of error is a worthwhile goal, however the method chosen will need to be realistic, cost effective and easily implemented by all laboratories in order to be successful.

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ABBREVIATIONS

CI	Confidence Interval
CCU	Coronary Care Unit
DSU	Day Surgery Unit
ED	Emergency Department
EHCF	External Health Care Facility
EMU	Emergency Medical Unit
FBC	Full Blood Count
HBsAb	Hepatitis B Surface Antibody
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
ICU	Intensive Care Unit
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Organisation for Standardisation
IV	Intra venous
KIMMS	Key Incident Monitoring and Management Systems
LIS	Laboratory Information System
NATA	National Association of Testing Authorities, Australia
NICU	Neonatal Intensive Care Unit
OT	Operating theatres
PP	Private Practitioner
PQ	Pathology Queensland
QH	Queensland Health
QI	Quality Indicators
QUPP	Quality Use of Pathology Project
RCPA	Royal College of Pathologists of Australasia
SCN	Special Care Nursery

TTH	The Townsville Hospital
UK	United Kingdom
URN	Unit Record Number
WBIT	Wrong Blood in Tube

CHAPTER 1
GENERAL INTRODUCTION

Understanding of the complex issue of adverse events in the Australian Health Care system gained a huge leap forward with the publication of The Quality in Australian Health Care Study in 1995 (R. M. Wilson et al., 1995). This extensive review of patient records in two Australian States found over 16% of admissions were associated with an adverse event, and that half of these adverse events were highly preventable, placing the focus on prevention, rather than litigation. In the year 2000, a report was released by the Committee on Quality Health Care in America titled "To Err is Human" (Kohn, Corrigan, & Donaldson, 2000). The authors defined patient safety as "freedom from accidental injury", and had many recommendations, including raising awareness of errors by monitoring and evaluating errors, and implementing error reduction methods. The diagnostic pathology laboratory, although present in nearly every major hospital in both Australia and the United States, was not explicitly mentioned in either of these early reports, outside of a brief mention of pathology reports being an important source of data for identifying trends (Kohn et al., 2000). The follow up report published in 2016, Improving Diagnosis in Healthcare, acknowledges the need for better recognition of the critical role pathology plays in the diagnostic process, and recommends collaboration among health professionals to improve skills and knowledge in the diagnosis of patients (Balogh, Miller, & Ball, 2016). This renewed focus on the importance of a quality pathology system and appropriate utilisation of pathology highlights the need for further research in these areas.

Historically, pathology laboratories have concentrated on reducing errors during the analysis of specimens, and technological advances in automated analysers have reduced these errors significantly (Mario Plebani, Laposata, & Lundberg, 2011; Stroobants, Goldschmidt, & Plebani, 2003), alongside the widespread use of process controls and external quality assurance programs (Howanitz, 2005). However, diagnostic pathology testing as a whole encompasses everything from collection, to analysis, and reporting of

results. The concept of pathology testing being a “brain-to-brain loop” was first introduced by Lundberg in 1981, and it has developed over time to be widely considered as the “total testing process”, encompassing pre-analytical, analytical and post-analytical phases (Mario Plebani et al., 2011). In each of these three phases of testing in the laboratory, there are many opportunities for errors to occur. Pre-analytical error, thought to account for up to 85% of all errors in the laboratory (Lippi, Guidi, Mattiuzzi, & Plebani, 2006; M. Plebani, 2006), can be as simple as a missing signature on a request form or blood tube, or as complex as specimens collected from the wrong site or even the wrong patient altogether (M. Plebani, Sciacovelli, Aita, Padoan, & Chiozza, 2014). Analytical errors are those that occur during the analysis of the specimen (usually due to mechanical or reagent failure), while post-analytical errors are related to the reporting and interpretation of results (Bonini, Plebani, Ceriotti, & Rubboli, 2002).

The impact of pre-analytical error may be as minor as the inconvenience of a repeat blood test (Jacobs, Costello, & Beckles, 2012), or as devastating as an incompatible blood transfusion (Quillen & Murphy, 2006). The cost to the health care facility can also vary, especially when considering unnecessary inpatient admissions, inappropriate use of medication such as antibiotics or unwarranted surgical intervention (Archibald, Pallangyo, Kazembe, & Reller, 2006; Bates, Goldman, & Lee, 1991). A recent study estimated the average cost of an episode of pre-analytical error in North American institutions to be $208 (USD) and in European institutions the equivalent of $204 (USD) (Green, 2013). These costs can quickly compound into a substantial total considering pre-analytical error rates have been reported in up to 5% of all samples processed by a laboratory (Kemp, Bird, & Barth, 2012), and therefore errors should be minimised as much as possible to reduce these costs. Any interventional strategy that is proposed to reduce occurrences of pre-analytical error must be evidence based. That is, it must be targeted towards both the type errors and the particular characteristics of the clinical area involved. It has previously been shown that interventions lacking in either of these requirements are not successful in the long term (Kemp et al., 2012).

It is the aim of this study to determine the rate of pre-analytical error in a medium sized laboratory and to evaluate the types and sources of these errors to inform an evidence based intervention to reduce these rates of error.

CHAPTER 2
LITERATURE REVIEW

2.1 Introduction

In the seminal publication, To Err is Human: building a safer health system, the American Institute of Medicine reported on the current state of medical error and patient safety in the United States (Kohn et al., 2000). The report is widely considered to be the most comprehensive of its type, and has drawn attention to the issues of patient safety throughout the healthcare system. Traditionally, the laboratory has led the way in quality management due to its highly regulated analytical phase (M. Plebani, 2006), however recently the laboratory has broadened its focus to include the extra-analytical phases (Pansini, Di Serio, & Tampoia, 2003).

The complete cycle of laboratory testing was first described in detail by Gambino in 1970, who defined the following nine steps; ordering, collection, transport, identification, separation, analysis, reporting, evaluation, and action (S. R. Gambino, 1970). Expanding on this idea, Lundberg characterised these steps as the "brain to brain turnaround time", envisioning a feedback loop that can be disrupted at any stage, resulting in an open and ineffective loop (Lundberg, 1981). This loop is now more commonly referred to as the total testing process, and consists of all the steps between the physician ordering the test and when the results are provided to the clinician for interpretation and action (Da Rin, 2009; Wians, 2009). Guder (1999) argues that the aim of any pathology test is to determine the true value of an analyte at the time of sampling, and that there is an assumption that the composition of the sample is not altered during the pre-analytical phase, this assumption has clearly been tested in recent years (R. Hawkins, 2012; Lippi et al., 2007; Lippi, Salvagno, Brocco, & Guidi, 2005; Lippi, Salvagno, Montagnana, Brocco, & Cesare Guidi, 2006; Lippi, Salvagno,

Montagnana, Brocco, & Guidi, 2006; Lippi, Salvagno, Montagnana, Franchini, & Guidi, 2006; Lippi, Salvagno, Montagnana, Poli, & Guidi, 2006a, 2006b). Therefore anything that interferes with, changes, or otherwise affects the result of a pathology test can be considered an error.

The ability to detect errors in pathology results using patient data as its own control has been suggested as far back as the 1970's (Ladenson). By comparing cumulative results for patients and repeat analysis of their specimens, he narrowed down any errors to two potential causes, noted as Group A – occurring outside the laboratory, and Group B - occurring within the laboratory. Over time, these errors have been reclassified into three broad categories, Pre-analytical error, Analytical error, and post-analytical error. While not specifically "within" or "outside" of the laboratory, these categories are considered to be a more accurate means of describing error associated with the laboratory testing process. The pre-analytical phase is considered to be anything that occurs to the request or specimen from the actual requesting by medical staff, right up to the testing of the specimen. The Analytical phase is restricted to the analysis of the specimen while the post-analytical phase is the reporting, interpretation, and follow up of the test result.

2.2 Sources Of Error In The Laboratory

2.2.1 Pre-analytical error

Examples of pre-analytical error include haemolysis, collection from the wrong patient, inappropriate anticoagulant, inappropriate volume collected, clotting, IV fluid contamination, incorrect tourniquet use, unlabelled and mislabelled specimens and request form related errors (Da Rin, 2009; Salvagno, Lippi, Bassi, Poli, & Guidi, 2008; Wians, 2009). These errors will be discussed in more detail in a subsequent section of this review.

2.2.2 Analytical error

Analytical errors have been broadly described by Wians (2009) as either random (i.e. errors that occur randomly, independent of the operator) or systematic (such as a change in the instrument calibration). Examples of analytical error include equipment malfunction, failures in quality control procedures and laboratory mix up of specimens. Witte, VanNess, Angstadt, and Pennell (1997) found an analytical error rate of 447 ppm (0.05%) of tests performed in their chemical pathology laboratory, while previously a sample of laboratories in Australia were found to have analytical error rates between 2% and 30% when external quality assurance results were surveyed (Khoury, Burnett, & Mackay, 1996). The wide variance of these results illustrates the need for a standardised system of error reporting, as what constitutes an error in one study may not apply in another.

2.2.3 Post-analytical error

Post-analytical error includes validation of suspect results, transcription errors, incorrect interpretation of results, excessive turnaround times and failure to notify physician of critical results (Da Rin, 2009; M. Plebani & Carraro, 1997; Wians, 2009). It is also acknowledged that the clinician has a responsibility to follow up on tests requested, and relay these results to the patient in a timely manner (Graber, 2006). Failure to do so is also an example of post-analytical error. One study found that as many as 37% of clinicians surveyed had discovered a patient whose previous significant test results had not been followed up (Wahls & Cram, 2007). As these tests included diagnostic testing for malignancies, and only included patients who returned for follow up, this number is particularly alarming. A more comprehensive review of the post-analytical process, including result review, patient notification of significant results and appropriated follow up, found the average rate of missed results to be 7.1% (Casalino et al., 2009).

However the individual practice rates varied substantially, from nil to 26.2%. This is indicative of a lack of standard procedures for notifying patients of abnormal results, even between staff at the same practice. Failure to notify patients of important laboratory results is not restricted to clinics or general practice, as demonstrated by a study performed in the hospital setting. Roy et al. (2005) found that 0.9% of discharged patients had significant results that were not notified to the patient or their primary care clinician. These studies suggest that follow up of clinically urgent or significant results can be inconsistent and requires attention by both the laboratory and the clinicians.

2.3 Types Of Pre-Analytical Error

While patient identification is undoubtedly one of the most important pre-analytical steps, it is just one in a long list of variables that can be classified into the following categories: Patient identification related, request related, collection related and sample related.

2.3.1 Patient identification and labelling of samples

In order to determine if misidentification of patients having pathology specimens collected was widespread, a large prospective study was undertaken into identification errors within the general clinical laboratory, over a substantial number of institutions (Valenstein, Raab, & Walsh, 2006). The authors separated the errors into those detected before validation of results, and those detected after validation, with the hypothesis that institutions detecting more errors before validation would have lower post-validation error detection rates. Overall, the pre-validation error rate was 324 identification errors per 1,000,000 billable tests (0.0324%), and post-validation error rate was 55 errors per 1,000,000 billable tests (0.0055%). The authors report that significantly lower post-validation error rates were reported by institutions that already had an identification

error tracking program in place, so they are likely to be more vigilant in detecting such errors than institutions that relied on spurious results alone to detect errors. The authors have also attempted to outline the potential impact of these errors by asking participants to record adverse events associated with the reported errors. A total of 345 of these were reported, with the majority being linked to material inconvenience to the patient, without permanent harm. While a substantial volume of data was collected for this study, it relied on self-reporting by the institutions and was only performed over a 5 week period. There is potential for a longer data collection period to show more accurate identification error rates, in addition to other pre-analytical errors that may not have been considered an identification error, yet still contributed to adverse events.

A more recent study by Carraro et al. (2012) investigated what they classified "pre-pre-analytical errors", the initial steps of the testing process that occurs on the hospital ward, before specimens are collected and supplied to the laboratory. By observing clinical staff from test request to specimen collection, they recorded any non-compliance with protocols over a week long period. Of particular concern in this study was the number of patients who underwent specimen collection without their identity being verified by nursing staff (15 cases), which resulted in three confirmed cases of misidentification. The authors also noted that in 2 of these cases, the blood was collected into pre-labelled tubes, a further breach in protocol. If these results were to be extrapolated, there are potentially 156 cases of misidentifications occurring annually in the facility where the study was performed.

2.3.2 Patient related variables

Patient related variables are mostly variables that can only be controlled for, not eliminated, such as fasting status, posture, medication status, exercise and pre-existing medical conditions such as pregnancy (Garza D, 1999). For example, collection for cortisol, a diurnal hormone, is performed in either the morning (peak) or afternoon (trough). It is important to know which the clinician is testing for in order to collect at the most appropriate time. Other patient related variables include disease states such as leukaemia, increased platelet and white blood cells and hyperglobulinaemia (Dalal & Brigden, 2009).

2.3.3 Test request errors

Request related variables include all the details which are required on the request form such as patient details, clinician details, signature of collector, in addition to clinical information which may be helpful to the laboratory, and the tests that are being requested by the clinician. Requirements may vary by laboratory (Dzik et al., 2003). A study assessing the impact of missing information on request forms found the most common incomplete information related to patient medication, which was missing from 89.6% of all forms (Nutt, Zemlin, & Erasmus, 2008). Although medication history may seem unimportant to the laboratory, it is vital in the interpretation of some tests, such as the APTT for heparin infusion monitoring or therapeutic drug levels such as gentamycin. Failure to provide this information may lead to unnecessary investigations by the laboratory (including mixing studies, Lupus anticoagulant investigation), or bothersome phone calls to clinical staff to confirm dosage and administration. Both are a waste of time and resources that could be better utilised. Other missing information noted was contact information for the clinician (61.2%), diagnosis or clinical information (19.1%), time of specimen collection (15.3%) and date of specimen collection (3.3%). Lack of clinical information is also anecdotally a frustrating problem

for laboratory scientists, as interpretation of results is restricted by the information provided. For example, if results indicate renal failure, the laboratory is dependent on clinical information to determine if this constitutes a critical result (requiring immediate notification of results to the clinician), or if the patient is in chronic renal failure and the result does not require notification. Missing time and date of collection can also impact on interpretation of results, as the age of the specimen and subsequent degradation can mimic results of true clinical states. Contact information for clinicians is essential for notification of critical results, and lack of this information on request forms may lead to delay in notification, or in the worst cases, no notification at all.

2.3.4 Sample collection and quality errors

Collection related variables include tourniquet technique, order of draw, quality of sample (overfilled/under filled, haemolysed samples, clotted samples, IV contamination, bacterial contamination), and most importantly, the collection must be from the correct patient. It is important that these collection related variables are well understood by the personnel collecting the specimens, as correct technique is essential for producing a quality specimen (Young, 2003).

2.3.4.1 Haemolysis

Haemolysis is defined as the breakdown or rupture of red blood cells, and the resultant release of intracellular contents, leading to the artefactual increase of these components such as potassium into the specimen (Stankovic & Smith, 2004). This rupture can be the result of poor phlebotomy techniques such as using an inappropriate size needle, drawing back too fast on a syringe plunger, prolonged tourniquet use and excessive mixing of specimen tubes (Garza D, 1999; Saleem, Mani, Chadwick, Creanor, & Ayling, 2009). As intravascular haemolysis can also occur, it is important for

artefactual haemolysis to be minimised whenever possible.

