Identification and Reduction of Pre-analytical Errors in Clinical Chemistry through Expert Advice

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Abstract

Background: Diagnostics in Clinical chemistry laboratory is a pivotal part of clinical decision-making but is not exempt from 'human errors'. Scientific innovations such as automation and electronic order test requesting have contributed to substantial improvements in the field of laboratory science, but errors still occur. One major example of such failing is connected to the prevalence of errors occurring in pre-analytical phase of the Total Testing Process (TTP). Pre-analytical errors can occur at the time of patient assessment, test order entry, patient identification, sample collection, sample transport, or sample receipt in the laboratory. Previous work and clinical insights suggest that most errors in the TTP are extra-laboratory (i.e. they occur before the samples reach the laboratory for analysis). Such errors are frequently the results of human mistakes during phlebotomy practice. Therefore to reduce these errors the pre-analytical phase of the TTP must be prioritised.

Study objective: To investigate the sources of pre-analytical errors in the TTP, categorize these errors in order to identify the error prone steps, and evaluate error-reporting frequencies, with the aim of improving service.

Methods: The first part of the study was a query of the laboratory information management system (LIMS) for samples rejected due to pre-analytical errors. Data collection was done retrospectively to cover two periods from 2007-2008 (manual paper test requesting) and 2012-2013 (after implementation of electronic test ordering, Anglia-ICE). Pre- and post- implementation Anglia-ICE error data were transferred to excel spreadsheets and compared by chi-squared test. The contribution of each error category to total sample error received in the laboratory

was also determined. The second part of the study was a questionnaire survey of pre-analytical procedures to capture the attitudes of phlebotomists towards current practice in Sheffield Teaching Hospitals NHS Foundation Trust (STH NHS FT).

Results: The results of the first part of the study indicated that of the 416,703 specimens collected pre-Anglia ICE, 2,055 (0.49%) were recorded as errors compared with 1,616 errors (0.11%) of 903,814 specimens collected post-Anglia ICE implementation, which represents a 0.31% ($p<0.05$) absolute error reduction rate, although more samples were received post-Anglia-ICE. The results of the second part (questionnaire survey) indicate that recommended procedure for phlebotomy practice was not strictly followed by a large percentage of the staff surveyed.

Conclusion: This study is the first inquiry linking venous blood sampling (VBS) practices in phlebotomy to retrospective LIMS pre-analytical data in a UK NHS Hospital. The results suggest low compliance by staff with recommended practice, which may be responsible for the prevalence of certain categories of pre-analytical errors in the TTP and may also be associated with increased risks to attending patients. It is suggested that the development of a local guideline for VBS and compliance to this guideline will improve phlebotomy practice, improve the quality of sample testing in the clinical chemistry laboratory, reduce pre-analytical errors in TTP and consequently improve the safety of patients.

Contents **Page**

Abstract ii

List of Chapter and Sections iv

List of Appendices viii

List of Tables ix

List of Figures x

Abbreviations xiii

Acknowledgements xv

Chapter 1 Review of literature 1

1.1 Introduction 1

1.1.1 Historical perspectives 2

1.1.2 The clinical chemistry laboratory 5

1.1.3 Laboratory and diagnostic Errors 6

1.1.4 Patient safety 7

1.1.5 Recent advances in understanding pre-analytical errors 8

1.1.6 Brain-to-brain loop: The Lundberg concept 9

1.2 The total testing process 11

1.2.1 The pre-analytical Phase 14

1.2.2 The analytical Phase 16

1.2.3 The post- analytical phase 17

1.2.4 Sources of uncertainty in the pre-analytical phase 18

1.2.5 Common errors generated in pre-analytical phase of TTP 20

1.2.5.1 Inappropriate test requesting 20

1.2.5.2 Incomplete laboratory requisition 20

1.2.5.3 Wrong patient identification 21

1.2.5.4 Wrong labelling of sample container 21

1.2.5.5 Poor phlebotomy practice 22

1.2.4.6 Inadequate/ insufficient sample volume 23

1.2.5.7 Interfering matrix in sample (e.g. haemolysis) 23

1.2.5.8 Problems with sample preparation, storage and transport 24

1.3 Clinical laboratory informatics 25

1.3.1 Laboratory information systems 26

1.3.2 Laboratory test ordering: Manual versus ICE order 28

1.3.3 Sources of pre-analytical information 29

1.4 Approaches for reducing pre-analytical errors in the clinical chemistry laboratory 29

1.4.1 Developing clear written standard operating procedures 30

1.4.2 Improving healthcare professionals' training 31

1.4.3 Acquiring automated technologies (e.g. LIMS) 31

1.4.4 Developing and monitoring quality indicators (QIs) 31

1.4.5 Improved communication between clinical chemistry laboratory staff and other healthcare professionals 33

1.4.6 Quality indicators in the pre-analytical phase 34

1.5 Sample rejection and error reporting protocol in STH NHS FT 37

1.6 Research application and ethical approval 38

1.7 Aims and objectives of the study 39

Chapter 2 Materials and methods 40

2.1 Introduction 40

2.2 Study Design 41

2.2.1 Interrogating the laboratory information Management system (LIMS) 41

2.2.2 Pilot study for the purpose of categorising errors 42

2.2.3 Statistical analysis - LIMS study 42

2.3 Questionnaire survey 43

2.3.1 Questionnaire design and validation 44

2.3.2 Ethical considerations 45

2.3.3 Statistical analysis – questionnaire study 45

Chapter 3 Results I (LISM study) 47

3.1 Laboratory information management system (LIMS) study data collection and processing 47

3.2 Coding of pre-analytical errors from LIMS 53

3.3 Results of LIMS study 55

3.4 Discussion – LIMS study results 59

Chapter 4 Results II (Questionnaire study) 62

4.1 Questionnaire study (evaluation of practice) 62

4.1.1 Employment, training and routine procedures in phlebotomy practice 63

4.1.2 Patient Identification (PID) processes undertaken by phlebotomists 68

4.1.3 Managing test requests 71

4.1.4 Responsibility for marking sampling time on sample/request forms 73

4.1.5	Marking sampling time on sample/request forms	73
4.1.6	Vacutainer tube labelling	73
4.1.7	Patient preparation, venous stasis and venipuncture	76
4.1.8	Specimen handling procedures	81
4.1.9	Incident/error reporting in phlebotomy	84
4.2	Respondents comments/suggestions for improving phlebotomy service	87
4.3	Discussion on questionnaire study regarding phlebotomist practice	89
4.3.1	Patient preparation prior to phlebotomy	95
4.3.2	The handling of test requests	98
4.3.3	Responsibility for marking sampling time on sample/request forms	100
4.3.4	Vacutainer tube labelling	101
4.3.5	Online laboratory manual and information search	104
4.3.6	Specimen handling procedures	104
4.3.7	Incident/error reporting in phlebotomy	106
4.3.8	Staff opinions and suggestions	108
Chapter 5	**General conclusion**	109
5.1	General considerations from the study	109
5.2	Findings from this study	111
5.3	Is there a relationship between the LISM study and staff responses in the questionnaire survey?	115
5.4	Limitations of study	118
5.5	Recommendations for practice in STH NHS FT	119
5.6	Recommendation for future research	120

5.7 Conclusion 121

References 122

Appendices

Appendix I Approval of Research and Supervisory Team

Appendix II Ethical Approval from Sheffield Hallam University

Appendix III Research and Development Governance Approval

Appendix IV Questionnaire cover letter

Appendix V Questionnaire survey

Appendix VI SPSS Statistical Analysis (Questionnaire study)

Appendix VII Statistical analysis of LISM data to test significance

Appendix VIII Raw data from LIMS study

Appendix IX Incident report template

Appendix X Raw data from questionnaire study

Appendix XI ICE requesting on vacutainer tube

Appendix XII Results from the LIMS pilot study

Appendix XIII Electronic order test request form (ICE)

Appendix XIV Manual test request form

Appendix XV Standard operating procedure for phlebotomy unit

Appendix XVI Service evaluation report

List of tables **Page**

1.1	Quality indicators in the pre-analytic phase.	35
3.1	Absolute difference in error rates pre- and post-Anglia-ICE	49
3.2	Comparison of pre-analytical errors and frequencies in TTP prior to and after implementation of Anglia-ICE	50
3.3	Total number of samples received from Sheffield requesting centres between the two periods under review	51
3.4	Coding and categorisation of pre-analytical error in the Pre-analytical phase of TTP	54
4.3	Institute of Biomedical Science professional guidance document for receipt and identification of samples	92

List of figures Page

1.1	Brain-to-Brain Loop Concept for Laboratory Testing	10
1.2	Total Testing Process (TTP)	12
3.1	Screen capture of a few pre-analytic error data from LISM 2007- 2008	47
3.2	Screen capture of a few pre-analytic error data from LISM 2012- 2013	48
3.3	Total number of samples received from requesting centres across Sheffield between the two periods under review	52
3.4	Error frequencies as a proportion (per 100,000 samples) of the total samples received from various centres during Pre-ICE(2007/2008) and Post- ICE (2012/2013) period	58
4.1a	Distribution of length of time in employment for staff in STH NHS FT phlebotomy unit	64
4.1b	Distribution of length of time in training of staff in STH NHS FT phlebotomy unit	64
4.2	Correlation between length of time in service and years in VBS training of staff	65
4.3	Percentages of phlebotomy staff involved in VBS procedure in STH NHS FT	65
4.4a	Percentages of staff with awareness of documented routines for VBS in phlebotomy unit	67
4.4b	Percentages of staff with awareness of undocumented routines for VBS in phlebotomy unit	67

4.5a	Percentages of staff signifying interest in further training in the phlebotomy unit	67
4.5b	Percentages of staff signifying interest in receiving further information in phlebotomy practice	67
4.6	Staff approaches to patient identification procedures before VBS	69
4.7	Staff approaches to test requesting procedures before VBS	72
4.8	Staff responses regarding marking of sampling time by other colleagues during VBS	74
4.9	Staff responses regarding marking sampling time on test requests	74
4.10	Staff responses regarding sample-labelling procedure during VBS	75
4.11	Staff responses regarding patient preparation before VBS	77
4.12	Staff responses regarding use of stasis during VBS	77
4.13	Staff responses regarding access to laboratory handbook for VBS	80
4.14	Staff responses regarding specimen handling during VBS	82
4.15	Staff responses regarding sample storage after VBS	83
4.16	Staff responses regarding error reporting in phlebotomy practice	85
4.17	Staff responses regarding error-reporting responsibilities in VBS	86
4.18	Staff responses to suggestions to improve phlebotomy practice	88

Abbreviations

A&E	Accident and Emergency
B-T-B	Brain to Brain
CEU	Clinical Effectiveness Unit
CHI	Community Health Index
CPOE	Computerised Physician Order Entry
CoE	Computer order Entry
CSLI	Clinical Science Laboratory Institute
DOA	Drugs of Abuse
DOB	Date of Birth
EDTA	Ethylene Diamine Tetra-acetic Acid
ECLLS	European Committee on Clinical Laboratory Standards
EFLM	European Federation of Laboratory Medicine
EFLM-WG	European Federation of Laboratory Medicine-Working Group
EQA	External Quality Assurance
GP	General Practioner
HCPC	Health and Care Professions Council
IBMS	Institute of Biomedical Science
IOM	Institute of Medicine
IQC	Internal Quality Control
ISO	International Organization for Standardization
IFCC	International Federation of Clinical Chemistry
IT	Information Technology
LIMS	Laboratory Information Management System
NHS	National Health Service

OGTT	Oral Glucose Tolerance Test
PDP	Professional Development Portfolio
PID	Patient Identification Details
PMI	Private Medical Insurance
PT	Proficiency testing
PTST	Pneumatic Tube System Transport
QI	Quality Indicators
RCP	Royal College of Pathologists
REC	Research Ethics Committee
SOP	Standard Operating Procedure
SPSS	Statistical Package for the Social Sciences
STH NHS FT	Sheffield Teaching Hospitals NHS Foundation Trust
TAT	Turn around Time
TDM	Therapeutic Drug Management
TTP	Total Testing Process
TQM	Total Quality Management
UKAS	The United Kingdom Accreditation Service
UK NEQAS	United Kingdom National External Quality Assessment Service
VBS	Venous Blood Sampling
WHO	World Health Organization
PM	Post Morterm
HMC	Her Majesties Coroners
SHOT	Serious Hazards Of Transfusion

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Chapter 1 Review of the Literature

1.1 Introduction

"The more human beings proceed by plan, the more effectively they may be hit by accident."
(Friedrich Durrenmatt)

Diagnostics in the clinical chemistry laboratory is a pivotal part of clinical decision-making but is not exempt from 'human errors' (IOM, 2000). Generally errors generated in the laboratory setting are commonly referred to as 'analytical errors', which unfortunately is misleading since the analytical phase in the total testing process (TTP) is strictly controlled (Bonini *et al*., 2002; Kalra, 2004). Most errors in the Clinical chemistry laboratory occur before or after the laboratory testing of samples (Plebani, 2010). Healthcare professionals seldom consider preventable errors, nevertheless in reality the statistics are staggering (Hollensead *et al*., 2004; Hammerling, 2012; Šimundić, 2015).

A recent publication by the World Health Organisation (WHO) revealed that 1 in 10 patients in the developed world are at the risk of some kind of error during hospitalization (WHO, 2015), in addition about 10% of patients in countries that make up the European Union are believed to have experienced avoidable adverse events (European Commission on Patient Safety, 2014). It cannot be denied that laboratory errors play a significant role to the overall risk of error in healthcare (Šimundić, 2015); because laboratory medicine like any other diagnostic field is susceptible to errors. It is evident that most of the errors occur in the pre-analytical phase of the TTP (Šimundić and Lippi, 2012; Šimundić, 2015), which comprises sample collection, handling and transportation. It is not surprising therefore that a significant amount of attention is being paid to patient safety by the European Commission considering the

significance of laboratory testing on the total patient management decision process. The high error rate in the pre-analytical stage, where human participation is maximal, reaffirms the vulnerability of a manual process to error. Several studies (Plebani and Carraro, 1997; Astion *et al.*, 2003; Carraro and Plebani, 2007; Laposta and Dighe, 2007) indicate that human mistakes contribute largely to pre-analytical errors. These researchers observed that about two-thirds of errors in the clinical chemistry laboratory occur in the pre-analytical phase, when compared to the analytical or post-analytical phase. This is plausible because the pre-analytical stage requires more human intervention when compared to the analytical and post-analytical phases of the TTP.

Significant advances in automation; robotics; laboratory information management systems (LIMS) and precision engineering have remarkably simplified many laborious and cumbersome procedures in the clinical chemistry laboratory. Therefore, analytical errors are no longer the main factors influencing the reliability of clinical application of laboratory diagnostics (Ashakiran *et al.*, 2011; Lippi and Šimundić, 2010). There is growing concern about the high degree of errors reported in the literature (Adegoke *et al*., 2011; Agarwal, 2013; Astion *et al*., 2003; Binita *et al*., 2010), which undermines the quality of the analytical process. This calls for the active involvement of non-laboratory workers, particularly clinicians, nurses and phlebotomists and other healthcare professionals, to address this issue.

1.1.1 Historical perspectives

In the 1970s a new term "pre-analytical phase" was introduced to the laboratory medicine lexicon (Statland and Winkel, 1977). In the 1980s terminologies such as

interfering factors were introduced to professional training programmes, culminating in the publishing of the first book on pre-analytical variables in 1987 (Einer and Zawta, 1987); and these have become part of the terminologies used in clinical laboratory sciences vocabulary (Dybkaer, 1997) and international guidelines (CLSI, 2004). In 1981, the Clinical Science Laboratory Institute (CSLI) introduced pre-analytical standards to examine pre-analytical procedures, and the European Committee on Clinical Laboratory standards (ECCLS) followed this movement. The actions of these bodies meant that the term 'pre-analytical phase' was included in training and teaching programmes in clinical chemistry and laboratory medicine (Guder and Wahlefeld, 1983; Hagemann, 2005; ISO, 2007).

Bonini *et al.,* (2002) were among the first researchers to publish that more than 60% of errors in the TTP were generated in the pre-analytical stage. In the same year the WHO published recommendations on sample type and stability, which has led to greater awareness of pre-analytical variables in laboratory medicine (WHO, 2002), generating useful discussions at conferences and meetings around the globe (Becton-Dickson Vacutainer Systems, 1996, 1997, 1998; IFCC, 2002; EFLM-BD, 2013). In 2012, the European Federation for Laboratory Medicine established a working group (EFLM-WG) with the primary objective of increasing the level of awareness about the significance of the pre-analytical phase among laboratory staff and other healthcare professionals, who are users of the services that the laboratory provides. As part of the drive to raise awareness on the importance of the pre-analytical phase, the EFLM-WG introduced a series of biannual conferences, which attract a huge number of participants globally; the last meeting took place in Portugal, 2015 (EFLM-WG, 2015; The Pathologist, 2015).

Pre-analysis describes the extra-laboratory procedures preceding the analytical phase. The primary function of the clinical chemistry laboratory is the performance of biochemical analysis of body fluids such as blood (whole blood, serum or plasma), urine, cerebrospinal fluid, and other effusions etc. Intrinsically, sample collection, its identification, storage and transport for laboratory analysis have always been part of the diagnostic process. The introduction of statistical quality assurance of the analytical processes in the first quarter of the 1970s led to the awareness that other extra-analytical variables had a bearing on the capability of the clinical chemistry laboratory to generate accurate results (Keller *et al.*, 1985; Gruder, 2014). For many decades it has been common knowledge that factors such as patient preparation before the blood sample was drawn, time and site of sampling, choice of anticoagulant, temperature and storage, transport, centrifugation time and sample separation impacted on clinical chemistry laboratory results. Since the analytical variables were still largely unknown these extra-analytical factors could not be measured until 2002, when Bonini and co-workers were able to quantify the impact of pre-analytical variables on overall laboratory errors in clinical chemistry.

Historical examples of pre-analytical errors may help us understand how 'seemingly normal' extra-laboratory routines may impact on the analytical phase and lead to spurious results. For example in the early 1960s, clinicians requested urinary amylase measurements in order to exclude pancreatitis as the cause of acute abdominal pain. Surprisingly most of the results showed increased amylase activity even though some of the patients showed no signs of 'pancreatitis'. It was soon discovered that because the urine samples were collected in open vessels, they apparently became contaminated by salivary amylase from drops of spittle from the nursing staff as they

held discussions over the urine samples when transporting them to the laboratory for analysis (Guder, 2014). The cause of the pre-analytical error was eventually eliminated by collecting the samples in closed containers (Guder, 2014). Fluid or blood amylase samples have now increasingly become the samples of choice for pancreatic amylase activity investigation.

1.1.2 The clinical chemistry laboratory in Sheffield Teaching Hospital NHS Foundation Trust (STH NHS FT)

The clinical chemistry department provides a comprehensive diagnostic and interpretative biochemistry service to the Sheffield Teaching Hospitals, other regional hospitals, and general practitioners (GPs). The clinical chemistry laboratory also provides specialist endocrinology and toxicology services. All these services are available to users on a regional as well as national basis. The endocrinology unit provides an extensive peptide and steroid hormone assay service, to include reproductive, adrenal and growth endocrinology. The manual endocrinology unit is one of only three trophoblastic tumour screening service centres in the UK.

The toxicology laboratory provides a monitoring and interpretative service for a wide scope of therapeutic drugs (TD), drugs of abuse (DOA) as well as receiving post mortem (PM) samples from HM Coroners for forensic toxicology services. The trace metals section of toxicology provides a range of assays covering essential elements (selenium, zinc, copper) and also serves as a regional centre for NHS hospitals with renal departments requiring aluminium monitoring. The section is equipped to provide occupational screening for those working with heavy metals such as lead and mercury.

The clinical chemistry department is an approved training centre for biomedical and clinical scientists and is affiliated to Sheffield Hallam University and University of Sheffield. It has maintained continuous accreditation with the United Kingdom Accreditation Service (UKAS) since 1992.

1.1.3 Laboratory and diagnostic errors

"An error does not become a mistake until you refuse to correct it" – Anonymous

A laboratory error is defined as any defect, from test ordering to reporting test results and appropriately interpreting and reacting on these results (Kalra, 2004; Plebani, 2006; Lippi *et al.*, 2009; Kalra *et al*., 2013). Conventionally medical errors are grouped into 4 types namely: errors of diagnosis, errors of treatment, errors of prevention and errors of miscellaneous origin (Kalra *et al.,* 2013). Errors in the TTP are associated with all of the four error groupings mentioned, albeit most medical errors are closely linked to 'errors of diagnosis'. Diagnostic errors are the leading cause of payout claims involving medical malpractice in the United States (Green, 2013).