The haemolysis of specimens for laboratory investigation can impact on the analysis of the specimen. For example, lysed specimens were found to result in statistically significant overestimation of Prothrombin time and D-dimer, and underestimation of Activated Partial Thromboplastin Time and Fibrinogen (Lippi, Montagnana, Salvagno, & Guidi, 2006). In a separate study, it was also found that increased haemolysis resulted in overestimation of many biochemical analytes, including potassium, urea, creatine kinase and lactate dehydrogenase, and a decrease in albumin, chloride, glucose and sodium among others (Lippi, Salvagno, Montagnana, Brocco, & Guidi, 2006). The actual cause for these effects can either be due to interference of the cellular compounds that are released into the plasma with the test reagents, change in absorbance of light due to free haemoglobin or direct increase of the concentration of intracellular components such as occurs with the measurement of potassium and lactate dehydrogenase (Lippi et al., 2008).

Higher rates of haemolysed specimens have traditionally been noted in emergency departments, where routine collection of laboratory specimens through intravenous catheter is more likely to occur (R. C. Hawkins, 2010; Salvagno et al., 2008). Pretlow, Gandy, Leibach, Russell, and Kraj (2008) found that the source of haemolysis in their emergency department could be identified as collection technique. They eliminated both laboratory processing and collection equipment as possible causes of increased haemolysis, however this study appears to be limited to venepuncture with butterfly assembly, and does not include blood drawn from intravenous catheter. They did note a few cases of syringe draw, and subsequent forcing of the collection into evacuated tubes, and heavily discouraged this practice.

In an effort to determine if haemolysis rates differed between intravenous catheter draw methods, Stauss et al. (2012) compared the collection of specimens directly from intravenous catheter hub with those collected through extension tubing, and found no significant difference in haemolysis rates. In fact, the rate of haemolysis with both methods was unacceptably high (at around 30% of all specimens in both groups having visible haemolysis). This study also documented some of the beliefs of the nursing staff at their institution with regards to haemolysis. They believed that they knew when a specimen was haemolysed, that haemolysis was dependant on the laboratory staff performing the analysis, and that anticoagulant therapy might cause haemolysis in the samples. This highlights the need for detailed education of all staff undertaking collection of blood for laboratory specimens, especially concerning their role in the collection of a quality sample.

An audit performed in the United Kingdom found the estimated cost of repeating specimens that were haemolysed in the emergency department was £4355 a month, which equates to £52260 per year (Jacobs et al., 2012). The authors argue that the cost of employing a dedicated phlebotomist would be offset by the cost savings of less repeated samples. However, a study in 2008 showed that a reduction in haemolysis rates can also occur when a dedicated venepuncture is used by nursing staff to collect blood samples (Lowe et al., 2008). This demonstrates that employing specialised phlebotomy staff, while ideal, is not essential to keep haemolysis rates low. This finding was confirmed by a separate group in 2011, who found the haemolysis rate dropped from 23% to 6.6% when policy was changed to mandate separate venepuncture for laboratory specimen collection by nursing and clinical staff (Straszewski et al., 2011), further demonstrating the importance of proper sample collection.

2.3.4.2 EDTA contamination

The order of draw, or the order that tubes of blood are collected from the patient, is vital in maintaining sample integrity and reducing chance of contamination of the specimen. The current recommendation for order of draw is 1) blood cultures, 2) sodium citrate (coagulation), 3) Plain serum, 4) Lithium heparin, 5) K-EDTA and 6) Fluoride oxalate (M. Cornes et al., 2016). By collecting serum and lithium heparin before potassium EDTA, it has been argued that this reduces the likelihood of contamination of specimens for clinical chemistry analysis with large amounts of K-EDTA. However, several studies have found that when correct phlebotomy technique is utilised, there is no contamination demonstrated (M. R. Cornes et al., 2012; Sulaiman et al., 2011). The differences in results from these studies suggests variation in both phlebotomy technique and equipment, however the phenomenon of EDTA contamination is not restricted to order of draw disparity. Other causes include EDTA anticoagulated specimen being intentionally added to a serum or heparin tube (for example to "top up" the level of blood) and lids from EDTA and heparin tubes being unintentionally reversed (and potentially corrected before sending to the laboratory) (Davidson, 2002). It is still important for laboratory scientists to be aware of the effects of such contamination to avoid the release of spurious results. The most common result affected, with the exception of potassium, is a lowered serum/plasma calcium level. This is due to the chelating effect of potassium-EDTA, it binds to calcium in the blood (which is how it anti-coagulates), and the calcium is therefore unavailable for measurement (Davidson, 2002). This can make detection of EDTA contamination easier, however a calcium panel is not always requested by the clinician, leaving potassium the most likely indicator of contamination in the laboratory.

2.3.4.3 Pseudo-hyperkalaemia due to improper collection

Several studies have investigated the phenomena of pseudo-hyperkalaemia, where the potassium level seems to be artefactually increased, often normalises after repeat collection, and cannot be attributed to haemolysis, transport or storage conditions (Bailey & Thurlow, 2008; Don, Sebastian, Cheitlin, Christiansen, & Schambelan, 1990; R. Gambino, Sanfilippo, & Lazcano, 2009; Trull et al., 2004). In particular, the authors of these studies found that clenching of the hand or fingers during phlebotomy caused in an increase in the potassium concentration in the resulting specimen, with results being significantly raised from the actual potassium level in the patient.

2.3.5 Sample transport and processing errors

Sample related variables centre around the treatment of the specimen once it has been collected – transport to the laboratory, centrifugation, exposure to light and extremes of temperature. While seemingly self-explanatory, these variables are very important especially when the specimens are collected at a distance from the laboratory, for example at an outlying health care facility or collection centre. The conditions of transport for specimens are not often monitored, so specimens cannot be rejected for analysis unless the transport chain has been obviously inadequate, for example arrival at the laboratory with melted ice bricks. When monitoring occurred in one study, almost 20% of transportations exceeded temperature limits (Zaninotto et al., 2012b). Introduction of a standardised sample transport system reduced the unacceptable transportations to just 2.5% over 3 years.

A study into the effects of transportation found wide variations in results for some analytes, particularly potassium, alanine amino-transferase (ALT) and the activated partial thromboplastin time (APTT) when specimens were transported without monitoring of conditions (Zaninotto et al., 2012a). After the introduction of the integrated standardised transport system described in the previous study, the effect of sample transport declined. This study confirms that transport conditions are critical for maintaining the integrity of specimens for laboratory analysis. In a separate study, the effect of seasonal ambient temperature on potassium levels was investigated (Sinclair, Briston, Young, & Pepin, 2003). It was found that in the cooler months, the mean serum potassium concentration of specimens transported from an external collection room was higher than in the warmer months. In hospital samples not subjected to the transport, mean concentrations did not show any significant differences between seasons. This is consistent with the known artefactual increase in potassium in specimens which are stored in refrigerated conditions before centrifugation. Insulated transport conditions were also introduced in another study, where the ambient temperature of -3°C was causing spuriously high potassium levels in specimens transported from an external collection centre (Smellie, 2007). The insulation reduced spurious results successfully. It is important that the measured potassium level accurately reflects that of the patient to avoid any unnecessary treatment for hyperkalaemia, or in some cases when hypokalaemia subsequently goes undetected due to artefactually raised potassium levels. Prompt centrifugation of specimens after collection is therefore vital in ensuring accurate results are returned to the clinician. Particularly, in patients with acute lymphoblastic leukaemia and chronic lymphocytic leukaemia, it has been demonstrated that breakdown of white cells between collection and centrifugation of the specimen could result in a significant increase in potassium (Smellie, 2007; Wills & Fraser, 1964). Pseudo hyperkalaemia has also been reported in a family who were found to have abnormal leakage of potassium from cells when specimens are left standing at room temperature, in comparison to cold or refrigerated specimens as previously noted (Stewart, Corrall, Fyffe, Stockdill, & Strong, 1979). When centrifuged immediately, the plasma potassium levels for these patients were normal.

2.3.6 Pre-analytical errors in transfusion medicine

The area of transfusion medicine has perhaps had the largest focus on pre-analytical errors, specifically patient identification errors, due to the potentially catastrophic result of transfusing a patient with the wrong blood group. Wrong blood in tube (WBIT) is the term used to describe a sample where the blood group obtained differs from the blood group on file, and is therefore considered to be from the wrong patient (Dzik et al., 2003). Most studies acknowledge that the true WBIT rate is likely to be higher than the reported rate, due to silent WBIT, so called because the wrong patient may have been collected, but coincidentally have the same blood group as the patient intended for transfusion. Correction factors can be applied; however the true WBIT rate is still just estimation. Rates of WBIT are estimated range from 0.007% to 0.6%, depending on the study (Dzik et al., 2003; Linden, Wagner, Voytovich, & Sheehan, 2000; Murphy, Stearn, & Dzik, 2004; Quillen & Murphy, 2006). While these results could be extrapolated to include other areas of the laboratory such as haematology or clinical chemistry, the more stringent legal requirements for transfusion specimens is likely to result in a lower error rate overall than may be seen in the wider pathology laboratory.

As previously mentioned, patient data can be used as its own control in other departments, primarily by the use of delta checks in automated laboratory systems (Ladenson, 1975). These methods compare the difference between current values, and previous values, flagging potential changes that may be due to erroneous sample collection or another error that can be detected by the validating scientist before results are sent to the clinician. However even these methods have their limits, with erroneous results not always detected, especially falsely normal results (Kazmierczak & Catrou, 1993; Valenstein & Sirota, 2004).

2.4 Quality Monitoring, Analysis And Improvement

While technological advances have helped to reduce the errors associated with the analytical process to rates as low as 13% of all errors (M. Plebani & Carraro, 1997), 1997), a detailed review of the literature in 2002 found up to 31% of errors in a laboratory were due to analytical causes (Bonini et al., 2002). This review also reports pre-analytical error rates ranging from 31 to 75% of errors, and post-analytical rates from 9 to 31%. The wide variance in frequencies reported across the data may be due to differences in criteria used for defining what constituted an "error", and also in how they were reported (whether by chance finding or by detailed retrospective analysis). A more recent study found the analytical error rate to be lowest at 15%, with 62% of errors at the pre-analytical stage and 23% at the post-analytical stage (Carraro & Plebani, 2007). This suggests that more work is needed in the area of identifying and preventing pre-analytical errors.

Until recently, there has been no standardised classification system for detecting and tracking of pre-analytical errors in the laboratory. A survey of laboratories in the United States sought to determine the most commonly used quality indicators within the laboratories (Preston, 2008). Despite the low response rate (6.58%), sufficient laboratories returned surveys to determine that there was little standardisation of quality indicators, with even the most common indicator (patient specimen identification accuracy) having only a 57% rate of compliance across the laboratories. The authors acknowledge the limitations of their data and recommend further data collection in this area.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established a working group to investigate Laboratory Errors and Patient Safety (LEPS),

who in 2009 published a list of quality indicators for standardisation of monitoring errors in the laboratory (L. Sciacovelli & Plebani, 2009). The indicators were developed in association with 26 international laboratories who volunteered to be enrolled in the study. The resultant list of 25 indicators is exhaustive, and includes 16 related to the pre-analytical phase, 4 to the analytical phase, and 5 to the post-analytical phase. The universal use of these indicators would allow for comparisons to be made across laboratories, and indeed across countries, as the categories would be common no matter where the laboratory is located. This, however, requires international acceptance of the proposed quality indicators. In addition to comparison across laboratories, having a standardised system of quality indicators would allow for benchmarking and monitoring of error within individual laboratories over time. The IFCC LEPS working group is continuing to develop and improve these quality indicators in an effort to achieve international consensus (M. Plebani, 2012).

Several authors have suggested the application of Six Sigma strategy in laboratories as means of monitoring laboratory performance against a recognisable standard (Gras & Philippe, 2007; Llopis et al., 2011; Nevalainen et al., 2000). Originally applied to the manufacturing and aviation industries, six sigma is a tool for total quality management that can also be applied to the laboratory setting to either solve problems and reduce defects, or quantify the performance of the laboratory on the sigma scale (Gras & Philippe, 2007). The six sigma strategy measures the deviation of a process from its end goal, the higher the sigma value, the less likely there will be defects in the process (Nevalainen et al., 2000). It is thought that average companies perform at a sigma level of 4, and exceptional companies close to a sigma level of 6. The sigma value is determined by defects per million (ppm). Llopis et al. (2011) found an average sigma value of 4.6 for pre-analytical processes outside the laboratory, and an average sigma value of 3.3 for pre-analytical processes within the laboratory. These values indicate a need for improvement in the laboratory based processes. The calculation and monitoring of sigma values in the laboratory is a worthwhile indicator of quality, and can be used as a benchmark for improvement and should be considered by each

laboratory when appropriate. If used in collaboration with standardised quality indicators as discussed previously, laboratories can monitor all aspects of error within their processes and display improvements in real time to policy makers.

Suggestions for quality improvement were discussed in a review by Hinckley (1997), when evaluating methods for quality design. The suggestions made are to focus on results, don't blame individuals for mistakes, invest in prevention rather than correction of non-conformances and that quality is in the process not the documentation. There are many advantages to taking a prevention approach to quality, including maximising efficiency (less time wasted following up on error) and more importantly, an overall reduction in error will also reduce the impact of these errors.

Two short term interventions to reduce the frequency of pre-analytical error were trialled at a hospital in the UK in 2010-2011 (Kemp et al., 2012). The first intervention involved displaying posters to raise awareness of some types of pre-analytical error (insufficient sample volume, inappropriate tube selection and clerical errors). These posters were displayed for a period of two weeks, and during this period pre-analytical error was discussed informally with ward staff. The second intervention involved a reminder screensaver being deployed on computers within the test hospital, ten weeks after the conclusion of the first intervention. The authors of this study found no significant effect on the frequency of these pre-analytical errors was obtained from either intervention. The authors conclude that "time constraints and high workloads mean that human error will occur unless human input is eliminated by automation". While a seemingly logical statement, the errors they sought to reduce (sample volume, tube selection and clerical errors), all require some level of human input and cannot be wholly replaced by automated means. This data suggests that a long term or more intensive intervention is required to have any significant impact on the frequency of pre-analytical errors in a health care facility, and demonstrates the need for a collaborative approach to reducing errors. Simply presenting the information without follow up or

interaction between the laboratory and clinical staff is insufficient.

A combined approach to reducing error had been previously suggested by Graber (2006) who noted that both the laboratory and physicians need to better understand each other's needs in order to improve safety associated with laboratory testing. Some of the relevant suggestions include keeping the physicians up to date with appropriate testing practices, and ensuring they are made aware of the factors that can result in false positive or negative tests. Both of these factors apply to the area of pre-analytical error.

2.5 Perception Of The Cause And Impact Of Pre-Analytical Error

While several studies have focussed on the knowledge and experience of staff performing blood collections (Chaturvedi, Suri, Pant, & Rusia, 2006; Manochiopinij, Sirisali, & Leelahakul, 1999; Wallin, Soderberg, Van Guelpen, Brulin, & Grankvist, 2007), little research has been performed to assess the perceptions of nursing and medical staff in relation to pre-analytical error. A recent observation study of nursing staff noted that staff were convinced haemolysis was related to the laboratory technician who analysed the specimen (Stauss et al., 2012), which indicates these staff performing blood collections assumed no personal responsibility for haemolysed specimens. This observation alone shows the need for further education of all staff that are responsible for collection of specimens, especially in the area of pre-analytical error prevention.

While investigating the cause of haemolysis in samples from ED, the authors of a study noted that ED staff believed excessive haemolysis rates to be a result of processing delays in the laboratory (Pretlow et al., 2008). When this belief was shown to be false, the ED staff still took a position of no-fault in relation to the haemolysis of samples.