According to recent data, diagnostic errors rank as the most common source, most costly and most precarious of medical mistakes for inpatients as well as patients for attending outpatient clinics or departments (Green, 2013). Despite the ubiquitous nature of diagnostic errors that often lead to avoidable disability or death in some cases, diagnostic errors still remain a relatively unmeasured subject area of patient safety (Kalra, 2004; Bonini, 2009; Plebani and Piva 2010). Medical errors can result in physical and emotional suffering for the patient and frequently lead to a number of

mortalities annually, along with excess economic burden and litigations (Karla, 2004; Green 2013; Kalra *et al*., 2013).

Medical errors that put patients at risk have generated a lot of media attention in recent years, so much so that publications such as that of the Institute of Medicine (IOM), estimate that preventable errors leading to about 1.5 million adverse events occur in the United States annually and that between 44,000 to 98,000 deaths occur annually as a result of medical errors, excluding unreported events (IOM, 2000; Kalra *et al*., 2013). About 55% of missed or delayed diagnoses in the ambulatory setting and about 58% in accident and emergency departments arise from failure to request appropriate diagnostic and laboratory tests in the pre-analytical phase of the TTP (Plebani, 2009; Plebani, 2010; Plebani *et al.,* 2011, Plebani, 2011).

1.1.4 Patient safety

Laboratory errors have the likelihood of causing irreversible harm when linked with patient care. Therefore current emphasis on addressing errors in the pathology laboratory especially in the pre-analytical phase of the TTP, is an imperative component of the national and global agenda on patient safety (Lippi and Plebani, 2009). This has informed the recent launch of the World Alliance for Patient Safety by the WHO in response to a World Health Assembly resolution in 2002 exhorting member states and the WHO to give consideration to addressing the challenging issues affecting patient safety (World Alliance for Patient Safety, 2004; Lippi and Plebani, 2009). To this end the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) through its Education and Management Division (EMD) have initiated a 'Working Committee' on laboratory errors and patient safety with the

purpose of encouraging investigations/studies on the subject of errors in pathology laboratory, to gather existing data on this topic, analyse it and recommend approaches and put in place standardized procedures to improve patient safety (IFCC-EMD, 2015).

Unsafe medical practices may be responsible for the yearly disabling injuries or deaths suffered by million of patients globally (WHO, 2013). Almost 1 in 10 patients may have suffered harm due to avoidable causes whilst receiving care in healthcare institutions with cutting-edge facilities (WHO, 2008). Investigation into understanding the phenomena surrounding unsafe medical practices and care and to recognise probable solutions may include diverse scientific strategies and methodologies. For instance, enquiry may be centred on a retrospective investigation of medical/pathology laboratory records, staff surveys, interviews, observational studies, controlled randomized designs or the use of simulations (WHO, 2013).

1.1.5 Recent advances in understanding pre-analytical errors

A wide gap still exists between our current knowledge of pre-analytical errors in routine analysis and communicating these findings to end-users of the laboratory service. There are several publications reflecting the immense interest, challenges, and complexities of the subject in the clinical chemistry laboratory. Recent literature has focused on the reduction of errors in all the stages of the TTP (Figure 1) in clinical chemistry. Many authors (Plebani and Bonini, 2002; Bates and Gawande, 2003; Plebani, 2006; Lippi and Guidi, 2007; Plebani *et al.*, 2011; Plebani, 2012; Šimundić and Lippi, 2012; Šimundić *et al.*, 2011; Šimundić, 2015) have undertaken extensive studies on errors in the pre-analytical stages. Yet, literature, citing communication of these outcomes to users of the laboratory service appears to be scarce. The importance

of information and adequate communication of this between the laboratory staff and users of the service cannot be overstated.

1.1.6 Brain-to-brain: The Lundberg concept

It was Lundberg (1981, 1999), who first proposed the brain-to brain loop concept (Figure 1.1) to describe the total testing cycle (Figure 1.2). According to Lundberg, the activity loop begins outside the walls of the clinical chemistry laboratory with a clinical question in the physician's mind. This leads to test requesting or ordering, collection of the patient's sample and identification, transportation of sample to the laboratory, sample separation (by centrifugation to make it suitable for analysis), sample aliquoting and sorting into batches (Da Rin, 2009; Plebani, 2012). Next, the sample is delivered for analysis on automated platforms. In the final step results are generated and reported, and action taken (interpretation and decision making) by the physician. Each stage in this complex loop, when performed correctly guarantees quality procedures in the clinical chemistry laboratory, thus ensuring valuable medical decision making and effective patient management (Lundberg, 1999; Plebani, 2012).

It can be appreciated that several transitional steps are involved in the loop, some of which are pre-analytic (before laboratory testing of samples); some are analytic (relating to the actual laboratory testing of samples) and a post-analytic step that involve the transmission and interpretation of test results into the health records. The introduction of the brain-to-brain model resulted in an identification and classification of errors related to laboratory testing. Previous studies (Plebani and Carraro, 1997; Carraro and Plebani, 2007; Plebani, 2006, 2007, 2009, 2011) suggested that most errors in the 'Lundberg loop' do not occur within the analytical stage, nor do they

frequently fall within the 'pre-analytical' or 'post-analytical' stages under the control of biomedical scientists.

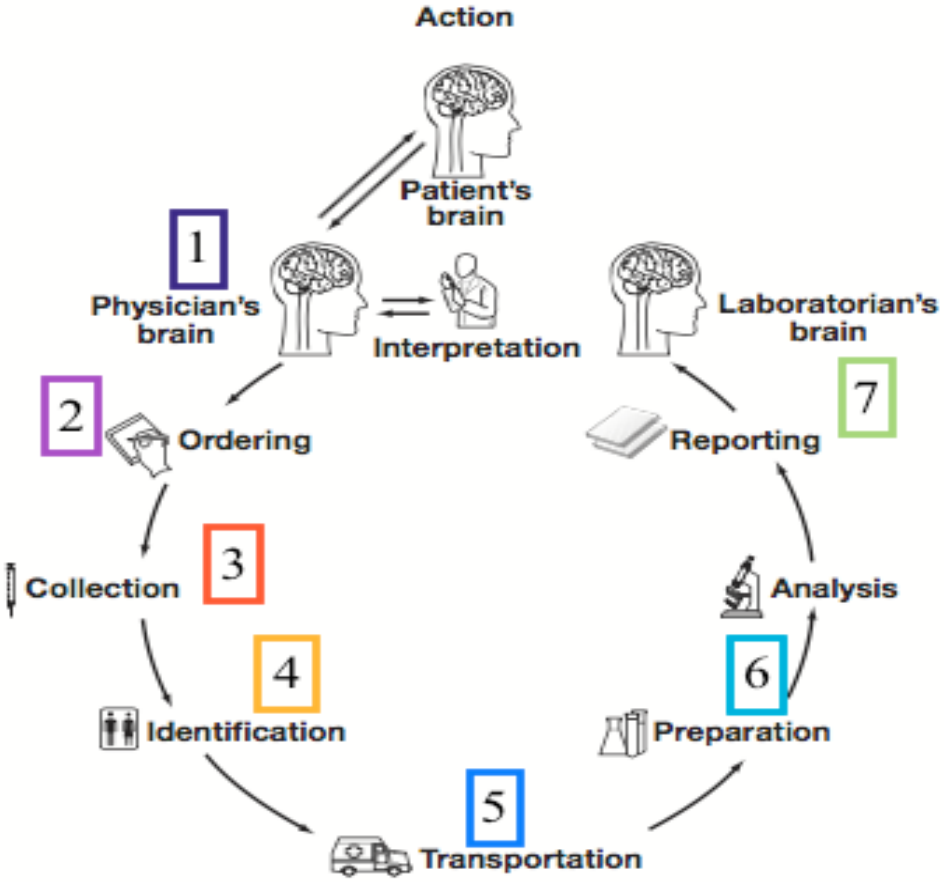


Figure 1.1: Brain-to-Brain Loop Concept for Laboratory Testing. Adapted from Plebani *et. al.,* (2011). Am J Clin Pathol 2011; 136:829-833.

Sepulveda (2013) summarized the Lundberg loop in seven steps shown by the coloured numbered boxes:

1. The right question was asked from the patient by the clinician or physician
2. The right test was ordered by the physician
3. The right sample was collected on the right patient, at the correct time, with appropriate patient preparation.
4. The right technique was used collecting the sample to avoid contamination with intravenous fluids, tissue damage, prolonged venous stasis, or haemolysis.

5. The sample was properly transported to the laboratory, stored at the right temperature, processed for analysis, and analysed in a manner that avoids artifactual changes in the measured analyte levels.

6. The analytical assay measured the concentration of the analyte corresponding to its "true" level (compared to a "gold standard" measurement) within a clinically acceptable margin of error (the total acceptable analytical error (TAAE).

7. The report reaching the clinician contained the right result, together with interpretative information, such as a reference range and other comments, aiding clinicians in the decision-making process.

It has been established that most of the errors occur before and after laboratory analysis (Plebani, 2010), and that the pre- and the post analytical phase are responsible for up to 96% of total Turn around Time (TAT) anomalies (Manor, 1999; Rodriquez-Borja *et al.*, 2014 Rodriquez-Borja, 2015). Therefore incorrect interpretation of laboratory or diagnostic tests in the final stages of the brain-to-brain loop (B-T-B) also causes a large proportion of errors in the ambulatory and emergency settings (Kachalia *et al.*, 2007).

1.2 The total testing process (TTP)[§]

The total testing process (TTP) is the sequence of events starting with the ordering of a test by a clinician and ending with the interpretation of the test result by the clinician (Figure 1.2). The TTP concept is similar to the previously described Lundberg's loop, the difference being that it occurs in phases. To fully appreciate the processes involved in generating a result for a patient's sample in a clinical chemistry laboratory it is imperative to elucidate the three phases of the TTP: Any analytical process in the clinical chemistry laboratory involves these three major stages:

1. The **pre-analytical stage**, which involves patient specimen acquisition and

preparation.

2. The **analytical stage**, which is the measurement of the test analyte.

3. The **post-analytical step**, which consists of reporting results.

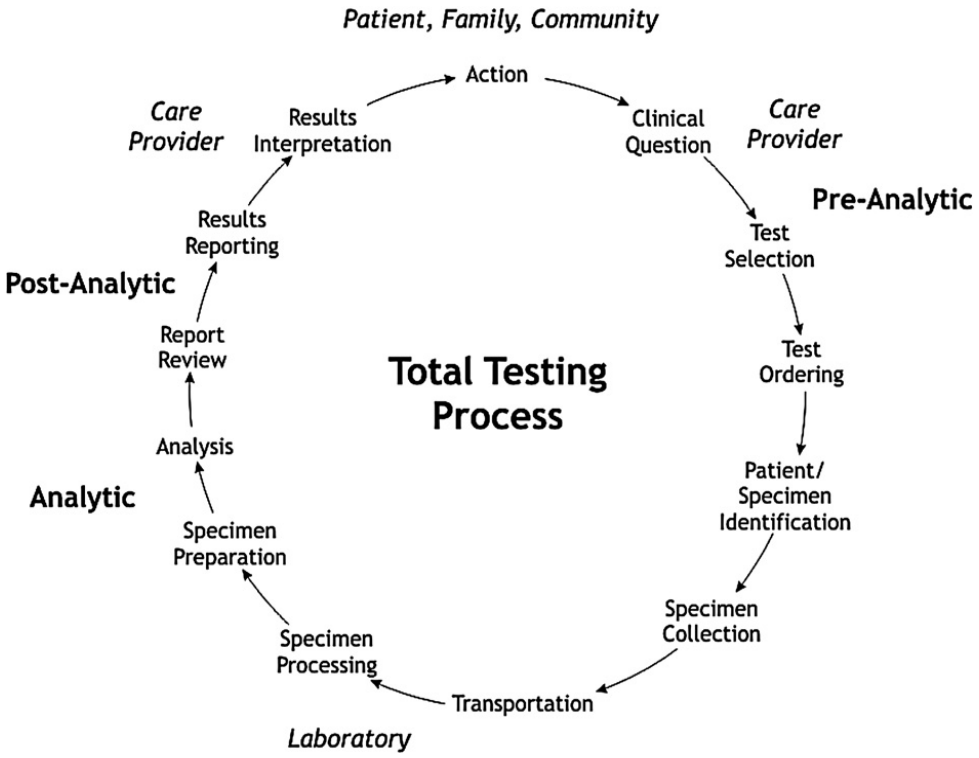


Figure 1.2. Total Testing Process (TTP): Adapted from Boone (2007): Presentation at the Institute on Critical Issues in Health Laboratory Practice: Managing For Better Health, September 23–26, 2007 Atlanta, GA, USA Centers for Disease Control and Prevention.

§The TTP begins and terminates with the patient. The patient visits a family General Practitioner (GP) and explains that he or she has a health problem. The GP proceeds with a medical assessment and if necessary, translates the patient's medical history, signs and symptoms into the ordering of one or several biochemical tests. The phlebotomist performs patient preparation, sample collection and sample handling according to standard procedures (Appendix XV). The sample is thereafter transported to the clinical chemistry laboratory for analysis. The analytical part of the process ends with the generation of an accurate test result, which is then delivered to the GP. This test result, when correctly interpreted by the GP, will ultimately contribute to the treatment or management of the patient.

Laboratory testing in clinical chemistry is a significant source of medical errors affecting patient management and safety (Da Rin, 2009; Plebani, 2012). Errors generated in the pre-analytical phase decisively influence the total error and consequently the diagnostic accuracy (Lippi *et al*., 2009; Da Rin, 2009). The pre-analytical phase is probably the most important step in the TTP in the clinical chemistry laboratory and indeed in laboratory medicine, if total laboratory quality is to be achieved (Chillar *et al*., 2011 Guder, 2014; Plebani, 2014). This assertion is true because the pre-analytical phase is conceivably the most complex and highly vulnerable to uncertainties (such as biological variations) and untoward incidents (Wallin *et al*., 2008). Recent studies carried out by a number of investigators (Lippi *et al.*, 2009; Sciacovellia and Plebani, 2009; Jo-Gile, 2011) have shown that approximately 93% of errors encountered within the TTP is due to the lack of standardised operating protocols for sample collection, which includes patient preparation, phlebotomy, sample handling/transportation and storage.

Errors relating to pre-analytical stages of the TTP are arduous to control and therefore require the adoption of drastic but suitable approaches for the prevention (or reduction) of these errors. A number of suitable strategies for error prevention have been examined and streamlined into the TTP (Ashakiran *et al*., 2011; Plebani, 2011). The major challenge for biomedical scientists and other laboratory staff has been the absence of an effective communication system with which to engage with the end-users of the clinical chemistry laboratory service (i.e. physicians, nurses, consultants, phlebotomists and other healthcare professionals). A good communication system is essential for prevention or reduction of pre-analytical errors.

Currently there has been increased focus on the reduction of pre-analytical errors (by healthcare professionals working in the clinical chemistry laboratory) and the possible impact on patient management by development of quality improvement 'tools' such as quality indicators (QIs) and increased analyser intelligence (Jekelis, 2005, Plebani, 2012).

1.2.1 The pre-analytical phase

This phase involves patient assessment, test order entry, request completion, patient identification, specimen collection, specimen transport, and sample receipt in the laboratory. Errors can occur at any of these stages. Bonini *et al*., (2002) in a study in Italy, observed that pre-analytical errors were widespread in the laboratory, ranging from 31.6% to 75%. In a separate study, Khoury *et al.,* (1996) reported error rates of 39% for 'identification' transcription in five clinical chemistry laboratories in Australia. A transcription error rate of this magnitude has the likelihood of seriously compromising patient identification data.

This finding was corroborated by Ashakiran *et al.,* (2011), who carried out a prospective study over three months in the clinical biochemistry laboratory of a hospital in India by monitoring the frequency and types of pre-analytical errors, screening 139 venous blood samples per day received from in-patient wards. They observed that pre-analytical errors amounted to an average of 44.7 % of the samples per day. They recorded their findings under the following categories of pre-analytical variables:

- Incorrect patient identification
- Improper sample labelling

• Improper test request

• Incorrect timing of sample

• Insufficient sample volume

• *In-vitro* haemolysis

• Collecting sample into wrong tube or container

• Incorrect sample handling and transport

Ashakiran and co-workers, (2011) reported similar figures to Kalra (2004) in his work on pre-analytical variations. Binita *et al.*, (2010) also agree that pre-analytical errors were ubiquitous with a high figure of 71.1 % in their study. Using similar variables Carraro and Plebani (2007) observed that among other causes of pre-analytical errors reported in previous studies were: ordering tests on the wrong patient, ordering the wrong test, transferring sample from a 'wrong' container into an 'appropriate' container. The most commonly reported types of errors from these previous studies, in the pre-analytical phase are: a) missing sample and/or test request; b) wrong or missing patient identification; c) contamination from intravenous infusion route; d) haemolysed, clotted, and insufficient samples; e) inappropriate containers; f) inappropriate ratio of blood to anticoagulant, and g) inappropriate transport and storage conditions (Karla, 2004; Lippi *et al.*, 2009; Binita *et al.*, 2010; Ashakiran *et al.*, 2011; Plebani *et al.*, 2012).

Although the studies discussed in the preceding paragraph describe alarming statistics relating to the category and frequency of errors in the pre-analytical phase, the precise magnitude of the error rate in the laboratory is still debatable and difficult to estimate simply because 'error' has no 'definite and universally accepted definition'. A primary limitation identified in some of these studies is the use of small sample size

numbers (Ashakiran *et al.*, 2011). Other issues relate to the acknowledgement by some authors that some 'errors' may have gone unobserved (Kalra, 2004). Reduction of errors in the pre-analytical phase can be achieved by consciously taking specific rigorous pre-emptive steps that are desirable for good laboratory practice (GLP). A holistic approach suggested by Lippi and Guidi (2007) stressed that overcoming these shortcomings entails: a) prediction of accidental events and b) efficient communication with healthcare providers. Effective communication is an imperative characteristic of the clinical chemistry laboratory. To be effective, the opportunity for dialogue between laboratory personnel and health care providers (users of the laboratory service) must be readily accessible. Provision must be adequate for bidirectional interaction, because the information provided is nearly always quantitative and interpretive.

1.2.2 The analytical phase

The analytical phase begins when the prepared patient sample is delivered to the analytical platforms for testing, and it ends when the test result is interpreted and verified by the biomedical scientist in the laboratory. Validating assay methodology, performance specifications such as sensitivity, specificity, accuracy, precision and linearity are crucial steps along the continuum which (if ignored) can lead to irreversible errors in the analytical phase of laboratory analysis in clinical chemistry. During the analytical phase, it is particularly important to design the manual work procedures such that the risk of placing patient samples in an incorrectly labelled test receptacle is minimised. A valid result provided for the wrong patient can have dire consequences including death. Many resources have been harnessed to improve

analytical quality in the clinical chemistry laboratory by establishing and investing in internal quality controls (IQC) and external quality assessment (EQA) schemes.

The role of EQA and proficiency testing (PT) is to provide reliable information allowing laboratories to assess and monitor the quality status of internal procedures and processes, the suitability of the diagnostic systems, the accountability and competence of the staff, along with the definition of measurement of uncertainty (discussed in section 1.2.4) in laboratory results. Biomedical scientists working in the clinical chemistry laboratory are directly responsible for appropriately analysing EQA materials. They report results, identify trends or bias that may not be apparent in analytical runs, investigate root causes producing unacceptable performances, apply and monitor appropriate actions for eliminating the underlying causes, authenticate the effectiveness, and, retrospectively determine whether the problem affected the clinical decision (Sciacovelli *et al.*, 2011). Potential sources of errors in the analytical phase may be broken equipment, improper mixing of samples or reagents, interferences (endogenous or exogenous), not detecting errors during equipment calibration and quality control (Bonini *et al*., 2000; Boone, 2004; Carraro and Plebani, 2007; The Pathologist, 2015).

1.2.3 The post-analytical phase

This phase involves validation of the patient test result and then transmission of the results to the clinicians and other healthcare professionals, in order to arrive at a clinical decision to manage their patients. Test turnaround time (TAT), an important aspect of the quality of the testing process, relies heavily on both the pre-analytic and analytic phases, to the point that any delays in these phases can create potential

problems that adversely affect patient care. A particularly important patient safety risk is the reporting of 'critical limits' defined as values that represent situations that could be life threatening without treatment (Lundberg, 1981). Result reporting is subject to specific communication and interpretation errors, which may originate in the pre-analytic and analytic phases. Potential sources of errors in the post-analytical phase are: incorrect validation of results, errors in reporting and delivering reports and prolonged TAT. Incorrect validation and incorrect reporting may lead to incorrect interpretation by the requesting physician. This may lead to wrong diagnosis or treatment and may cause harm to the patient. Biomedical scientists must be aware of the importance of relevant clinical information when validating and authorising results, especially when cumulative records are available. An unexpected test result can highlight the possibility of an incorrectly labelled sample or request form and should be investigated immediately.