When interviewing ward staff in regards to pre-analytical errors, 29% of staff gave the

opinion that equipment was the main contributing factor to their errors, and 23% admitted to lack of knowledge for appropriate tubes to collect for testing (Kemp et al., 2012).

2.6 Impacts Of Pre-Analytical Error

2.6.1 Impact on the patient

In the 1995 report "The Quality in Australian Health Care Study" (R. M. Wilson et al., 1995), it was estimated that 16.6% of hospital admissions were associated with an adverse event caused by health care management, resulting in extended hospital stays or a disability for the patient. This extensive study analysed the medical records of over 14000 patients for evidence of adverse events, using criteria determined by medical researchers. However, none of the 18 categories explicitly included laboratory related error, the categories had broad scope such as "Unplanned transfer from general care to intensive care" and "Unplanned readmission after discharge from index admission". This indicates the need for a more focussed study regarding the impacts of laboratory error on the patient in the Australian context. La Pietra, Calligaris, Molendini, Quattrin, and Brusaferro (2005) recommend that to analyse and plan to remedy a problem (in this case pre-analytical error rates in pathology), data collection is first required (for example chart review or event audits) and then summarisation of the data.

The broad impacts of pre-analytical error in the laboratory were estimated using process and risk analysis in 5 laboratories in Italy (Signori et al., 2007). In particular, the authors aimed to quantify the risk of such errors, define a uniform strategy for detection benchmarking errors, and to measure the impact of these errors on the laboratory outcome. A panel of experts defined the levels of damage as follows:

Level of Damage	Consequence
No damage	There are no consequences for the patient
Minimal damage	The only consequence for the patient is to repeat the test
Medium damage	Resulting in a delay in treatment or diagnosis
High damage	Resulting in inappropriate treatment or diagnosis

(Signori et al., 2007)

The authors of the study used the laboratory database to determine if any patients were recalled for recollection, and this was their sole measure of impact in the study. However, this limits the impacts measured to those where the clinician or laboratory detected the need for recall, "minimal damage" as per their definition, and does not register any potential cases of medium or high damage. Further data collection or review of patient charts would be needed to determine if these impacts occurred.

O'Kane, Lynch, and McGowan (2008) also attempted to assign an impact, or grading, of quality failures in their laboratory using similar criteria, with 5 overall categories of failure. However, they gave two scores for each failure, an actual (A score) and potential (P score) for the impact that was, or could have been, caused by the error. A and P scores were given as follows:

Failure Score	Description
1	Quality failure resulted in no change in clinical management and no adverse patient outcome
2	Quality failure resulted in minor clinical management change but no adverse patient outcome, e.g. delay in reporting test result caused a short delay in diagnosis but patient outcome was not affected
3	Quality failure resulted in minor adverse patient outcome e.g. need for additional venepunture
4	Quality failure resulted in moderate adverse patient outcome, e.g. patient started on lipid-lowering therapy on the basis of an incorrect cholesterol result
5	Quality failure resulted in significant adverse patient outcome, e.g. significant morbidity, mortality

(O'Kane et al., 2008)

This system is more thorough, and allows for the potential impact of the error to be assessed, even if the actual impact was limited. Over the 19-month study period, 72.7% of quality failures (across the laboratory, not just pre-analytical errors) were given an actual score of Grade 1, with all failures given an A score of Grade 3 or less. However the P scores were scored much higher, with 65.9% of failures scored at a P of Grade 5. This indicates the very high potential for patient harm, even though actual harm may be low due to the early detection of these errors by the laboratory.

2.6.2 Transfusion safety

The largest body of work regarding implications of pre-analytical error is again in the area of transfusion medicine, due mostly to the degree of potential consequences of such error. While a significant risk of transfusion is that of transmitting infectious disease, as early as 1992 it was postulated that a blood product transfused to an

unintended recipient can be just as hazardous (Linden, Paul, & Dressler, 1992). A report of transfusion errors at this time in just one state of the US found three fatal incidents that could be attributed to acute transfusion reaction, due to the administration of the incorrect blood group, while a further 51 non-fatal incidents of ABO incompatible red cells were reported, including one patient who received 7 incompatible units before the error was picked up. These examples demonstrate the importance of pre-analytical safety in the entire chain of events, as any error made in the initial collection of the specimen may result in the administration of an incompatible blood product (Dzik et al., 2003).

2.6.3 Contaminated blood cultures

An example of a test which attracts attention for the quality of the specimen provided is that of the blood culture. Collected to assess if a patient has a bacteraemia, it is essential that the collection is aseptic, so that any bacteria subsequently grown in culture are truly representative of the patient, rather than a contaminant (Bates et al., 1991). While a false positive culture result may not initially seem detrimental, the actual cost to both the patient and the hospital may be significant. As true bacteraemia requires urgent antimicrobial intervention, positive blood culture results are considered significant until proven otherwise, resulting in unnecessary treatment and extended hospital stays when the microbe is proven to be a contaminant (Segal & Chamberlain, 2000). Studies have shown the economic cost to the patient (or the organisation) for a false positive result to range from an extra $642 to as much as $2500, mostly due to the increase in pharmacy costs and extended length of hospital admission (Segal & Chamberlain, 2000; Souvenir et al., 1998; Weinbaum et al., 1997). Published contamination rates differ depending on the institution and their policies, with frequencies reported from 1.3% to 10.2% (Archibald et al., 2006; Gander et al., 2009; Norberg, Christopher, Ramundo, Bower, & Berman, 2003; Segal & Chamberlain, 2000; Weinbaum et al., 1997). Importantly, the lowest contamination rates were associated with dedicated phlebotomy staff (Weinbaum et al., 1997) and the introduction of policy for dedicated phlebotomy draw (as opposed

to collection from an existing intravenous catheter) resulted in a significant reduction in contamination rates from 9.1% to 2.8% (Norberg et al., 2003). These studies show the importance of a quality sample collected in the pre-analytical phase of the testing process.

2.6.4 Medication Errors

When laboratory testing is requested to directly monitor therapeutic drug levels, or analytes for which physicians rely on for medication dosing (such as INR for warfarin dosing), it is vitally important to produce the correct result, and also the correct interpretive commenting on the pathology report. For example, Zemlin, Nutt, Burgess, Eiman, and Erasmus (2009) examined the information provided on request forms for thyroid function testing. They found that 74.5% of requests were missing medication history for the patient which may lead to inappropriate treatment of patients either already using thyroxine replacement therapy, or unnecessary reflex testing to determine a diagnosis which has been previously confirmed. This study was limited to potential impacts, as the patients were not followed up to determine if either of these effects had actually occurred.

2.7 Conclusions

There is a distinct lack of literature regarding pre-analytical error in the Australian context, especially relating to the economic impact of these errors on the healthcare system. The proposed study will fill the gaps in the literature, and propose interventional measures that aim to reduce these errors, and therefore the impact on both the patient and the healthcare system.

CHAPTER 3
GENERAL MATERIALS AND METHODS

3.1 Location of Study

This study was conducted at the pathology laboratory of the Townsville Hospital, a tertiary referral hospital with over 600 beds located in regional Queensland Australia. The Townsville Health Service district has a catchment population of over 230,000, and the laboratory performs pathology testing for the Townsville Hospital, several outlying hospitals, and private clients such as General Practitioners. A majority of testing is completed on site, however some complex and low-incidence testing is referred to the central laboratory in Brisbane.

3.2 Unique Identifying Number

Each specimen that is received into the Townsville pathology laboratory is designated a unique specimen identification barcode (lab number), to which the test requests are assigned in the laboratory information system Auslab (Citadel-Health, 2015). If multiple tests are requested for a single collection episode, the tests are all registered against a single laboratory number. For example, multiple tubes of blood taken from the same patient at the same time for renal function, haemoglobin, hepatitis serology and cross-matching will all share the same laboratory number. This laboratory number is dependent on sample type, thus different specimen types (e.g. blood and urine) will receive different laboratory numbers and are considered to be separate collection events. These laboratory numbers are assigned to, but different from, the Unit Record Number (URN) of each patient that is given by the hospital on the first admission for the patient, and therefore remains unchanged throughout their life.

3.3 Identifying Pre-Analytical Error – The "No-Test"

When a specimen cannot be processed or processing is delayed due to a pre-analytical error, a test code known as a "no-test" is registered against the laboratory number in accordance with Pathology Queensland procedures. The application of this test code is two-fold. It generates a report (both electronic and a paper copy when required) to inform the clinician that the testing will not proceed, so they can arrange a recollection if necessary, and it also keeps a record of the errors that were associated with the specimen. In some cases, usually only with minor clerical errors such as missing clinician or ward details on the request form, testing proceeds once the errors have been corrected. The no-test code will remain attached to the specimen to retain evidence of the original error. Thus, each no-test registration was considered an incidence of pre-analytical error for the purposes of this study. An example of an electronic no-test report page is shown in Appendix I.

3.4 Retrieval Of The Master Data List

A list of specimen identification numbers was retrieved retrospectively from the Laboratory Information System "Auslab" (Citadel-Health, 2015) using the extended enquiries statistical module. As the LIS database contains results for all 34 public pathology laboratories in Queensland, the following data limits were set:

- **Date:** 1-31st May 2008 May was chosen to ensure that variations such as new intern rotation and school holidays were limited.
- **Requesting Laboratory:** Townsville The LIS database separates the laboratory where tests are registered from those where the test is performed. By searching for all specimens registered in Townsville, this encompasses all the specimens whose primary specimen reception is performed in the Townsville pathology laboratory, even though they may have been collected at an external health care facility (such as Ingham or Palm Island Hospitals) or have tests that will be

performed in another laboratory (such as specialised molecular testing in Brisbane).

- **Test Code:** NOTEST A specimen is assigned a No-test registration if a pre-analytical error is detected and therefore testing cannot proceed..

3.5 Detailed Examination Of Laboratory Numbers

The list generated was then used to examine each of these lab numbers to record detail of the specimen, request form, pre-analytical error and subsequent requests by hand onto a worksheet (an example of this worksheet is shown in Appendix II). The information recorded was under the following categories:

- **Laboratory number:** Each specimen received into the laboratory receives its own laboratory number, a different number for each sample collection, type of sample taken (such as blood, urine, faeces), or site of sample collection (eg nasal swab, rectal swab). The only exception to this rule (for account billing purposes) is that all histology specimens taken on a specific date receive the same number, regardless of site sampled or type of specimen taken.

- **Date:** To ensure specimen was collected within the designated time frame for this study. Collection date was recorded from the registration screen and confirmed on the request form image.

- **Specimen type:** Although a majority of specimens received into the laboratory are blood, there are also a number of other specimen types processed, such as (but not limited to) urine, faeces, sputum, swabs, bone marrow and tissue. Specimen type was recorded from the registration screen and confirmed on the request form image.

- **Reason for specimen rejection:** To ascertain the pre-analytical error associated with the request, each no-test report page was examined. In addition, the

specimen notes (viewable only to the laboratory staff), request form digital image, and any other scanned documentation were also examined. This is important as the field “reason for rejection” may be blank, or the laboratory staff member may only record minimal information.

- **Ward:** The clinical area, external healthcare facility, or private practitioner where the specimen was collected.

- **Collector:** The request form and registration details were examined to determine if the specimen was collected by Clinical staff (Nurse or clinician), or by a Phlebotomist. In the Townsville Hospital, the phlebotomists are employed and trained by Pathology Queensland. As such, the Phlebotomist are required to identify themselves on the request form, therefore any collectors signature not determined to be a laboratory phlebotomist was recorded as Clinical staff. For the purposes of this study, a phlebotomist in the Townsville Hospital refers only to those employed by Pathology Queensland, and is not a general term for anyone collecting blood from patients.

- **Recollection occurrence:** Cumulative specimen history was reviewed for each incidence of pre-analytical error to determine if a recollection was performed in response to a no-test report. A subsequent specimen collection and registration was deemed to be a recollection if it was requested on the same day and collected immediately following the previously rejected test/specimen, or if the request form image specifically stated “recollection”.

3.6 Coding And Tabulation Of Data In Preparation For Analysis

The data was reviewed and coded by hand to ensure accurate description of all freehand data fields. A database was subsequently formed by entering this coded data into SPSS statistical software (SPSS 16.0 Graduate Student Version, IBM Analytics, St Leonards NSW). This master database was used for all studies in this thesis.

3.7 Statistical Analysis And Graphs

Descriptive statistics and frequencies were calculated using SPSS statistical software (IBM Analytics) and graphs were generated in Microsoft Excel. Significance was determined using Chi-squared test of independence.

CHAPTER 4
DETERMINING THE FREQUENCY AND ORIGINS OF PRE-ANALYTICAL ERROR

4.1 Introduction

Pathology testing is a vital part of the health system, with clinicians relying on a pathology test to make up to 70% of their treatment decisions (Carter, 2008). Despite its importance, consumers are often not aware of the many steps and people involved in their pathology testing, and are only aware of having a test when they are billed for it (Campbell, Linzer, & Dufour, 2014).

The total testing process in pathology consists of three main stages – pre-analytical (from requesting to point of analysis), analytical and post-analytical (reporting and interpretation of results). As each collection episode and sample progresses through the stages, there are many opportunities for error to occur and to affect the results that are issued to the clinician. The challenge in the laboratory is to recognise when an error has occurred and to prevent an incorrect result which may impact on the patient or the health care provider.

Examples of pre-analytical error include those relating to the request itself (e.g. inappropriate test requested or incomplete request form information), relating to the collection of the specimen (e.g. haemolysis or insufficient sample collection) and relating to treatment of the specimen (delayed centrifugation or delivery to the laboratory) (M. Plebani, 2012; M. Plebani, Sciacovelli, Aita, & Chiozza, 2014; L. Sciacovelli & Plebani, 2009).

It has been suggested that varying work practices and workload between clinical areas can

be a factor in the rates of pre-analytical error. For example high workload (R. C. Hawkins, 2010) and trained phlebotomy staff (Gander et al., 2009) have both been cited as having an impact on the rate of pre-analytical errors.

This study aims to determine the overall rate of pre-analytical errors in specimens received into the Townsville Hospital Laboratory, the origins of these errors and if any variation in work practices can be identified as influencing the rate of error in different clinical areas.

4.2 Materials and Methods

4.2.1 Frequency of pre-analytical error in the Townsville laboratory

Each specimen that is received into the Townsville pathology laboratory is designated a unique specimen identification number barcode (laboratory number), to which the test requests are assigned in the laboratory information system Auslab (Citadel-Health, 2015). When a specimen cannot be processed or processing is delayed due to a pre-analytical error, a test code known as a "no-test" is registered against the laboratory number in accordance with Pathology Queensland procedures. Therefore a permanent record of pre-analytical error is retained. Each no-test registration was considered an incidence of pre-analytical error for the purposes of this study.

No-test registration data for the month of May 2008 was obtained from the laboratory information system using the extended enquiries module as described in Chapter 3. Each registration was recorded, including examining the request form, results and any subsequent recollection episode. The total frequency of pre-analytical error for the Townsville laboratory was then determined by comparing the number of collection episodes with a no-test registration (and therefore pre-analytical error), with the total

number of registrations for the month of May 2008.

4.2.2 Comparison to similar studies

A review of the literature identified similar studies determining the frequency of pre-analytical error in other healthcare facilities. This allowed comparison of the frequency calculated in step 4.2.1.