Each individual phase of the TTP can be targeted for quality improvement (figure 1.1). In one study, Lippi *et al.,* (2010) showed that the TTP error rate ranges widely from 0.1% to 3.0%. In another study by Carraro and Plebani (2007), a decline in laboratory error rates from 0.47% to 0.33% was reported. They reported that the use of scientific innovations such as development of automation and robotics to handle some process previously performed manually by staff and the implementation of electronic order test requesting had contributed to reducing errors in the TTP.

1.2.4 Sources of uncertainty in the pre-analytical stage

In clinical chemistry measurements, the uncertainty in patient results includes both pre-analytical and analytical variation, as well as intra-individual biological variation.

The assessment of uncertainty in the pre-analytical stages in sample preparation is often essentially overlooked. Pre-analytical factors are diverse, ranging from biological and physiological events to technical details of specimen collection and transport (ISO, 2012). When standardized procedures are followed, pre-analytical variation can be minimized (Plebani, 2012) and the number of errors decreased (Kouri *et al.,* 2005). Traditionally, laboratories have focused on the uncertainty in the analytical phase, but characterization of uncertainty should include the whole process from phlebotomy up to reporting of results (Kouri *et al.,* 2005). With all uncertainties quantified and presented together in tabular form as an uncertainty budget, the laboratory will have a tool to identify important uncertainty sources (Boone, 2007; Magari, 2007; The pathologist, 2015; IBMS, 2016). The combined uncertainty is a function of the magnitude and probability distribution of the different uncertainty sources and the number of such sources. The uncertainty can be reduced, and laboratory quality improved, by focusing on the sources that contribute most to the combined uncertainty (Kouri *et al.,* 2005; Magari, 2007; Cararo and Plebani, 2007; Carraro *et al*., 2012).

Development and widespread implementation of a Total Quality Management (TQM) system is the most effective strategy to minimize uncertainty in laboratory diagnostics. Pragmatically, this can be achieved using three complementary actions: preventing adverse events (error prevention), making them visible (error detection), and mitigating their adverse consequences when they occur (Kouri *et al.,* 2005; Lippi *et al*, 2010).

1.2.5 Common errors generated in pre-analytical phase of TTP

According to previous studies (Söderberg, 2009; Plebani and Piva, 2010; Sumera *et. al.*, 2012) the most common errors generated in the pre-analytical stage are outlined below.

1.2.5.1 Inappropriate laboratory test requisition

The misappropriation of laboratory services through requesting inappropriate laboratory tests requests impacts, on total costs (Kalra, 2004; Green, 2013), and the inherent increased risk of diagnostic errors and injury. The estimations of inappropriate laboratory tests vary from 11% to 70% for general biochemistry and 17.4% to 55% for cardiac enzymes and thyroid tests (Silverstein, 2003; Kirchner *et al.*, 2007).

1.2.5.2 Incomplete laboratory test requisitions

One important source of pre-analytical error is incorrect or incomplete information on the test request forms or labels which have been found in more than two thirds of all rejected samples in the laboratory (Adegoke *et al.*, 2011). Several other studies confirm that test requests can be a clinically important source of errors (Kirchner *et al*., 2007). Paper - based test requests are precarious as they can be incompletely filled, placed in the wrong collection box, or simply be lost. Incomplete laboratory requests forms are rarely rejected at the service point. In many instances, the phlebotomy section or reception staff in the laboratory may not know the significance of the missing data. Specific missing information included the physician's name, misidentification of patient and requested tests (CLSI, 2004; Bilic-Zule *et al*., 2010; Favaloro *et al*., 2012).

1.2.5.3 Wrong patient identification

Patient identification is the cornerstone of patient safety (Da Rin, 2009). Correct patient identification is the vital task in all laboratory medicine. Therefore, efforts to ensure compliance with standardized identification routines should be prioritized (Sumera *et al.*, 2012). Errors in patient identification before specimen collection is responsible for up to 25% of all pre-analytical errors (Valenstein *et al*, 2006). Critical patient identification errors occur in approximately 1 out of 1200 tests requested (Wiwanitkit, 2001). Mistakes in patient identification often occur during manual tasks, which can be avoided, using electronic technologies like barcodes, radiofrequency identification and wristbands (Lau *et al.*, 2000; Dzik, 2007). Wristbands have patient's name and identification number, and sometimes have a barcode. A previous study by Howanitz *et al.,(*2002) has reported error rates of 3.05 – 7.40% while examining 1757,730 wristbands over 2 years, for identification wristbands mostly comprising of missing or incomplete wristbands, and wrong wristband on the patient.

1.2.5.4 Wrong labelling of the sample containers

Labelling of specimen containers should always be done immediately after sample collection while, labelling them before sample collection increases the risk of the specimen collection from the wrong patient. Mislabelling is responsible for 50% of all identification errors (Carraro, 2000). Information from SHOT (Serious Hazards Of Transfusion) shows that mislabelled specimens are 40 times more likely to contain the wrong patient's sample (IBMS, 2014). Ambiguous or erroneous identification of patients presents a risk to patient's health and can result in misdiagnosis, mistreatment, ill-health or mortality.

1.2.5.5 Poor phlebotomy practice

Proper sample collection (phlebotomy) is an important part of good laboratory practice and improper collection can lead to delays in reporting, unnecessary re-draws and re-tests, decreased end-user confidence, increased costs, incorrect diagnosis / treatment, injury and occasionally loss of life. Studies have shown the importance of checking for specimen adequacy as a critical factor in test result accuracy and usefulness (Lippi *et al.,* 2006). Samples that are missing, coagulated, haemolysed, insufficient or inadequate volumes due to inappropriate specimen collection and handling account for a large percentage of pre-analytical mistakes.

Improper phlebotomy practices are the bane of the clinical chemistry laboratory and are one of the main causes of pre-analytical errors, which occur due to lack of knowledge or heavy workload/ tiredness, as experienced in most NHS institutions seeking to save money by reducing overheads and reduction in number of staff. This has put a strain on the ability of the clinical chemistry laboratory to provide an excellent service to the users of its services. The procedure should always be performed by trained /qualified phlebotomists. In the clinical laboratory, venipuncture is described as all of the steps involved in obtaining an appropriate and identified blood sample from the vein (Haverstick and Groszbach, 2014). According to recommended practice (CSLI, 2007, 2008), the phlebotomist should ensure that the patient is comfortable and if appropriate should verify whether the patient is fasting (for at least 12 hours or overnight as necessary for some chemistry analytes such as glucose and lipids); what medications are being taken or have been discontinued, as required (Haverstick and Groszbach, 2014).

1.2.5.6 Inadequate/insufficient sample volume

Insufficient sample volume is a major factor leading to rejection of samples. The main reason for this anomaly is the lack of knowledge of the phlebotomist, difficult sampling procedures relating to paediatric patients, debilitated cases, those on chemotherapy, and those with difficult to localize veins. Insufficient sample constituted the most frequent cause of test rejection (Hammerling, 2012)

1.2.5.7 Interfering matrix (lipemia and haemolysis)

Lipemic samples are often seen following collection after heavy meals or the due to pre-existing metabolic disorders (e.g. as seen in patients with hyperlipoproteinemias). Some of these errors can be avoided by collecting samples after an overnight fast or by mentioning the metabolic disorder in the requisition form. Dietary lipids interfere with optical reading of the instrument and can affect electrolyte values (e.g. sodium). Too many lipemic samples are often due to non-dissemination of information regarding patient preparation by the clinicians, non-compliance and/or miscomprehension by the patient (Dzik *et al.,* 2003). It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection.

Haemolysis accounts for the majority of rejections in specimens, received in the laboratory (Sumera *et al.*, 2012). Sample haemolysis occurs when blood is forced through a fine needle during phlebotomy, shaking the tubes containing blood sample vigorously, and centrifuging the sample specimens before clotting (Lippi *et al.*, 2006). The introduction of vacuum tubes along with the closed system of blood collection has made blood collection efficient and easy. However, lack of staff training in

phlebotomy is an impediment for expediting sample collection and transport. Freezing and thawing of blood specimens also causes massive haemolysis. A study reported that over 95% of the haemolysed samples were due to incorrect sampling procedure or transportation (Lippi *et al.,* 2006). Haemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of some test analytes such as potassium, aspartate amino transferase, lactate dehydrogenase, folic acid, creatinine kinase, vitamin B12, phosphate, magnesium and ferritin.

1.2.5.8 Problems with sample preparation, storage and transportation

The length of time of sample preparation, including the speed and temperature of centrifugation, exposure to light and preparing aliquots, are important factors that must be considered before analysis. Proper sample storage condition is paramount (this relates to the length of storage, temperature, freezing and thawing). However during transport, a sample may be exposed to shaking, changes in light conditions, and changes in temperature. Transport delays to the laboratory can give rise to clinically important errors if transport conditions are not optimized (Meylan: Becton-Dickinson, 1995,1996,1997; Astion *et al.*, 2003).

The National Committee for Clinical Laboratory Standards (NCCLS) H5-A3 1994 recommended a maximum of 2 hours for transporting blood samples at a temperature of 10–22 °C. Delay in transporting the specimen to the laboratory where processing begins, not only prolongs the time until the attending physician receives a test result but also impacts specimen integrity that may lead to a false-negative or false-positive result of analysis and a misleading answer. A delay in transporting a blood sample to the laboratory for measurement of ‘blood sugar’ is likely to cause a ‘falsely reduced’

blood glucose result. Such errors that occur at this stage cannot be corrected later. These mistakes would require collection of fresh blood samples, which could be quite distressing for the patient. The sample preparation steps contribute to approximately 19% of the overall cost of analysing a single sample (Sumera *et al.*, 2012) and are time-consuming (37% of time spent in producing result). Other important sources of pre-analytical error not related to human mistakes include prescribed medications, which can cause errors through analytical (*in vitro*) or biological (*in vivo)* effects. Other patient-related physical variables such as stress, diet and exercise can also affect test results (Kouri *et al*., 2005; Blomback *et al.*, 2009).

1.3 Clinical laboratory informatics

The Lord Carter (2008) Review of Pathology recommended that information technology (IT) connectivity be put in place in all NHS pathology services as a matter of urgency, to improve the way that pathology enabled decisions about diagnosis and treatment are made by assemblage and analysis of data retrieved from LIMS. Recently 'Order Communications' have been comprehensively promoted as a way of improving efficiency and effectiveness of laboratory testing services (Yorkshire Centre for Health Informatics, 2014) through a number of perceived improvements in resource utilisation. Effective electronic communication between the clinical chemistry laboratory on the one hand and healthcare providers on the other hand is considered as an indispensable element of any efficient and effective pathology service, as it would help address gratuitous demands (such as unnecessary test requesting) and reduce or eliminate the risk of errors (Health Commissions Report, 2007).