4.2.3 Pre-analytical error associations with type of collector

The request form image for each occurrence of error was examined to determine who collected the specimen. Phlebotomists at our facility are required to identify themselves on the request form, allowing each episode to be allocated into Clinical staff or phlebotomist categories. The rate of error associated with each collector type was examined.

4.2.4 Frequency of pre-analytical error and associations with clinical area

The data was categorised according to the originating clinical area (ward or health care facility). Inpatient clinical areas that share staff and resources were grouped together (e.g. medical wards 1-3, surgical wards 1-3), and all external health care facilities were grouped together for the purposes of this study. The rate of error associated with each clinical area was determined, and the statistical significance of differences in error rates between the clinical areas was estimated by Chi-squared test analysis.

4.3 Results

4.3.1 Frequency of Pre-analytical error in the Townsville laboratory

A total of 24572 specimens were registered into the laboratory for the month of May 2008 in the Townsville Laboratory. Of these, 1039 were found to have pre-analytical error, which is 4.22% of the total registrations (95% CI 3.98 – 4.49).

4.3.2 Total frequency of error and comparisons to similar studies

The rate of pre-analytical error in the Townsville pathology laboratory was found to be significantly different (p = <0.01) to the rate of error found in similar studies conducted in other facilities (Figure 4.1). Figure 4.1 shows the results of these studies, and their comparison to the current study.

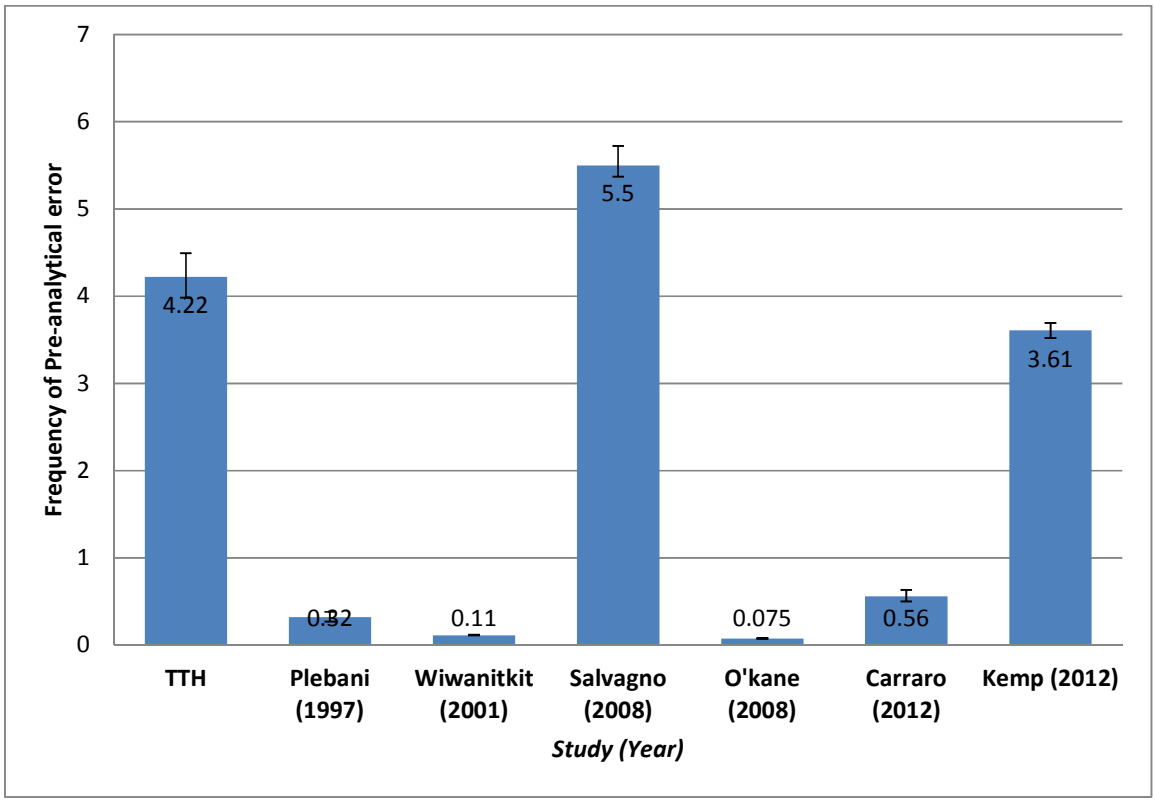

Figure 4.1: Frequency of pre-analytical error compared with available literature where error bars denote 95% Confidence Interval

4.3.3 Pre-analytical error associations with type of collector

The data showed a larger proportion of the errors occurred when specimens were collected by persons other than trained phlebotomists. A majority (82.3%) were collected by the clinical staff and 17.7% were collected by phlebotomists.

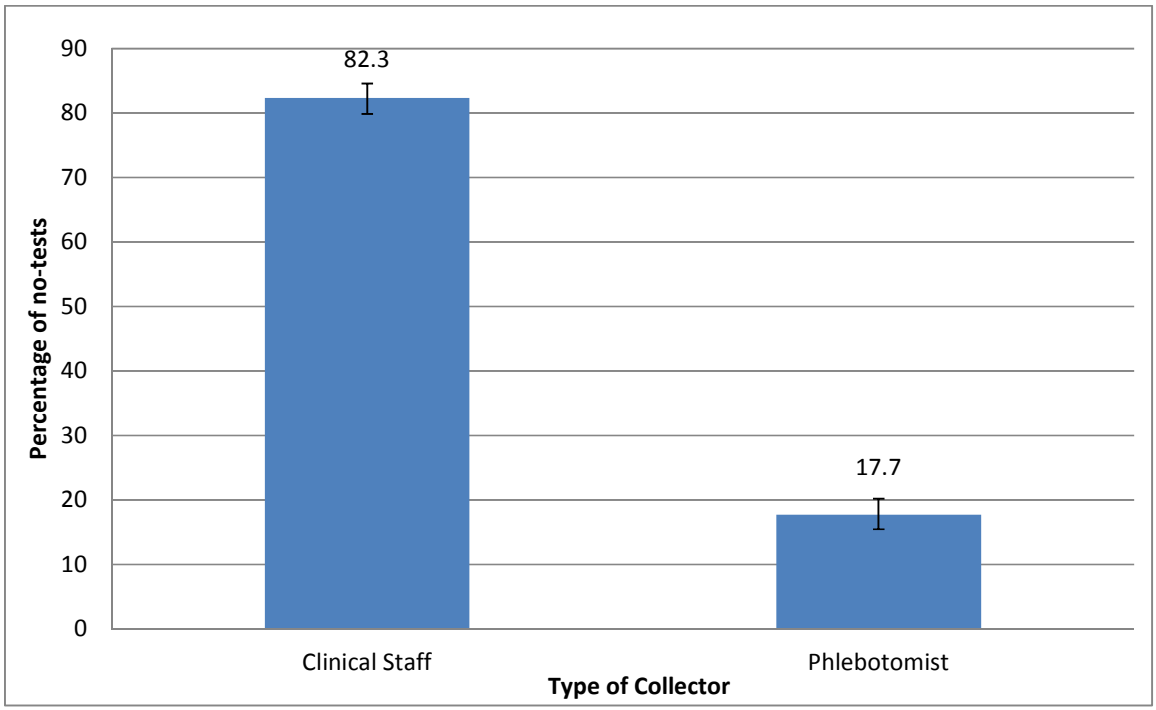

Figure 4.2: Frequency of pre-analytical error by type of collector, where error bars denote 95% Confidence Interval

4.3.4 Frequency of pre-analytical error and associations with clinical area

Registrations were categorised according to the clinical area of collection. The source of the highest number of errors was the emergency department (*n* = 212) which is twice that of the medical wards (*n*= 105), as depicted in table 4.1 below. The number of errors for the external healthcare facilities was also high (*n* = 137). When the overall workload for each ward is taken into account, the total percentage of pre-analytical error for the emergency department falls to just over 5%, which is lower than the rate seen in other departments (Figure 4.2). The ward with the highest error rate (as a percentage of total specimens) is the renal ward (15.44%), followed by the maternity ward/birth suite (11.70%). The wards with the lowest error rates are the neonatal wards (1.35%) and the Intensive Care Unit (1.40%). Using the Chi-squared test, the clinical areas were compared to determine if statistically

significant relationship existed. It was found that amongst clinical areas with the highest percentage of error, the Renal Unit and Maternity/Birth Suite showed significantly different ($p<0.01$) rates of error when compared against all the other clinical areas (but not each other), as indicated on the graph by an asterisk. Among clinical areas with low percentages of error, Neonatal and Intensive care wards show significantly different ($p<0.01$) rates when compared to most other clinical areas (the exceptions are mental health ward and theatres due to low overall numbers from these wards).

Table 4.1: Frequency of Pre-analytical error for specimens received into the Townsville pathology laboratory, categorised by clinical area

Clinical area	Total Registrations	Pre-analytical error Registrations	Frequency % (95% CI)
Renal Unit	434	67	15.44 (12.17 – 19.19)
Maternity/Birth Suite	342	40	11.70 (8.49 – 15.58)
Paediatrics	245	22	8.98 (5.74 – 13.28)
Emergency	3353	212	6.32 (5.52 – 7.2)
Emergency Medical Unit	786	46	5.85 (4.32 – 7.73)
Surgical Wards	1748	97	5.55 (4.52 – 6.73)
External Health Facilities	2681	137	5.11 (4.31 – 6.01)
Medical Wards	2000	105	4.99 (4.1 – 6.01)
Rehabilitation Ward	318	15	4.72 (2.66 – 7.66)
Cardiac Care Ward	440	20	4.55 (2.8 – 6.93)
Clinic and Outpatients	2597	94	3.62 (2.93 – 4.41)
Oncology and Onc Day Unit	1049	43	4.06 (2.95 – 5.43)
GP’s	916	28	3.06 (2.4 – 4.39)
Commercial Clients	1593	47	2.95 (2.18 – 3.9)
Mental Health Wards	139	4	2.88 (0.79 – 7.2)
Day Surgery and Theatre	387	7	1.81 (0.73 – 3.69)
Neonatal Wards	1185	16	1.35 (0.77 – 2.18)
Intensive Care Unit	1789	25	1.40 (0.91 – 2.06)
Other	2455	14	0.57 (0.31 – 0.96)

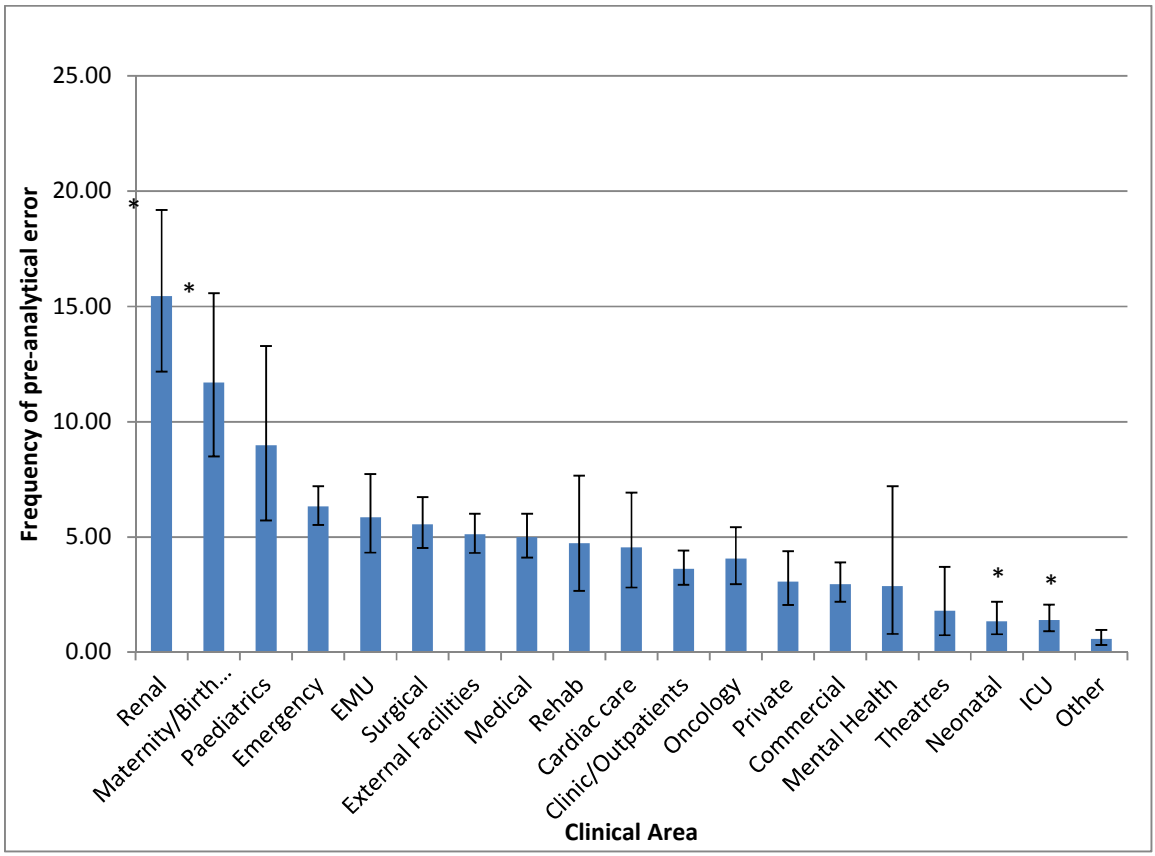

Figure 4.3: Frequency of pre-analytical error for each clinical area where error bars denote 95% Confidence Interval and *indicates significant difference at p <0.01

4.4 Discussion

4.4.1 Frequency of Pre-analytical error in the Townsville Pathology Laboratory

The current study found the Townsville Pathology Laboratory to have a total error rate of 4.22% (95% CI 3.98 – 4.49). The strict sample labelling and request form requirements in the laboratory may result in an increased reporting of errors, especially those that may not be considered errors in other laboratories. For example, it is a requirement for all samples coming into the laboratory to have a collector signature on both the sample and the form, regardless of the tests requested. In other laboratories, this may be restricted to specimens for pre-transfusion testing (a legal requirement for these tests). The laboratory is also rigorous in regards to complete identification on specimens and request forms, for example the patient name must be written in full (no initials) and spelled correctly, and the requesting doctor must endorse the request by signing the form.

4.4.2 Comparisons to similar studies

To determine if the rate of error in the current study is higher than other studies, a review of the literature was conducted. The percentage error of 4.22% in the current study was the second highest rate of the studies found in the literature. M. Plebani and Carraro (1997) determined the rate of pre-analytical errors to be 0.32% (95% CI 0.27 – 0.38; 129 errors in 40490 tests) in their laboratory over a three month period. Wiwanitkit (2001) also had a low error rate of 0.11% (95% CI 0.11 – 0.12; 1048 in 935896 samples). The rate of pre-analytical errors detected by Salvagno et al. (2008) was 5.5% (95% CI 5.37 – 5.72; 3617 of 65283 samples) which is similar that determined in the current study. In the study published by O'Kane et al. (2008), the reported error rate is 0.075% (95% CI 0.07 – 0.08; 353 of 468285 samples) while in the study conducted by Carraro et al. (2012) an overall error rate

of 0.56% (95% CI 0.5 – 0.63; 304 of 53987 tests) was found. Kemp et al. (2012) found an error rate of 3.61% (95% CI 3.52 – 3.69; 7058 errors in 195695 samples) which is the closest to the rate observed in the current study.