Informatics relates to gathering, management, and processing of information usually involving computing. Medical informatics involves the design, management, and the study of systems that store and communicate medical information (Jackson *et al.*, 2008). It follows therefore that Clinical Informatics is an offshoot of medical informatics and is primarily concerned with the communication and management of information associated with laboratory analysis, generation of results and interpretation of test results (EFLM in the Pathologist, 2015). Efficient clinical laboratory operation relies heavily on informatics (Harrison and Geoffrey, 2008), since the function of the clinical laboratory is the creation and communication of information for patient diagnosis and management. Clinical informatics relates to processes that extend beyond the confines of clinical chemistry laboratory and may involve diverse 'extra-laboratory' processes, which embraces the support of correct test ordering by healthcare professionals, the accurate communication and storage of order requests, correct test interpretation and finally the management of information necessary for optimal performance by the clinical laboratory (Harrison and Geoffrey, 2008; EFLM in The Pathologist, 2015).

1.3.1 Laboratory information systems

Laboratory information systems (LIS) form a dynamic connection between the biomedical scientist, the clinical chemistry laboratory analytical platforms and the healthcare professionals. The clinical chemistry laboratory at STH NHS FT currently uses microcomputers in every phase of the TTP including pre-analytical workstations, analytical platforms, reagent inventory control, quality control, data interpretation, and online monitoring of analytical performance. All these aspects are integrated through a common database and communications network and in this way it is able to support

the extensive laboratory information system (Ashwood and Bruns, 2008; The Pathologist, 2015). Presently the total management of the pre-analytical as well as the post-analytical processes are entirely dependent on computer applications. The use of barcode technology has facilitated the automation of all the processes from patient and sample identification to sample testing on the analyser platforms (Da Rin, 2009; Hill et al., 2010; Ashwood and Bruns, 2008; EFLM in the Pathologist, 2015). Sophisticated and intelligent computer software programmes are now able to produce further information that may be used for identifying pre-analytical errors in the TTP (Harrison and Geoffrey, 2008), leading to better diagnoses, which maybe useful for managing patients and thus improve their wellbeing and safety (Ashikiran *et al.*, 2011; Plebani *et al.*, 2012). A key role of the LIS is to help reduce chances for errors, be it technical or human in origin.

The information generated by laboratory workflow is received, processed and stored and archived by the LIS. The LIS supports a myriad of laboratory functions by automating the flow of virtually all the extensive database applications that are embedded in clinical laboratory operations (Bates *et al*., 2001; Harrison and Mcdowell, 2008). It is becoming very common in most health institutions to interface LIS with Electronic Health Records (EHR) in order to link patient registration information with electronic test requesting (commonly referred to as 'Order coms'). The amalgamation of the LIS and EHR is commonly designated as Laboratory Information Management Systems (LIMS). A well-designed health information management system, which incorporates reliable, accurate and timely availability of data is widely acknowledged as a foundation of a robust public health system. The development of LIMS as part of the NHS has helped to support a variety of

programmes and functions such as internal and external quality assurance, research and information dissemination and governance (Georgiou *et al.*, 2007). Specifically the LIMS systems perform a myriad of functions from pre-analytics (test ordering and specimen collection), analytics as well as post analytics (reporting of test results) to healthcare professionals.

1.3.2 Laboratory test ordering: Manual versus ICE Order entry

Conventionally healthcare providers have always ordered laboratory tests using manual requisitions (paper-based orders). Healthcare providers would place a tick or write the name of the requested test on a pre-printed hospital laboratory order form. The sample would then be collected, labeled by a phlebotomist and placed in a specimen bag along with the requisition, and delivered to the clinical chemistry laboratory for analysis. However due to increasing pre-analytical errors, complexities, challenges, and resource constraints of modern healthcare systems (Hill *et al*., 2010), paper orders are becoming increasingly unsuitable. Manual order requests are gradually being replaced by electronic order entry systems, which allow direct healthcare provider input of diagnostic testing orders into requests into a computer system are known as Computerized Provider Order Entry (CPOE) systems. Anglia-ICE is an example of a CPOE systems used by STH NHS FT. Implementation of laboratory CPOE systems may offer healthcare centres many benefits, including reduced test turnaround time, improved test utilization (Hill *et al*., 2010). Electronic requesting should improve the accuracy of patient demographic information (Yorkshire Centre for Health Informatics, 2014); allow better tracking of results and allow laboratories to report the results of tests they send away for analysis via their normal reporting systems.

1.3.3 Sources of pre-analytical information

The Sheffield Teaching Hospital's clinical chemistry laboratory department maintains an on-line (intranet) laboratory handbook that provides information about correct pre-analytical procedures for phlebotomy staff and other healthcare professionals (consultants, registrars, house officers, nurses and midwives) who use the laboratory services to manage or treat patients. Medical, nursing and other healthcare professionals must be familiar with and understand the rationale of laboratory procedures and standards (IBMS, 2015). Their knowledge of these procedures is evaluated annually through training seminars and competency assessments and Continuous Professional Development (CPD) portfolios. There should be clear written guidelines for phlebotomists, nursing and midwifery staff who obtain samples from a patient on behalf of the requesting clinician or other healthcare practitioner. This online service is updated regularly to reflect current practices in clinical chemistry and procedures relating to sample collection, storage conditions, and the transportation of the samples to the laboratory (including those which are referred from external sites). The database also includes the addresses of other laboratories for referred tests.

1.4 Approaches for reducing pre- analytical errors in clinical chemistry

'*No measurement, no improvement*' – Lord Kelvin

A comprehensive and methodical approach to reducing pre-analytical errors has been previously described (Plebani and Bonini, 2002; Bates and Gawande, 2003; Plebani, 2006; Lippi and Guidi, 2007, Plebani *et al*., 2012, The Pathologist, 2015) and consists of five interrelated stages listed below:

a) Developing clear written standard operating procedures (SOPs) for routine and urgent clinical work.

b) Improving healthcare professionals' training.

c) Acquiring automated technologies / information systems, both for support operations and for executive operations.

d) Developing and monitoring quality indicators (QIs)

e) Improving communication between laboratory staff and other healthcare professionals.

1.4.1 Developing clear written standard operating procedures (SOPs)

Standard Operating Procedures (SOPs) should be controlled and must be unambiguous (Plebani, 2006; Da Rin, 2009; Bonini, 2009; Plebani, 2011). Trained laboratory staff charged with performing the pre-analytical procedures must understand the procedures in place and follow them exactly. They need to be aware of possible errors that may occur if the operating procedures are not followed, and what consequences these errors can have on sample analysis and eventually on patient management. The ISO 15189 Standard (2012) instructs laboratories to prepare a manual for the pre-analytical procedure that will give clear instructions to the patient before the collection of biological samples. Among other things, and depending on the type of analysis, patients would be instructed to control their diet, physical activities, stress, use of medications etc. This problem is most easily solved by the application of computerized referrals, where all the necessary data are obtained from the patient; however, the problem is much bigger when samples are collected at sites distant from the laboratory.

1.4.2 Improving healthcare professionals' training

Biomedical scientists and other laboratory staff have their training/competencies reviewed annually as part of a professional development portfolio (PDP) and Knowledge and skills framework (KSF). Biomedical scientists need to apply the knowledge and skills in a number of dimensions to achieve the expectations of their post (www.nhsemployers.org/SimplifiedKSF; www.ibms.org/learning/cpd/)

1.4.3 Acquiring automated technologies and laboratory information systems

The introduction of information technology (IT) and automated platforms has lead to an appreciable reduction in pre-analytical errors in the clinical chemistry laboratory (Da Rin, 2009). Computerized order entry (CoE) simplifies test ordering and eliminates a second person from transcribing the orders. The introduction of sample barcoding (to simplify specimen routing and tracking) and pre-analytical automated workstations abridge the process of sample separation, aliquoting and sorting into batches and thus reduce the number of manual steps and less staff (Jekelis, 2005; Da Rin, 2009) and helps to reduce human induced errors.

1.4.4 Developing and monitoring quality indicators, QIs

Performance and outcome measures can significantly improve the quality of patient care (Plebani, 2011). Such measurements of improvement can be achieved through the development and monitoring of specific quality indicators (QI) in the TTP (Mainz, 2004; Plebani, 2006). The pre-analytical phases in clinical chemistry are more prone to errors than the analytical and post-analytical phase (Plebani, 2001; 2010). Evidence abounds that before the turn of the century, reliable QIs and quality specifications have been developed and introduced for effective management of analytical processes

(Plebani, 2011; Sciacovelli *et al.*, 2011). The development of these specific QIs were an extension to the Internal Quality Control (IQC) systems coupled with availability of different External Quality Assessment (EQA)[1] schemes already in place, which have made it possible for the clinical chemistry laboratory to measure, monitor and improve their analytical performance on a monthly basis, although retrospectively (www.ukneqas.org.uk).

QIs have been defined as vital tools (IOM, 2000) for enabling clinical chemistry laboratory staff to quantify the quality of a selected aspect of patient care by comparing it against a defined criteria (ISO 15189: 2012). A QI objectively measures and evaluates all of 6 critical domains as outlined by the IOM, namely:

a) Patient safety, b) Patient-centeredness, c) Effectiveness, d) Efficiency, e) Equity and f) Timeliness. Assessment of QI is therefore based on the evidence associated with the aforementioned domains and can be implemented in a constant and comparable manner across settings and over a period (IOM, 2000); the identification of a reliable QI represents an essential stage in the schemes targeting evaluation and improvement of the quality of patient care. Although many authors are in agreement that QIs are important in providing information on continued improvement it has two major shortcomings: firstly, it is often difficult to compare data reported in the literature because of differences in QIs used (Plebani *et al.*, 2012) and the methods of collecting these data. Secondly, while the most common errors in the pre- and post- analytical phases are considered, available QIs do not include appropriate choice and selection of tests (Barth, 2012) as well as appropriate interpretation and utilisation of laboratory results at the right time (Barth, 2012).

[1] Clinical chemistry laboratory Department participates in EQA schemes organised by UK NEQAS and HEATHCONTROL.