The literature shows no consensus on what constitutes *reportable* pre-analytical error, thus comparing these studies is problematic. Although a list of common pre-analytical errors can be identified, when it comes to recording the errors themselves, each study took a different approach. For example, M. Plebani and Carraro (1997) chose to omit any error which was discovered before results were issued, and thus the overall rate of error was quite low in comparison to the studies who included all errors whether results were issued or not (Kemp et al., 2012; Salvagno et al., 2008). While justified by the authors as limiting the study to medically recognised mistakes, by design this study omitted important pre-analytical errors coming into their laboratory and therefore reduced the reported error rate. Without acknowledging and quantifying these errors, there is no opportunity to reduce them.

The current study chose collection episode (or "sample") as the unit of measure (e.g. 1039 samples had an error), as did a majority of the studies in the literature, however Laura Sciacovelli et al. (2012) chose "test" (e.g. 304 tests involved) and reported overall error rate as parts per million (5630 ppm). As multiple tests can be performed on the same sample, this reduces the reported error rate when compared to the other studies if only one test result was affected (such as potassium in a haemolysed specimen with additional tests not affected by haemolysis). Regardless of how many test requests are made for a sample, if pre-analytical error is noted then the collection episode should be counted.

The quality of data generated by any study is dependent on the method of data collection. The current study chose data retrieval from the laboratory information system that is used routinely by all staff according to protocols established by Pathology Queensland. This ensures that variation across shifts and between staff is kept to a minimum and no

additional effort or procedures are required for staff to identify pre-analytical error. Wiwanitkit (2001) had a relatively low error rate of 0.11% (1048 in 935896 samples). In this study, errors were recorded by staff working on the bench, only when a “suspect” sample or result was identified by the scientist or technologist. While this will capture obvious errors that have led to an erroneous result, there is the possibility that this recorded error rate is lower than the actual rate of errors in the laboratory due to pre-analytical errors that did not change the results significantly enough to be detected by the technologist. Salvagno et al. (2008) was 5.5% (3617 of 65283) limited their focus to the coagulation laboratory, however the long study period of 2 years and the intensive training of staff in recognising and recording these errors, demonstrates sufficient rigour for the results to be comparable to whole of laboratory studies. In the study published by O'Kane et al. (2008), relied on identification of errors by laboratory staff, and admit that due to fluctuation of this reporting over time (varying between 3 and 43 reports per month), has likely led to under-reporting of errors in their study. The authors acknowledge that although staff may have recognised and even acted on errors, they may not have been reported to senior staff for investigation as was required to be included in the study. In the current study, errors were identified and recorded as no-tests by staff routinely and have done for many years before the study data was collected, therefore there is a high degree of confidence that the pre-analytical error rate of 4.22% demonstrated in this study accurately reflects the actual rate of pre-analytical error in the laboratory.

4.4.2 Pre-analytical error associations with type of collector

The staff member collecting the specimens was examined as a potential factor for pre-analytical error by categorising the number of no-tests for each type of collector. The data was divided into clinical staff (nurses and Doctors) and phlebotomists. A majority of the no-tests were found to be collected by clinical staff (82.3%), with 17.7% collected by the phlebotomy staff. This indicates that specialist training in specimen collection may reduce the number of no-tests produced. To see if this was true for individual wards, the data was further categorised by the ward. If the training provided to phlebotomists was effective in

reducing errors, then it is expected that the wards routinely attended by the phlebotomy staff would have the lowest error rates. As seen in table 4.1 and figure 4.3, this is not the case. In fact, the wards with the significantly lowest rates of pre-analytical errors are not serviced by phlebotomists at all (ICU and NICU). Therefore, the type of collector is not the sole reason for the widely differing error rates in the wards across the hospital although it remains to be seen if particular types of error were reduced in the phlebotomy serviced wards.

4.4.3 Frequency of pre-analytical error and associations with clinical area

This study identified a critical factor in determining the pre-analytical error rate was the ward from which the sample was collected. The wards with the most errors were the renal ward and the maternity ward (including birth suite). The wards with the least errors were the neonatal wards (Neonatal Intensive Care and Special Care Units) and the Adult Intensive Care ward - the phlebotomy staff does not routinely collect blood in these wards. The difference in no-test rates between these sets of wards was both striking and significant (p <0.01), especially when comparing the renal ward (15.44%) with the neonatal ward (1.35%). There are several factors that may influence the rates in these wards. The neonatal and intensive care units are staffed by highly skilled clinicians and nurses, with extra training required before blood samples can be taken. For example, in the neonatal ward nurses are required to complete a capillary blood skills competency (for heel prick collection), and a venous sampling competency (for venepuncture). The staff member to patient ratio is also higher in these wards, often just one or two patients per nurse, while in the maternity and renal wards the ratio is one nurse to as many as 5 patients. Looking at Figure 4.3, the error rates in the remaining wards were not significantly different to each other. The specimens in the majority of these wards are collected by both clinical staff and phlebotomists.

The high error rate in the renal ward was unexpected and introduces further questions. Why does this ward have more errors than any other? Does the answer lie in the type of errors that this ward is producing? This will be examined in detail in the next chapter.

4.5 Conclusions

The Townsville pathology laboratory has a pre-analytical error rate of 4.22% which is the second highest error rate in the available literature. While phlebotomy staff showed a lower pre-analytical error rate than clinical staff, the training provided to them does not prevent the occurrence of all pre-analytical errors. Wards with highly skilled clinical staff have a much lower rate of pre-analytical error than the other wards in our hospital. Further research into the types of pre-analytical error may shed light on the reasons for high pre-analytical error rates in the renal and maternity wards.

Until there is consensus on the identification and recording of pre-analytical errors, any comparison between studies should be done with caution and interpreted after proper examination of the study methods.

CHAPTER 5
CHARACTERISTATION AND FREQUENCY ANALYSIS OF THE DIFFERENT TYPES OF PRE-ANALYTICAL ERROR

5.1 Introduction

The landmark report "To Err is Human", released by the Committee on Quality Health Care in America bought a new focus to safety and error in healthcare (Kohn et al., 2000). The implications of this report for pathology have been widely discussed, especially in the area of error reduction in pathology (M. Plebani & Lippi, 2010; Sirota, 2000, 2005). This has led to an examination of the rates of error in the total testing process of Pathology, during the three phases; pre-analytical phase, the analytical phase and the post-analytical phase (Hollensead, Lockwood, & Elin, 2004; Khoury et al., 1996; M. Plebani & Carraro, 1997).

Errors in the pre-analytical phase account for up to 85% of error in the total testing process (Lippi, Guidi, et al., 2006), highlighting the potential for a large number of patients to be adversely affected. Many studies have been conducted to assess the total rate of pre-analytical errors in different types of laboratories worldwide (M. Plebani & Carraro, 1997; Salvagno et al., 2008; Wiwanitkit, 2001), it is only more recently that the types of errors are being examined in more detail. The need for Quality Indicators to measure error in the laboratory is becoming apparent (Barth, 2012a, 2012b; Kirchner et al., 2007; M. Plebani, Sciacovelli, Aita, & Chiozza, 2014; M. Plebani, Sciacovelli, Aita, Padoan, et al., 2014; Preston, 2008; L. Sciacovelli et al., 2011; L. Sciacovelli & Plebani, 2009; Shahangian & Snyder, 2009).

In 2008, a survey of laboratories in the United States found that although most laboratories were monitoring error using Quality Indicators, the exact indicators used varied widely

across the laboratories (Preston, 2008), this highlighted the need for a consensus on what constitutes an error in order for comparison of these errors across laboratories and internationally. To facilitate this aim, a working group was established by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and a number of laboratories worldwide contributed data to the project. Many publications have chronicled the journey towards a consensus (Lippi et al., 2015; M. Plebani, Sciacovelli, Aita, & Chiozza, 2014; M. Plebani, Sciacovelli, Aita, Padoan, et al., 2014; M. Plebani, Sciacovelli, & Lippi, 2011; L. Sciacovelli et al., 2011; L. Sciacovelli & Plebani, 2009). However, the application of these Quality Indicators in the day to day practice of pathology laboratories is yet to be established, although it has already been noted that monitoring Quality Indicators alone is not sufficient to reduce error without also implementing an interventional strategy (Laura Sciacovelli et al., 2012).

In the previous chapter, the overall frequency of pre-analytical error for the Townsville pathology laboratory was established, and it was determined that the definition of "reportable error" may differ between laboratories. Remediation and reduction of error requires a clear understanding of the actual cause and source of error. It is the aim of this study is to better characterise the types of pre-analytical error associated with specimens received into the Townsville pathology laboratory, by examining more closely the data recorded within a "no-test" and to compare these with published Quality Indicators.

5.2 Methods

5.2.1 Type of error

The master data set was examined to determine the individual types of pre-analytical error that occurred in specimens received into the Townsville pathology laboratory for the month of May 2008. Each instance of pre-analytical error for this time period was determined by examining the associated laboratory record, request form and patient history. The type of error was then recorded on a pre-printed worksheet. Initially, 9 types of error were listed on the worksheet; however it quickly became clear that this was insufficient so freehand recording of error type commenced.

5.2.2 Frequency of each error type

The types of error were individually coded and tabulated in SPSS for analysis. Descriptive statistics and frequency analysis were performed to determine the frequency of each error type.

5.2.3 Categorisation of error types

The types of error were examined for clustering and assembling into categories. The three categories chosen were specimen related error, collector related error and request related error. Results were then split into these three categories and examined by descriptive statistics and frequency analysis.

5.3 Results

5.3.1: Type of errors

1039 laboratory records with pre-analytical error were examined in detail to ascertain the type of error associated with each incidence. Prior to data collection, it was estimated that there were 9 types of pre-analytical error associated with specimens received into the Townsville pathology laboratory, and these were used on the pro-forma data collection worksheet. However when data collection began, it quickly became clear that there were many more types of error, necessitating freehand comments on this section of the worksheet. At the conclusion of data collection, 23 different types of error were recorded for specimens coming into the Townsville pathology laboratory during the month of May 2008. These errors are described in Table 5.3.1

Table 5.1: Type and frequency of pre-analytical error associated with specimens received into the Townsville pathology laboratory

	Type of Pre-analytical Error	*n*	% (95% CI)
1	**No specimen received;** for example a FBC, Coag and UE is requested, but only the tubes for FBC and UE are received into the laboratory	197	19 (16.62 – 21.48)
2	**Incomplete request form**; missing the name and/or signature of the specimen collector	160	15.4 (17.74 – 13.26)
3	**Insufficient specimen;** provided for the tests requested – usually applies to blood samples however may also apply to urine, CSF, fluids etc	97	9.3 (7.64 – 11.27)
4	**Test already performed;** the request was for a test previously performed (eg a request for syphilis testing on a patient known to be positive for syphilis)	82	7.9 (6.33 – 9.7)
5	**Specimen incompletely labelled**; missing information such as name, date of birth or medical record number, or completely unlabelled	77	7.4 (5.89 – 9.18)
6	**Specimen quality** – **under filled specimen or overfilled specimen**; mainly relating to sodium citrate tubes for coagulation testing, but may also include blood cultures	68	6.5 (5.12 – 8.22)
7	**Specimen quality; clotted** when an anticoagulated specimen is required (eg FBC, coagulation testing or blood gas specimen)	66	6.4 (4.95 – 8.01)
8	**Incorrect specimen type;** for the test requested (eg EDTA tube collected for coagulation testing or viral swab collected for bacterial culture)	58	5.6 (4.27 – 7.16)
9	**Gross haemolysis;** the specimen is haemolysed at or above 10 on the haemolysis scale as determined by the chemistry analyser, and is therefore unsuitable for any testing.	55	5.3 (4.01 – 6.84)
10	**Other;** any reason that does not fit into any of the other categories	34	3.3 (2.28 – 4.54)
11	**Patient identification mismatch;** collected from the wrong patient or the form and specimen ID do not match	27	2.6 (1.72 – 3.76)
12	**Incomplete request form Dr;** missing the name and/or signature of the requesting doctor	25	2.4 (1.56 – 3.53)

13	**TMLOG;** Shorthand for “transfusion medicine log”; a transfusion specimen has already been tested on this patient on the same day, and the current specimen is stored	21	2 (1.26 – 3.07)
14	**Test not required;** the laboratory was contacted and asked to stop testing due to test erroneously requested	18	1.7 (1.03 – 2.72)
15	**Patient discharged** ; Patient released after a request is made, but before the specimen is taken. May refer to initial test or any test added on later	12	1.2 (0.60 – 2.01)
16	**Specimen age;** the specimen is too old for the test requested (eg specimens for ammonia must be tested within 1 hour of collection)	10	1.0 (0.46 – 1.76)
17	**Specimen quality (leaked);** the specimen has leaked from its container in transit to the laboratory and is therefore unsuitable for testing	8	0.8 (0.33 – 1.51)
18	**Specimen with no associated test request;** and/or request form received into the laboratory	8	0.8 (0.33 – 1.51)
19	**Specimen quality;** specimen **contaminated** by intravenous fluids (saline, dextrose or therapeutic drug) or by incorrect order of draw (eg EDTA contamination in serum sample)	7	0.7 (0.27 – 1.38)
20	**Incomplete request form; patient** details such as date of birth, name or medical record number (UR)	4	0.4 (0.1 – 0.98)
21	**Incomplete request form** ;missing the **ward** details	2	0.2 (0.02 – 0.49)
22	**Specimen not signed by the collector**	2	0.2 (0.02 – 0.49)
23	**Specimen quality unspun;** specimen received into the laboratory from an external site without centrifugation	1	0.1 (0 – 0.43)

5.3.2 Frequency of each type of error

The most frequent error (19% with a 95% CI 16.62 – 21.48) was that where no specimen was received for the test requested. The least frequent error) was that where the specimen was not centrifuged when received from an external site (0.1% with a 95% CI 0 – 0.53). The frequency of all errors seen is shown in Figure 5.1, where error bars denote 95% confidence intervals.

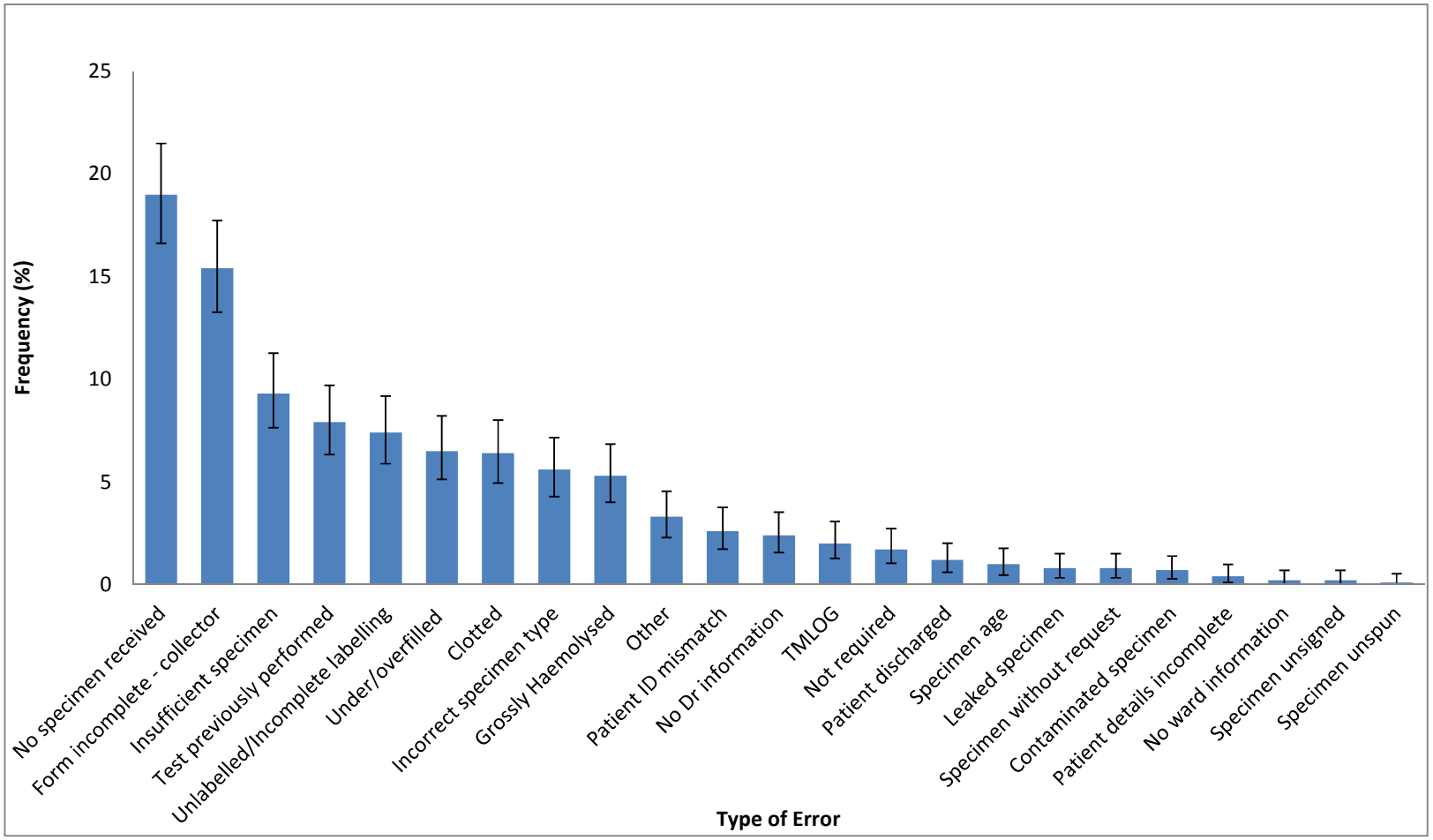

Figure 5.1: Frequency of each type of pre-analytical error associated with specimens received into the Townsville Pathology Laboratory where error bars denote 95% Confidence Interval

5.3.3 Categorisation of pre-analytical error types

Errors fell into three broad categories. Those related to the specimen itself, those related to the clerical input of the collector, and those related to the request itself (considered separately from the collection as it is usually filled out by a separate person). The error types were clustered into three categories, those relating to the specimen, those relating to the collector, and those relating to the request. The categories are shown in Table 5.2.

Table 5.2: Categorisation of pre-analytical error types

Specimen Related	Collector Clerical Related	Request Related	Other
No specimen received for request	Collector signature missing from request form	Test previously performed	Other
Insufficient specimen	Specimen unlabelled or incompletely labelled	Doctors information missing	
Under/overfilled specimen	Patient identification mismatch	Transfusion test previously performed	
Clotted specimen	Specimen unsigned	Test not required	
Incorrect specimen type		Patient details missing/incomplete	
Grossly haemolysed		Patient already discharged	
Specimen age		Specimen without corresponding test request	
Leaked specimen		Ward missing	
Contaminated specimen			
Not spun within timeframe			

Specimen related errors had a frequency of 55.34% (95% CI 52.26 – 58.39), collector related errors had a frequency of 25.6% (95% CI 22.97 – 28.37), request related errors had a frequency of 15.78% (95% CI 13.62 — 18.15) and all other errors had a frequency of 3.27% (95% CI 2.28 – 4.54).

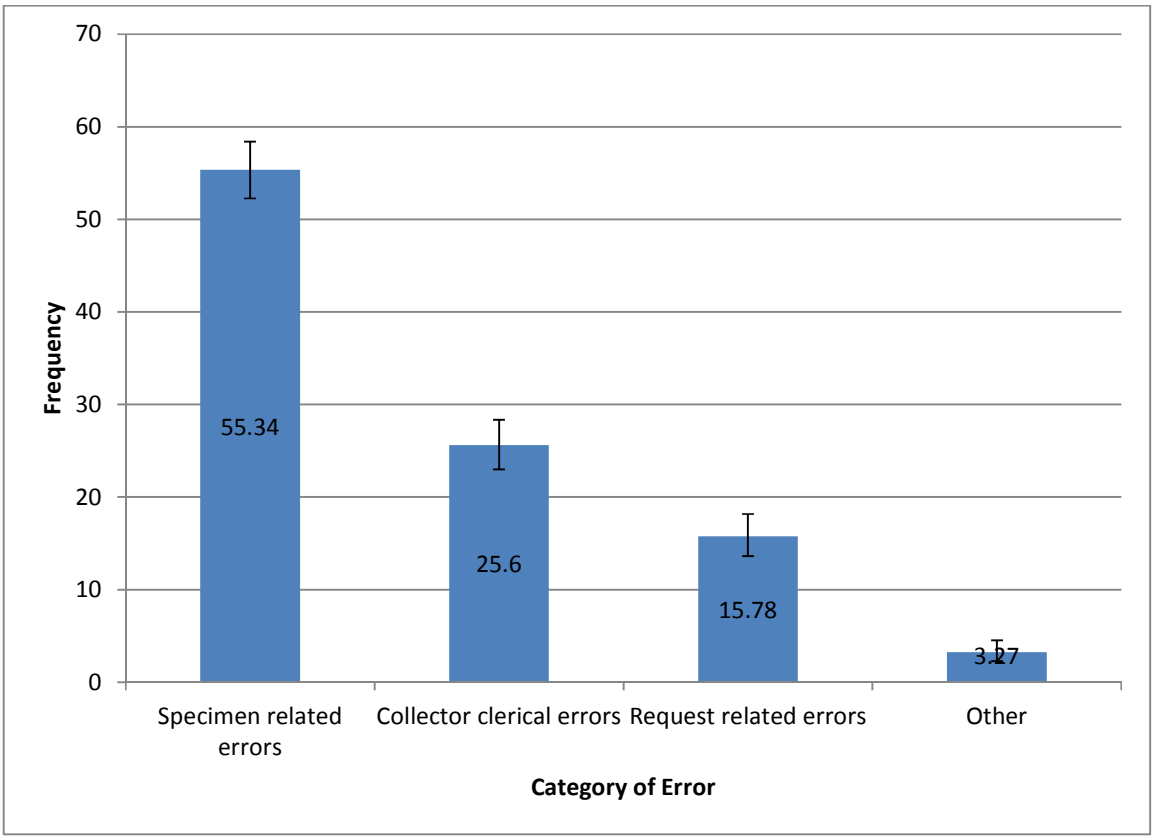

Figure 5.2: Frequency of the categories of Pre-analytical error where error bars denote 95% Confidence Interval

5.4 Discussion

5.4.1 Type of errors

It is clear from the results of this study that pre-analytical errors are many and varied, with 23 different types identified. However, previous studies have found differing numbers of errors in the laboratories. M. Plebani and Carraro (1997) found just 7 types of pre-analytical error in their initial study, and when repeated 10 years later (Carraro & Plebani, 2007), this number expanded to 15. Salvagno et al. (2008) determined 8 types of error to be associated with specimens in their coagulation laboratory, however this may not be directly comparable to the current study, as the scope was narrowed to just coagulation specimens. In a study restricted to the chemical pathology laboratory, Ashakiran, Sumati, and Murthy (2011) found 7 different types of error. The study that identified the smallest number of pre-analytical error types was performed by Wiwanitkit (2001) who found only 5 different types of error.

5.4.2 Quality indicators and pre-analytical error reporting

There has been a recent interest in identifying common quality indicators, for each laboratory to be assessed against regularly. A survey in 2008 of laboratories in the United States found that even within 21 laboratories located in the same state, there was no standardised approach for use of Quality Indicators (Preston, 2008). The authors concede that the very small sample size may indicate the sample is not representative of the larger population, and recommend that further studies be performed in the area to determine a consensus for quality indicators. A working group was established by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) to identify, implement and assess a Model of Quality Indicators (QI) for the total testing process in pathology (L. Sciacovelli & Plebani, 2009). In 2014 they listed their recommendations for Quality indicators for the pre-analytical phase of testing, a list comprising of 34 indicators (M.

Plebani, Sciacovelli, Aita, Padoan, et al., 2014). These are listed in table 5.3. The working group recommends a much higher level of detail in data collection than has been used in the current study, for example, the QI for inadequate sample volume for anticoagulant to sample volume ratio they recommend as a percentage only of total anticoagulated samples, in comparison to total samples as used in this study. The recommendation is also to separate specimens into departments, for example for haemolysed samples there is a QI for haematology and also a QI for chemistry. While theoretically possible for laboratories to record this level of detail, it may be particularly time consuming and labour intensive due to limitations in the different laboratory information systems being used by each laboratory. Ideally, a laboratory information system would have the in-built ability to collect this data with minimal additional input or information required from the operator, and it would be easily retrieved in a format compatible with analysis and submission to a reviewing authority (i.e. NATA, ISO, or RCPA).

Table 5.3: Quality Indicators in the Pre-analytical phase: Recommendations of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group (Plebani, Sciacovelli, Aita, Padoan, et al., 2014)

Category	Quality Indicator
Appropriateness of test request	Number of requests with clinical question (outpatients)/total number of requests (outpatients) Number of appropriate requests with respect to clinical question (outpatients)/total number/number of requests reporting clinical question (outpatients)
Patient identification	Number of requests with errors concerning patient identification/total number of requests Number of requests with errors concerning patient identification, detected before release of results/total number of requests Number of requests with errors concerning patient identification, detected after release of results/total number of requests Number of misidentified patients/total number of patients
Request form	Number of unintelligible outpatient requests/total number of outpatient requests
Order entry	Number of outpatient requests with erroneous identification of physician in physician's identification/total number of outpatients requests Number of outpatient requests with errors concerning test input (missing)/total number of outpatient requests Number of outpatient requests with errors concerning input of tests (added)/total number of outpatient requests Number of outpatient requests with errors concerning test input (misinterpreted)/total number of outpatient requests Number of inpatient requests with errors concerning test input (missing)/total number of inpatient requests Number of inpatient requests with errors concerning input of tests (added)/total number of inpatient requests Number of inpatient requests with errors concerning test input (misinterpreted)/total number of inpatient requests
Sample identification	Number of samples improperly labelled/total number of samples
Sample collection	Number of samples collected at inappropriate time/total number of samples Number of samples collected with inappropriate sample type/total number of samples Number of samples collected in inappropriate container/total number of samples Number of samples in insufficient volumes/total number of samples
Sample transportation	Number of samples damaged/total number of samples Number of samples transported at inappropriate time/total number of samples for which transport time is checked Number of samples transported under inappropriate temperature conditions/total number of samples for which the transport

	temperature - is checked - Number of samples improperly stored/total number of samples - Number of samples lost or not received/total number of samples
Sample acceptance/rejection	- Number of contaminated blood cultures/total number of blood cultures - Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant - Number of samples haemolysed (haematology)/total number of samples (haematology) - Number of samples haemolysed (chemistry)/total number of samples (chemistry) - Number of samples clotted (haematology)/total number of samples with anticoagulant (haematology) - Number of samples clotted (chemistry)/total number of samples with anticoagulant (chemistry) - Number of samples clotted (immunology)/total number of samples with anticoagulant (immunology) - Number of samples haemolysed (immunology)/total number of samples (immunology) - Number of lipaemic samples/total number of samples - Number of samples unacceptable (microbiology)/total number of samples (microbiology)

5.4.3 Pre-analytical error reporting in Australia

When considering pre-analytical error reporting in the Australian context, important work is underway. A group of interested stakeholders, headed by the Royal College of Pathologists of Australasia (RCPA), have come together to reach consensus on definitions for error, and also to assess error rates in individual institutions. With funding from the Quality Use of Pathology Program (QUPP), the RCPA launched an external Quality Assurance project called KIMMS – Key Incident Monitoring & Management Systems. By collecting information about pre and post-analytical error from laboratories, and providing reports in return, the KIMMS project brings attention and awareness of pre-analytical errors to the enrolled laboratories. As yet, there are no published results, however recommendations arising from the project have been presented to the funding body ("KIMMS," 2013). These recommendations are to standardise the definitions and terms for incident monitoring, and to discuss incorporation of KIMMS data requirements with Laboratory Information System providers.

5.4.4 Frequency of each type of error

Variability in error across the clinical areas was demonstrated in the data. The most frequent error was “no specimen received”, accounting for 19% of all errors, while the least frequent error was “specimen not spun”, with just 0.1% of all errors. This variance of frequencies reflects both the diverse range of error types discovered, and the heterogeneity of the clinical areas that the laboratory receives testing from. Outpatient and hospital clinic collections, for example, are performed in a room adjacent to the laboratory by trained phlebotomy staff, with minimal time delays and specimen transport needs as specimens are delivered directly to the laboratory after collection. Ward rounds within the hospital are also performed by trained phlebotomists, and specimens are delivered by pneumatic tube or ward clerk. In comparison, the Townsville pathology laboratory receives specimens from

several external healthcare facilities up to 400km away. Specimens are collected, processed (e.g. centrifuged or frozen), and packaged for transport (via Greyhound bus), all by nursing staff.

This indicated the need to further examine the types of errors produced by different sources, as interventions designed to ensure clinical staff fill out the request form appropriately are clearly irrelevant to the collection of the specimen by phlebotomy or nursing staff. In order to do this, the data was clustered into appropriate categories.

5.4.5 Categorisation of pre-analytical error types

The errors fell into three broad categories, those relating to the specimen (collection, transport and treatment), those relating to clerical duties of the collector, and those relating to the request itself. The results were therefore grouped into these categories. The most frequent errors were specimen related, accounting for 55.34% (95% CI 52.26 – 58.39) of the total errors. Errors related to collector clerical mistakes had a frequency of 25.6% (95% CI 22.97 – 28.37), request related errors had a frequency of 15.78% (95% CI 13.62 – 18.15.

The large proportion of these errors being attributed to specimen collection and transport indicates that current training provided to staff performing specimen collection is inadequate or potentially incomplete. However, as stated in the previous chapter, training of staff differs between wards within the hospital. In the next chapter, individual wards will be examined to determine if variation exists in the proportion of these categories of error.

5.5 Conclusions

Achieving a consensus on the definitions of pre-analytical error is a worthwhile goal; however it will need to be realistic and easily monitored by all laboratories in order to be effective. Any method requiring labour intensive data collection will likely be considered too difficult for ongoing monitoring and will fall out of favour with the laboratory. Ideally, the method for monitoring error should be considered when initially selecting a laboratory information system, however in reality, most laboratories already have established systems that are unlikely to be replaced. With this in mind, it is important for existing laboratory information system providers to consider an add-on package suited to collection of error data, although these may be cost-prohibitive for some laboratories.

CHAPTER 6
TARGETED INTERVENTION TO REDUCE THE FREQUENCY OF PRE-ANALYTICAL ERROR

6.1 Introduction

Retrospective observation and active monitoring of error rates in Pathology has consistently shown that pre-analytical errors contribute significantly to the overall rates of error, responsible for up to 85% of errors in the total testing process (Lippi, Guidi, et al., 2006). While monitoring error rates is both important and recommended, this alone will not result in a reduction of pre-analytical errors without an intervention. Steps need to be undertaken to ensure that improvements are made (Laura Sciacovelli et al., 2012).