According to the international standard for medical laboratories accreditation, QI should be part of an articulate and integrated quality improvement approach (ISO 15189: 2007) and should recognise the need to subdivide the TTP into phases (Plebani, 2006; Laposata and Dighe, 2007; Plebani, 2012). Assessing the quality of the clinical chemistry service using QIs means putting in place a systematic and consistent collection and analysis of data encompassing a comprehensive set of indicators that addresses all the phases of the TTP (Plebani, 2012).

1.4.5 Improved communication between clinical chemistry laboratory staff and other healthcare professionals.

Many mistakes generated in the TTP may be due to poor communication, action taken by others involved in the testing process (e.g., physicians, nurses and phlebotomists), or poorly designed processes, all of which are beyond the laboratory's control (Plebani, 2006). Inter-professional working to improve service delivery involves several healthcare professionals with expertise; knowledge and skill bases and experience being drawn together in a structure to provide services (Payne, 2000). These different professionals make adjustments and allowances in their responsibilities to take account and relate with the roles of others. Many workers value inter-professional team working as a source of mutual support in the face of internal and external pressures (Payne, 2000) and particularly the demands of working in the NHS and spending cuts. Failure to initiate and maintain communication between the laboratory and the users of its service may be responsible for causing certain medical errors. Clinical communication is highly complex and prone to errors especially during transitions of patient care and emergency situations. Standardised approaches and tools may

provide potential solutions to improve the quality of communication and prevent subsequent patient harm.

1.4.6 Quality indicators in the pre-analytic phase

IOM (2000) defined quality as:

"The degree to which health services for individuals and populations increase the likelihood of the desired health outcomes and are consistent with current professional knowledge"

As stated above, the pre-analytical phase should be subdivided into an extra-laboratory pre-analytical phase and a 'true' pre-analytical phase, which is undertaken within the laboratory after sample reception. The former phase, which comprises initial procedures usually performed neither in the clinical laboratory nor undertaken, at least in part, under the control of laboratory personnel, includes test requesting, patient and sample identification and sample collection. The latter phase involves the steps required to prepare samples for analysis (order entry into computer interface, centrifugation and aliquotting into secondary tubes etc.). In a patient-centred scenario, QIs should be designed to cover all steps of the pre-analytical phase, including the appropriateness of test selection, which is a key issue in projects aiming to ensure clinical effectiveness (Sciacovelli and Plebani, 2009). The IFCC Working Group in a recent study have identified 16 Quality Indicators to monitor the pre-analytical phase of TTP (Table 1.1)

Table 1.1 Quality indicators in the pre-analytic phase identified by the IFCC-WG

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

Adapted from Sciacovelli *et al*., (2011). Quality Indicators in Laboratory Medicine: from theory to practice. Clin Chem Lab Med. 49: 836–44.

The lack of patient identification or patient misidentification have serious consequences for reaching the final conclusion and clinical decision, as well as for patient safety, thus this is one of the key indicators in the process. Errors in patient identification may also occur during the procedures of sample preparation. Ordering inappropriate tests is another pre-analytical variable with a negative impact on patient safety. It is the cause of unnecessary test repetitions in up to 30% of cases (Plebani, 2006). Biomedical scientists in conjunction with clinical scientists should acquaint the clinician with the importance of biological variations, potentially significant in the pre-analytical process (test selection) but also in the post-analytical process (interpretation

of test results). It is necessary for the clinician to understand the concept of biological variations that include intra-individual biological variations (deviation of results in relation to the person's homeostasis) and inter-individual biological variations (variations between different persons in relation to the established homeostatic value). Based on such knowledge it is possible to select between two tests, the best one with the highest diagnostic value.

In the pre-analytical phase, major sources of variability - which includes biological variability, environmental conditions, postural changes, patient identification and sample labelling (Sumera *et al.*, 2012) tourniquet time, type of container (e.g., vacutainer tube), phlebotomy procedure (order of sample draw, contamination, mixing); sample transportation (time, pneumatic tube transport systems from wards and clinics); sample preparation for analysis (length, temperature of centrifugation, preparing aliquots (Sumera et al, 2012), can occur during patient preparation for phlebotomy. Errors that may occur in this process often become obvious in the analytical and post-analytical phase as well. For instance, the effects of interferences may be discovered during analysis or the clinical interpretation of results (for example a falsely elevated potassium result is observed in 'haemolysed' samples; similarly a sample with a high degree of lipemia or protein concentration will adversely affect the 'true' sodium result). For these reasons identification of quality indicators is necessary in order to avoid potential errors in the pre-analytical phase.

The most frequent deviations occur during patient identification in wards or patients attending clinics. Therefore, this phase requires special monitoring. The ISO 15189: 2012 Standard dictates what information a report form should include, regardless of whether it is in electronic or paper form, these are:

i. Unique patient identification – The STH NHS FT clinical chemistry laboratory requires that at least four identifiers (surname, first names, date of birth and NHS number) for patient identification (PID) must be accepted for in-patients and three for outpatients including cross-city samples, failing these 4 identifiers means samples are rejected. When the sample arrives at the laboratory reception, the common practice is to allocate a unique barcode that is used in conjunction with the PID during the TTP. The PID is a defining step in TTP.
ii. Name of requesting physician
iii. Type of primary sample
iv. Name of test (routine or urgent)
v. Relevant clinical information about the patient necessary for interpretation, date and time of primary sample collection.

1.5 Sample rejection and error reporting protocol in STH NHS FT

The STH NHS FT clinical chemistry laboratory has in place an established rejection criteria, but this is not strictly adhered to (personal observation). The Trust policy on sample labelling is that all samples must contain the patient's full name, date of birth, and hospital or NHS number. There must also be a clinical indication for the sample being taken, together with the requesting clinician's name and contact details. Failure to comply with this policy will result in the sample being rejected by the laboratory and not processed until the necessary information is provided.

It is sometimes difficult to reject a sample, but it must be remembered that a poor sample will give poor results (Sumera *et al.*, 2012). Management should regularly review the number of rejected samples and reasons for rejections by conducting audit and training on sample collection, and revising written procedures for sample management as and when needed. Staff members are always advised to record the reason for rejection (coded error comments) on a database and include all relevant information, and promptly inform the requesting clinician that the sample is unsuitable for testing and a request made for a repeat sample. The rejected sample is retained until a decision is finalized and in some circumstances, it may be necessary to proceed with the testing of a sample that is not optimal (Sumera *et al.*, 2012).

1.6 Research application and ethical approval

International guidelines define research as a systematic activity (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge (International Ethical Guidelines for Epidemiological studies, 2009). It is acknowledged that whilst 'participant-based' research is beneficial to research groups and globally, there could be associated risks to the research participants. Therefore in this research study appropriate steps were taken by following documented policies for conducting research, to protect participants by minimizing those risks. The research plan, including issues relating to informed consent and confidentiality were reviewed and approved by both the Scientific and Ethical Review Committee (REC) of Sheffield Hallam University (SHU) and the Clinical Effectiveness Unit (CEU) of STH NHS FT respectively. Approval letters (No. 03062014), from the Ethics committee of SHU, Research Degrees Sub-Committee and as well as the approval documents from the

research and development office of the STH NHS FT CEU (No. 5683) are included in the Appendices I, II and III).

1.7 Aims and Objectives of Study

The first part of this study involved an interrogation of the laboratory information management system to compare two separate periods before and after the implementation of Anglia-ICE (electronic test requesting) to determine whether the introduction of Anglia-ICE played a key role in reducing the occurrences of pre-analytical errors. This study, also included a survey of pre-analytical procedures in the phlebotomy units of STH NHS FT, in order to identify the potential sources of these errors and whether changing these practices may play a role in reducing the pre-analytical errors in the clinical chemistry laboratory.

Specific aims are:

- To investigate, categorise and determine the frequencies of pre-analytical errors in the TTP.
- To conduct a survey of pre-analytical procedures by phlebotomy staff to identify key error prone steps in the TTP.
- To draw any conclusions from phlebotomy staff practice and specific errors identified in the TTP.
- To engage with experts and seek advice to improve phlebotomy practice in STH NHS FT and to communicate the outcomes from the study to service users with the aim of improving the service and promote patient safety.

Chapter 2 Materials and Methods

2.1 Introduction

The practice of phlebotomy has spanned centuries and is still one of the most common invasive procedures in health care (WHO, 2014). It is important to note that every step in the process of drawing blood affects the quality of the sample and it is thus vital for preventing pre-analytical errors, patient injury and even fatality (Plebani *et. al.,* 2011; Salinas *et. al*., 2013; WHO, 2010, 2014). It is therefore imperative that healthcare workers undertaking phlebotomy practice are trained in procedures specific to the types of specimen they collect, in order to reduce pre-analytical errors, improve the quality of laboratory analysis and reduce harm to patients under their care. Poorly collected blood samples may yield inaccurate results, which may lead to incorrect interpretation by the requesting healthcare practitioner, and the patient may have to go through the inconvenience of repeat testing. Examples of the most common pre-analytical errors resulting from poor phlebotomy practice are inaccurate labelling/mislabelling of samples, sample haemolysis, contamination of sample, and poor sample storage practices.

LIMS constitute reliable, accurate and timely availability of patient data. It is widely recognized as the cornerstone of a good public health system. LIMS can support a variety of programs and functions including epidemiology surveillance and monitoring, outcomes assessment program planning and evaluation, quality assurance, policy analysis, research and information dissemination (Georgiou *et al.*, 2007; Wahls and Cram, 2007). LIMS have become key components of clinical and public health laboratory infrastructure in developed countries. Additionally this system performs a

variety of functions, from ordering tests to reporting results to health care providers. Computerised order Entry (COE) systems hold the promise of significant improvements to healthcare delivery and patient care (Georgiou *et al.*, 2007). The introduction of electronic requesting for laboratory testing has shown a gradual reduction in pre-analytical errors in the clinical chemistry laboratory over the last few years when compared with the old form of paper requesting (discussed in section **1.3.2**).

The benefits of COE systems have lead to improvements in patient outcomes, as well as major cost efficiencies (Green, 2013). This thesis considered the benefits of the COE over paper requesting within the two time periods under review. This present study sought the opinions of established professionals in Clinical chemistry laboratory practice and also sought advice from professional bodies such as IFCC, European Federation of Laboratory Medicine (EFLM), International Organization for Standardization (ISO), Clinical Science Laboratory Institute (CSLI), UKAS and the Institute of Biomedical Science (IBMS) etc. on strategies for reducing error rate in the pre-analytical phase of the total testing process (TTP), and improving the diagnostic services provided by the clinical chemistry laboratory.