Previous studies had investigated interventions designed to reduce error rates. Some interventions undertaken include specimen collection training programs (Kemp et al., 2012; Li et al., 2014; Ying Li et al., 2014), deployment of phlebotomy staff (Bologna & Mutter, 2002), implementation of automated pre-analytical tools (Da Rin, 2009; Hayden et al., 2008; Holman, Mifflin, Felder, & Demers, 2002), and application of a screening protocol for reducing unnecessary test orders (Stuart, Crooks, & Porton, 2002). While some improvement was shown with each intervention, the least successful of these relied on passive training; posters and screensavers with specimen collection advice and informal conversations with staff showed initial reduction, they failed to reduce the rates of error over a 6 month period (Kemp et al., 2012). Studies where protocol changes were implemented were more successful and resulted in a greater reduction in rates of error of between 30% and 40% (Li et al., 2014; Stuart et al., 2002; Ying Li et al., 2014). The implementation of automated or digitised steps in the pre-analytical pathway demonstrated the greatest error rate reduction, with up to 84% reduction in pre-analytical errors (Bates et al., 2001; Da Rin, 2009; Hayden et al., 2008; Holman et al., 2002). This indicates that a more involved intervention is necessary to effect real change in the workplace. Either a

change in official protocol or the implementation of a new process is required. A generalised intervention is less likely to lead to change in behaviour. Especially when the steps in the process are not able to be automated or require human input, to design a successful intervention, a specific target should be identified.

Although multiple studies have been undertaken to reduce errors, the impact of these interventions on the cost of error has been studied less frequently. A review undertaken by Green (2013), estimates that the average cost of pre-analytical errors in the United States medical system was between 0.23% and 1.2% of hospital operating costs. However it is difficult to extrapolate this in the Australian Healthcare context due to differing funding structure and insurance systems. Furthermore, Jacobs et al. (2012) estimated a cost of £4355 per month, purely for repeating haemolysed specimens from the emergency department of a British Hospital. It is clear from these two examples that the economic impact of pre-analytical error requires further study to gain a full understanding of the problem.

In the previous chapters, pre-analytical error rates have been examined to determine the source and the type of errors that occur independently of each other. This study aims to identify a target for intervention by analysing both the source and type of error in conjunction with each other, and to determine if an intervention is economically advisable by comparing the cost of pre-analytical errors with the cost of intervention in the target ward.

6.2 Materials and Methods

6.2.1 Frequency of pre-analytical errors categorised by error type

The data set was examined and errors were categorised by error type as determined in chapter 5. The frequency of each error type was determined for each clinical area and graphed in Microsoft Excel. By comparing the frequency of these error types across clinical areas the renal ward was identified as a target for intervention.

6.2.2 Approximate cost of request related errors occurring in the renal ward

By observation in the Townsville pathology laboratory, and consultation with the renal unit Nurse Unit Manager, average time for each step in specimen collection, transport and processing was estimated. The average wage per minute for each staff member involved was estimated from the Nursing, Operational, and Health Practitioner Award documentation.

6.2.3 Approximate cost of a theoretical intervention to reduce errors in the renal ward

Labour costs for a theoretical intervention were estimated both for a Scientific staff member to deliver an educational seminar, and Renal Unit staff to attend the seminar, from the Nursing and Health Practitioner Award documentation. Consumable costs were obtained from stores and procurement documentation.

6.3 Results

6.3.1 Frequency of pre-analytical errors categorised by error type

The frequency of errors related to specimen quality were found to range from 0.37 % in the clinical areas "other" (95% CI 0.17 – 0.69) to 5.71% in the paediatric ward (95% CI 3.16 – 9.4). There was no clinical area with a frequency that stood out as being significantly higher than the other areas, as shown by the large error bars in Figure 6.1

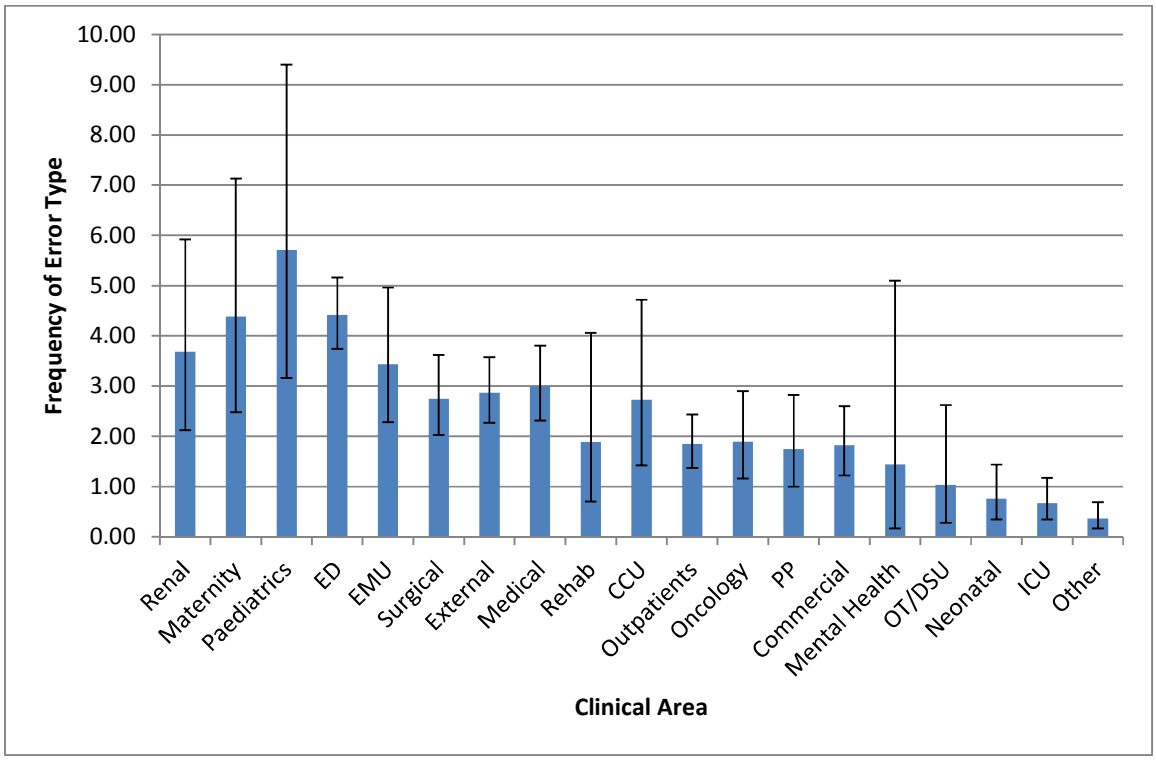

Figure 6.1: Pre-analytical errors related to specimen quality, where error bars denote 95% Confidence Interval

The frequency of errors relating to collector clerical errors was found to range from 0.12% in the "other" clinical areas (95% CI 0.03 – 0.36), to 3.80% in the maternity ward (95% CI

2.04 – 6.41). The large and overlapping error bars in Figure 6.2 show that none of the clinical areas have a significantly higher frequency of errors.

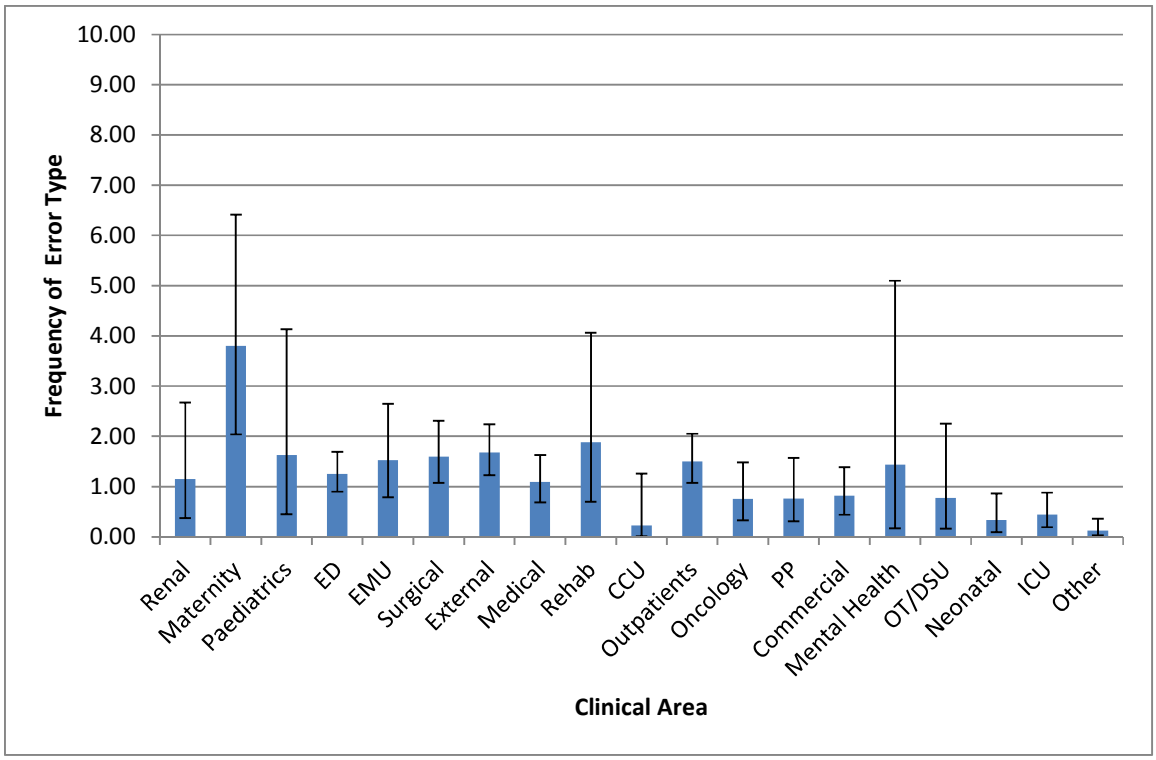

Figure 6.2: Pre-analytical errors related to clinical errors made by the collector, where error bars denote 95% Confidence Interval

The frequency of errors relating to the request was found to range from 0% (95% CI 0 – 0.95) for the Operating theatre and day surgery unit, to 10.60% (95% CI 7.86 – 13.88) for the renal ward. This high frequency in the renal ward was found to be significantly higher than the rest of the clinical areas (p = <0.01). The renal ward was therefore chosen as a target for intervention.

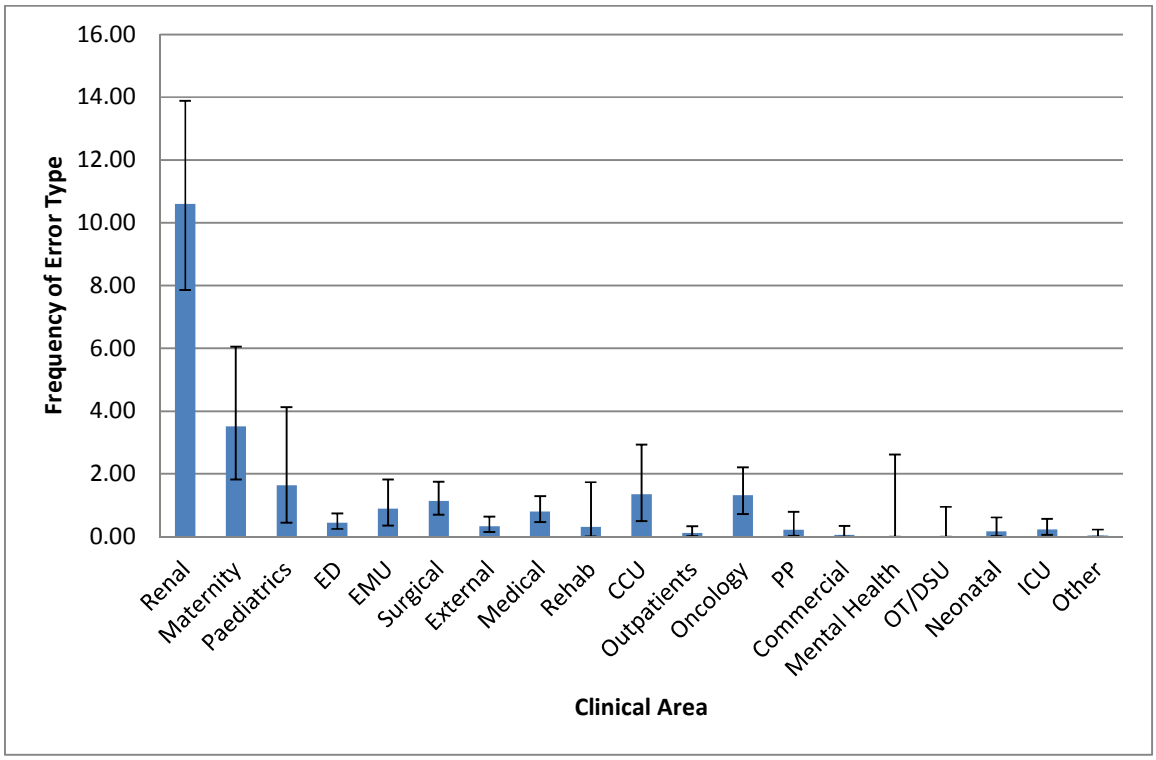

Figure 6.3: Pre-analytical errors relating to the specimen request, where error bars denote 95% Confidence Interval

6.3.2 Approximate cost of request related errors occurring in the renal ward

Table 6.1 shows the costs associated with pre-analytical errors in the renal ward relating to the request. The average time and cost per minute was estimated, giving an overall time of 27 minutes (range 21-42) and $15.01 (range $8.99 - $21.02) for each error.

Table 6.1: Time and labour cost associated with pre-analytical errors collected in the renal ward

	Average time for task (Range)	**Average Wage of Employee per Minute ($)**	**Average Cost (Time x Wage)**
Patient chart consulted	2 Minutes (1-3)	0.57	1.14 (0.57 – 1.70)
Request form written	2 Minutes (1-3)	0.57	1.14 (0.57 – 1.70)
Blood sample taken	6.5 Minutes (3-10)	0.59	3.84 (1.77 – 5.91)
Blood samples labelled, request form completed	4 Minutes (3-5)	0.59	2.37 (1.77 – 2.96)
Lamson to laboratory	5 Minutes	N/A	N/A
Specimen triaged/sorted/registered	4 Minutes (3-5)	0.46	1.86 (1.39 – 2.32)
Request checked/Patient history Checked	4 Minutes (3-5)	0.58	2.34 (1.75 – 2.92)
Notest performed	4 Minutes (2 – 6)	0.58	2.34 (1.17 – 3.51)
Total:	27 Minutes (21 – 42)		15.01 (8.99 – 21.02)

In table 6.2, the costs for consumable goods needed for specimen collection is given, the total is $2.70 for each error.

Table 6.2: Consumable costs associated with specimen collection

Consumable	Cost ($)	Total
Collection kit (syringe/needle/tube holder/alcowipe/cotton wool/specimen bag)	1.50	1.50
Tubes	0.35	0.70 (2 tubes for serology)
Total		**2.70**

In summary, the total cost of request related pre-analytical errors for the surveyed month was found to be $791.66 (range $537.74 - $1091.12). To estimate the total cost for one year, this was multiplied by 12 giving a total cost of $9499.92 (range $6452.88 - $13093.44). This is demonstrated below in table 6.3

Table 6.3: Total costs of pre-analytical error associated with requests in the renal ward

Item	Cost (Range)	Number of errors	Total cost for May 2008 (Range)	Total cost for 12 months (Range)
Labour	15.01 (8.99 – 21.02)			
Consumables	2.70			
Total	17.21 (11.69 – 23.72)	46	791.66 (537.74 – 1091.12)	**$9499.92 ($6452.88 – 13093.44)**

6.3.3 Approximate cost of a theoretical intervention to reduce errors in the renal ward

A theoretical intervention aimed to reduce the frequency of request related pre-analytical errors is proposed. The intervention consists of an instructive and informative presentation delivered to renal ward staff, detailing the need to consult the patient history to determine if serology testing is required. In addition, a checklist for the collection of the monthly renal bloods is suggested. Table 6.4 details the costs associated with delivering the intervention, specifically the wage costs for renal staff attending the presentation and the pathology staff member delivering the presentation, and consumable cost for handouts. The total cost was estimated to be $766.32.

Table 6.4: Labour and consumable cost estimate for a theoretical intervention

Item	**Cost per item ($)**	**Number of items**	**Total**
Labour for constructing power point presentation and handout	35.05 per hour (average HP wage)	2 hours	70.10
Labour of staff in renal ward attending presentation	35.48 per hour (average nursing wage)	3 half hour sessions 12 staff per session	638.64
Labour of HP staff delivering presentation	35.05 per hour (average HP wage)	3 half hour sessions	52.56
Paper and printing for handout	0.10 each	50 (all staff and spares)	5.00
Total			**766.32**

6.3.4 Cost analysis of Intervention

In table 6.5, the cost of both pre-analytical error and theoretical interventions are described to estimate any potential savings to the renal ward if these errors were reduced. It is estimated that $8733.60 could be saved over a period of 12 months if the intervention is successful in reducing errors associated with the request (specifically unnecessary serology requests).

Table 6.5: Summary of cost of error compared with cost of intervention

Cost of Pre-analytical error for one month	$791.66 ($537.74 – $1091.12)
Cost of Pre-analytical error for one year	$9499.92 ($6452.88 – $13093.44)
Cost of Intervention	$766.32
Potential savings for 12 month period	**$8733.60 ($5686.56 – $12327.12)**

6.4 Discussion

6.4.1 Frequency of pre-analytical errors categorised by error type

The results collected from The Townsville pathology Laboratory indicate that the frequency of both specimen quality related errors and clerical errors varied across different clinical areas of the hospital. None of the clinical areas had a significantly higher rate of error than any other. However, the renal ward clearly had significantly higher rates of error than any other clinical area (p=<0.01). When examining these results, it was found that the renal ward utilised a pre-printed request form for monthly screening bloods. All patients received the same testing protocol, regardless of their clinical history or previous results. In particular, serological screening for prior infections such as Hepatitis B and C requested every month, despite patients often having a previously positive result. This represents a potential source of error as these patients will continue to have a positive IgG result and these tests are ultimately "no-tested" by the laboratory staff every month. These errors represent a significant economic burden as the assays involved may be costly and time consuming. Ideally, implementation of automated screening of requests could reduce these instances. Any repeat testing on regular patients would be automatically rejected by the laboratory information system (LIS) upon registration. Unfortunately the LIS used by Pathology Queensland cannot differentiate between previous requests with positive results, and previous requests with negative results. Future versions of the software, however, may include this functionality, or Pathology Queensland may move to an altogether different system that has superior capabilities such as a decision support module.

The frequency of 10.6% request related errors in the renal ward was similar to that found by (Ağca, 2012). When looking at inappropriate Hepatitis B serology testing in their hospital, 11% of all requests for testing was found to be inappropriate, and a staggering 79% of requests for Hepatitis A testing were also found to be unwarranted. They attributed this widespread excess of testing to a combination of factors, including tick boxes on

request forms and the use of “blanket” ordering strategies, and recommend the development of diagnostic algorithms to assist clinicians in their test ordering. Similarly, (Demiray, Koroglu, Karakece, Özbek, & Altindis) found repeats of previously positive Hepatitis B Surface Antigen (HbSAg) testing to be 21.7%, and 26.7% for Hepatitis C. Both studies indicate a lack of clinical knowledge of the diagnostic algorithm or pathway for testing, and recommend some kind of electronic intervention. In another study targeting thyroid stimulating hormone, ferritin, Vitamin B12 + Folate and glycated haemoglobin, Sharma and Salzmann (2007) implemented an electronic intervention for automated test rejection, and showed a decrease in repeat testing from 4.0% to 2.8% over 4 years. It is important to note, however, that the tests in this study were not serological markers as in the previous studies, and the electronic intervention used was for a minimum retest interval. These intervals are already in place in the Pathology Queensland LIS, and are not capable of accounting for previous test results, only previous requests.

6.4.2 Approximate cost of request related errors occurring in the renal ward

The cost of unnecessary pathology testing has been increasingly targeted for cost cutting as health care providers, insurance companies and Government health departments look at reducing the overall spending on health care (Kwok & Jones, 2005) (Demiray et al.; May et al., 2006; Vegting et al., 2012; M. L. Wilson, 1997). In examining the financial burden of unnecessary serological testing, Demiray et al. (2015) estimated the cost to the Turkish health system to be over $1,000,000USD for a five year period (approximately $200,000 a year). This is a substantial cost, and is estimated for only Hepatitis B, C and HIV tests, without including labour or increased laboratory workload. It is reasonable to expect that the cost for inappropriate pathology testing in all departments (outside of serology) would be much higher.

In estimating the costs associated with the specific pre-analytical error of “request related error”, a flowchart of staff and resources used was established. It is important to note that

the cost of actually performing the tests was not included, as the laboratory process ensured the inappropriate test request was intercepted and not performed. Therefore, the costs included were for the time and consumables used to request, collect and deliver the sample to the laboratory, and the time taken for laboratory processing, test review and recording the no-test into the system. Consultation with the Nurse Unit Manager of the Renal Unit and observation in the laboratory determined average times for each task, and average wages were estimated from the relevant industrial relations documentation. The cost for each individual error was estimated to be $17.21 (Range $11.69 – $23.72). While this individual cost may seem insignificant, it adds up quickly, with the cost for just the 46 errors detected in this study (data collection period of one month) totalling $791.66 (Range $537.74 – $1091.12). As the renal ward performs these tests every month, extrapolating this cost over a 12-month period provides an accurate estimate of the yearly cost to Queensland Health of $9499.92 (Range $6452.88 – $13093.44). This is a hefty cost for just one type of error, in one ward.

6.4.3 Approximate cost of a theoretical intervention to reduce errors in the renal ward

Alonso-Cerezo, Martin, Garcia Montes, and de la Iglesia (2009) identified several barriers to the appropriate use of pathology testing, including the appropriate use of clinical guidelines. Particularly, they found that the implementation of guidelines is challenging and that even if guidelines exist; they are not followed by all physicians. Vegting et al. (2012) also found that national guidelines were not followed consistently in their hospital, and formulated an intervention to reduce unnecessary diagnostic testing including pathology costs by an overall target of 7.5%. In fact, their interventions resulted in a decrease of 21% and savings of 230,000 Euro in the internal medicine department (the target ward), with no measured reduction in the quality of care the patients received, and despite an increase in the overall number of admissions (Vegting et al., 2012). Although the intervention used was multi-faceted, the larger than expected decrease in testing was credited to increasing awareness among the clinicians in regards to unnecessary testing and increasing supervision of junior clinician test requests. Even though there was no estimate of the cost of the intervention itself, the significant cost reduction achieved is an impressive benchmark.

In the current study, the renal ward was identified as an ideal target for a similar simple intervention, as the cost of request related errors was both substantial and avoidable. By introducing a straightforward protocol tick sheet requiring patient charts to be consulted before ordering monthly pathology tests, the renal ward can reduce unnecessary testing and potentially save up to $8733.60 a year (Range $5686.56 – $12327.12). Currently, test requests are primarily done using handwritten or pre-printed request forms. Looking forward, and as more sophisticated technology is adopted by Pathology Queensland, electronic test ordering directly into the laboratory information system may allow for a more complicated re-test algorithm to allow for prior patient results to be considered and repeat test requests refused. Until this occurs, any electronic intervention at point of ordering is severely limited and unlikely to result in a reduction of this kind of error.

6.5 Conclusions

The cost of request related error in the health care system is significant and avoidable. This study identified the renal ward as a test site for cost reduction intervention. This intervention was designed to prevent unnecessary serological test requests, has the potential to save over $8000 a year in labour and consumable costs, and is a simple way to reduce these errors while electronic capability to intervene is lacking from the current laboratory information system.

CHAPTER 7
GENERAL DISCUSSION

The studies undertaken as part of this thesis have contributed to the body of knowledge surrounding pre-analytical errors in pathology, through a thorough examination of what types of error are associated with specimens received into the Townsville pathology laboratory, and comparing error rates across the hospital. Diversity in number and type of errors were demonstrated, and it was revealed that typical paradigms of where high error frequency was thought to occur (e.g. the emergency department) were challenged. Intervention to reduce error will need to be personalised to the type of error predominant in a particular clinical area and delivered to the relevant staff.

The frequency of pre-analytical errors in the Townsville pathology laboratory was to be 4.22%, with the highest number of errors relating to requests with specimens not received (19% of all errors). Overall, specimen related errors were predominant, over 55% of errors were in this category. The clinical area with the highest error rate was the renal ward, with an error rate of 10.6% for inappropriate test requests alone. This individual category of error was targeted in a theoretical intervention which showed the potential for substantial savings over a 12 month period.

While the frequency of pre-analytical error in the Townsville pathology laboratory was found to be high compared to other published studies, the variation in study designs made direct comparisons of error rates difficult. With discussions underway internationally to develop universal Quality Indicators for Pre-analytical processes, and therefore a consensus on how to numerate these indicators (M. Plebani, Sciacovelli, Aita, & Chiozza, 2014), it may soon be possible to more accurately compare error rates across institutions on different sides of the globe, and therefore opportunities to learn from each other will be more readily available. On the other hand, the ability to capture this data is entirely dependent on the

development of appropriate software capabilities, either as add-on modules to existing laboratory information systems or in new systems that are built from the ground up. Currently, relying on manual retrospective data collection as used in this study is very labour intensive, especially if the LIS does not routinely store the required information, or if viewing request form images is necessary. Asking staff to manually record errors as they happen, in addition to their regular workload, can lead to bias or missing data if it is seen by staff to interfere with their routines so is not a recommended method for long term data collection.

An analysis of the different types of error associated with specimens received into the Townsville pathology laboratory, found 23 individual error types. This was higher than anticipated, and clearly demonstrates the physical, technical and clerical complexities of the pre-analytical stage of testing. In fact, the work being undertaken by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) to harmonise Quality Indicators has recommended 34 different indicators for use (M. Plebani, Sciacovelli, Aita, & Chiozza, 2014). This introduces further refinements required for LIS software, if these indicators are to be monitored and reported in the future as a measure of external quality assurance. Ideally, any pre-analytical component of a LIS should be customisable for any future changes in the requirements of external quality assurance providers or laboratory specific needs.

By clustering the errors into specimen, request and clerical related categories, comparison between the clinical areas and their error rates was simplified. An unexpectedly high rate of request related error in the renal ward led to a theoretical intervention being proposed, which demonstrated that a small scale and relatively cheap intervention has the potential for substantial impact in reducing costs associated with request related pre-analytical error. Until there are further advancements in laboratory information systems that improve the capacity for intercepting inappropriate test requests, training of staff to reinforce protocol and education about pre-analytical variables and error is a viable option. As technology

develops, it will likely become more cost effective to limit test ordering using complex algorithms that exceed the capability of currently available options, especially with the current LIS used by Pathology Queensland.

Although these investigations of pre-analytical error resulted from a comprehensive collection and analysis of data, there are limitations in the study design that should be considered. Ideally, the data should be gathered over a longer period of time, to encompass (and potentially highlight) any variations that may occur due to staff rotation, seasonal temperature variation (especially in regards to transport of specimens to the laboratory from external healthcare facilities), and to track any changes made to test ordering policies. The month of May 2008 was originally chosen as a pilot study to test data collection methods and refine the list of error types. This larger study did not progress due to many factors including changes in personal circumstances. However, the smaller time frame for data collection in this study was very effective in demonstrating the diversity and wide scope of errors, despite the overall smaller numbers in some of the error categories. It is unlikely that a substantial number of supplementary causes of pre-analytical error would be identified in a longer data collection period, unless there was a change in protocols for test ordering (such as electronic order entry) or specimen collection that may introduce a previously unknown type of error.

In addition, the data obtained for these investigations was limited to pre-analytical errors recorded in the laboratory information system. It is possible that errors occurred that were not recorded as a “no-test”, therefore reducing the overall number of errors recorded. This may be due to protocol not being followed (errors occurring and not being recorded as per protocols), or errors that are not required to be recorded as a no-test. The category of error most likely to be affected is that of specimen quality. For example, if a specimen was haemolysed sufficiently to affect some biochemistry results, but not to the extent of gross haemolysis requiring a total recollection of the specimen, there is pre-analytical error without a no-test registration.

Despite the limitations, these investigations into pre-analytical error have highlighted areas for further research. A long term study of narrowed focus (for example selecting a smaller range of clinical areas), encompassing multiple staff rotations, school holiday periods, and variations in workload would enable an intervention to be both identified and implemented. By tracking error rates before, during, and after an intervention designed to reduce specific errors in one or more clinical areas, the true impact of this intervention could be accurately defined, and cost savings can be measured.

This study also demonstrates the necessity for research within our laboratories, by medical laboratory scientists. Escobar, Nydegger, Risch, and Risch (2012) found that medical laboratory scientists are underrepresented as authors when considering published articles relating to laboratory medicine. This indicates that the majority of research relating to laboratory medicine is executed by researchers external to the laboratories themselves. The relative lack of research performed in diagnostic laboratories, especially in Australia, may be reflective of the structure of the medical laboratory workforce, and the lack of requirement for postgraduate study for progression in a career as a scientist (Tony Badrick & St John, 2012). In order to develop and maintain evidence based practice within medical laboratory science, and to cultivate highly trained scientists, we need to encourage and foster such research by laboratory scientists (T. Badrick, 2013; Trenti, 2003).

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APPENDIX I

Example of No-test screen in Auslab

APPENDIX II

Sample data collection form

Lab Number	Date	Specimen Type	Reason	Ward	Collector	Recollected
		o Blood o Swab o Urine o Tissue o Faeces o CSF o Blood Gas o Other _____	o Patient Identification o Incomplete form – Ward o Incomplete form – Doctor o Incomplete form – Collector o Specimen not signed o Specimen not labelled/incomplete o Wrong specimen type (tube/swab etc) o Specimen quality – haemolysis o Specimen quality – under/overfilled	o ED o Medical o Surgical o ICU o Paeds o NICU o Oncology o External HCF o Other_____	o Dr o Nurse o Phlebotomist o Not identified o Other	o Yes o No o Fixed
		o Blood o Swab o Urine o Tissue o Faeces o CSF o Blood Gas o Other _____	o Patient Identification o Incomplete form – Ward o Incomplete form – Doctor o Incomplete form – Collector o Specimen not signed o Specimen not labelled/incomplete o Wrong specimen type (tube/swab etc) o Specimen quality – haemolysis o Specimen quality – under/overfilled	o ED o Medical o Surgical o ICU o Paeds o NICU o Oncology o External HCF o Other_____	o Dr o Nurse o Phlebotomist o Not identified o Other	o Yes o No o Fixed