2.2 Study Design

2.2.1 Interrogating the Laboratory Information Management System (LIMS)

The first part of this study was a restrospective interrogation of LIMS to retrieve data of laboratory errors. This included all test requests booked in as a set code "ERROR" in the clinical chemistry laboratory of STH NHS FT to cover two different periods (i.e. two years prior to the introduction of Anglia-ICE and two years post-implementation of Anglia-ICE

electronic test requesting). Anglia-ICE was implemented in STH NHS FT in 2010. The two periods were:

a) Pre-introduction of electronic requesting (2007 - 2008)
b) Post implementation of electronic requesting (2012 - 2013)

2.2.2 Pilot study - for the purpose of categorizing errors

A pilot study was carried out to extract data for the purpose of categorising errors in pre-analytical phase. A list of all sample errors (i.e. requests booked in as set code "error") in the clinical chemistry laboratory between February - March in 2013 were extracted from LIMS. Examples of such errors were: sample contamination errors, haemolysed sample errors, incorrect sample type and clotted sample errors. Results from the pilot study can be found in the Appendix XII.

2.2.3 Statistical Analysis – LIMS study

Pre-analytical raw data extracted from LIMS were entered into Excel 2010 spread sheet (Microsoft Corp., Redmond, WA) for pre-processing and coding. Differences in error frequencies between Pre-ICE procedure requesting and Post-ICE requesting procedure were compared using Chi-squared test. A p-value less than 0.05 was considered statistically significant. Chi-squared calculations and raw data from LIMS study are included in Appendices VII and VIII.

2.3 Questionnaire survey

The second part of the study was a questionnaire survey of pre-analytical practice of staff in the phlebotomy unit in STH NHS FT only and did not include phlebotomy units of A&E department and GP practice centres. The questionnaire survey was conceived on a cross-sectional study design. This study design collects data at one point in time and the matter of inquiry is captured as it manifests itself during the period of data collection (Polit and Beck, 2014). Significant practical advantages with the cross sectional study design are that it is economical and easy to manage (Polit and Beck, 2014). This design is also suitable when numerous variables are to be measured at the same time. Since the study investigated a moderate sample size of respondents and also several different practices, these features made the cross sectional design suitable. One important limitation with the cross sectional design is that 'causality' is difficult to establish since the exposure and the outcome will be measured at the same time. However, cross-sectional studies are appropriate when there is a strong theoretical framework guiding the analysis (Polit and Beck, 2014).

The questionnaire survey was undertaken because it has several benefits over interviews and observational studies - possibility for a greater number of respondents and no interview bias (Polit and Hungler, 1999; Polit and Beck, 2014). The questionnaire survey also allows for confidentiality, which is an advantage since this will increase the chance of a 'truthful response'. Questionnaires appear more suitable when using large sample sizes and for measuring practices (Polit and Beck, 2014). However, a questionnaire provides a measure of the reported practice, which does not necessarily correspond to the performed practice. This was considered when interpreting the results (Solderberg, 2009). Qualitative studies such as a questionnaire survey could be valuable

to provide a deeper understanding of important aspects of the pre-analytical phase that could not be gained by a quantitative approach. Insights in perceptions of the phlebotomy practices among medical and laboratory staff are useful when developing strategies for improving pre-analytical quality in the TTP.

2.3.1 Questionnaire Design and Validation

The questionnaire used for this study was developed and adapted from Wallin *et al*., (2010). The questionnaire was based on international procedures and recommendations for blood sampling (WHO, 2010, 2014), and designed to address phlebotomy practices and incident reporting in STH NHS FT as well as address the background characteristics of the respondents, such as years of experience and level of training in phlebotomy practice. After an initial pilot study, the questionnaire was further discussed and developed (for structure, construction, content, clarity, understanding and layout). The discussions involved experts in clinical chemistry testing and hospital staff with extensive phlebotomy experience including medical officers, staff nurses, section heads of phlebotomy units, medical laboratory assistants, clinical scientists, and biomedical scientists, laboratory manager in-charge of the clinical chemistry laboratory and the supervisory team for this study. Relevant and current literature and international guidelines (WHO, 2014) regarding the development of questionnaires was also accessed.

Wide-ranging consultations with experts in questionnaire design from the Clinical Effectiveness Unit (CEU) of STH NHS FT were made to guarantee that respondents clearly read and understood the content, then validated before the main research commenced. The questionnaire was limited to three pages to ensure the completion in a reasonable time frame. The questionnaire contained 18 questions, including a few open-

ended questions and sections for comments/suggestion in order to enable respondents to offer suggestions/opinions/comments relating to their practice. 80 copies of the questionnaire, including an introductory letter relating to the study were distributed to the two phlebotomy units of STH NHS FT. A copy of the questionnaire and error/incident reporting proforma are presented in Appendices IV, V and IX. The respondents were asked to return the completed questionnaires in envelopes, which were anonymised and sealed before delivery to the investigator.

2.3.2 Ethical considerations

This study did not require patients to attend STH NHS FT. This study was a survey of volunteer phlebotomy unit staff across both campuses of STH NHS FT only. Respondents were asked to state how they performed phlebotomy/error-reporting practices (Soderberg, 2009). The survey was to identify error prone steps in the TTP in order to be able to appropriately target interventions to improve practice. Identifying reported phlebotomy practice deficiencies has the potential to draw out a certain risk of 'feelings of guilt and self-criticism' among the respondents (Soderberg, 2009; Polit and Beck, 2014). This risk cannot be overlooked, but in order to minimise it, the questionnaire was strictly anonymous which should increase the likelihood of a 'truthful' answer. *An informed consent was made available to the respondents, explaining fully the procedures involved in the research; the return of the completed questionnaires was translated as acceptance of consent to participate in the study*, which was stated on the questionnaire.

2.3.3 Statistical analysis of questionnaire data

Completed questionnaire data and background characteristics of the respondents were typed in to an Excel 2010 for Macintosh data sheet (Microsoft Corp., Redmond, WA) and

then transferred to Statistical package for Macintosh, Version 23 (SPSS Inc., Chicago, IL), and basic descriptive statistics were used. Further analyses of data were performed with Prism 7 statistical software (GraphPad Software, Inc. 7825 Fay Avenue, La Jolla, CA 92037, USA) and Stats Direct statistical package (Stats Direct Ltd, 9 Bonville Chase, Altrincham, Cheshire WA14 4QA, UK). Some raw data and statistical analysis data from the questionnaire study are included in Appendices VI and X.

Chapter 3 Results I (LISM study)

3.1 Laboratory information management system (LIMS) study data collection and processing

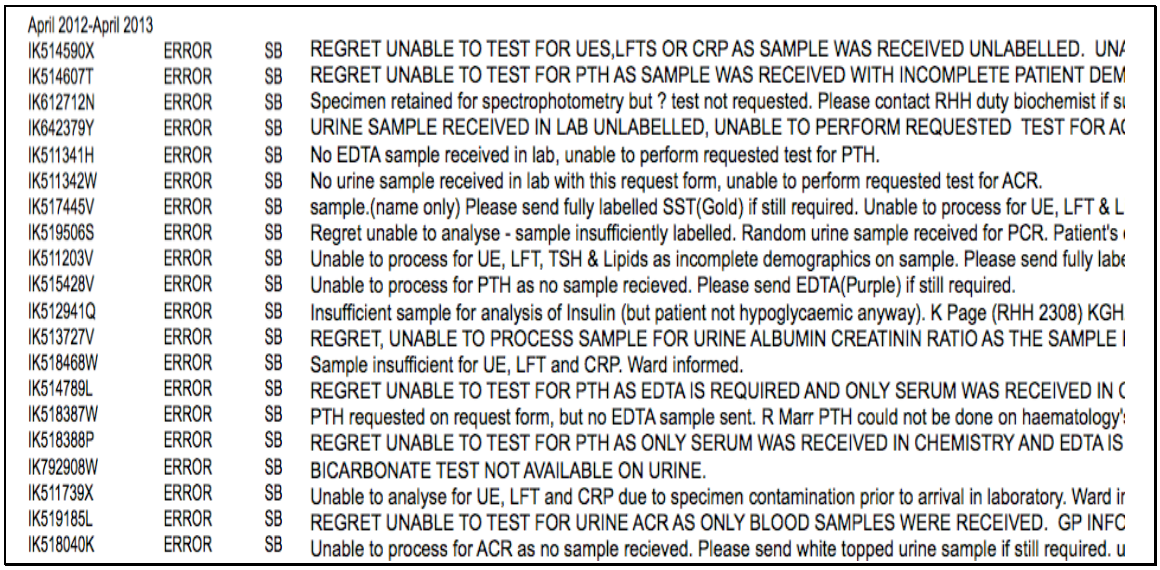
The first part of this thesis concerned the occurrence of errors in the pre-analytical phase of the TTP. To achieve this aim, a database search of the LIMS was instigated, setting the search criteria as "samples rejected for pre-analytical errors'' including the 'error comments' generated. The data collection was done retrospectively by querying APEX software and the LIMS system. The search included collection of data, booked into the system as a set code "ERROR" in the clinical chemistry laboratory of STH NHS FT to cover the period from 2007 to 2008 prior to the introduction of electronic test requesting (figure 3.1) and from 2012 to 2013 after migration to electronic test requesting (figure 3.2 below).

Figure 3.1 Screen capture of pre-analytical data from 2007- 2008 (pre Anglia-ICE implementation)

Raw data from Laboratory Information Management System query

IK505555K 10/07/2007 SB	Regret blood sample for U/E and LFT broke in centrifuge
IK657940K 21/11/2007 SB	Regret sample broken in centrifuge. Please repeat for TSH analysis Many apologies
IK728053V 15/02/2008 SB	Regret sample was broken in centrifuge. Unable to analyse for U&E
IK439564S 03/05/2007 SB	regret sample for LFT broken in centrifuge - please repeat
IK067427F 09/04/2007 SB	Sample unsuitable for analysis of U&E and LFT as grossly haemolysed. Ward informed and repea
IK070109Q 21/04/2007 SB	SAMPLE GROSSLY HAEMOLYSED.UNSUITABLE FOR U&E
IK074271V 08/05/2007 SB	SAMPLE GROSSLY HAEMOLYSED- WARD CONTACTED FOR REPEAT SAMPLE AT 15:20
IK079514R 28/05/2007 SB	sample for U/E LFT CRP Calcium Glucose & Amylase grossly haemolysed - please repeat
IK080015M 31/05/2007 SB	sample for U/E & CRP grossly haemolysed - please repeat
IK083090A 14/06/2007 SB	repeat sample requested for U&E and full LFT at 13:55 due to gross haemolysis
IK084086F 19/06/2007 SB	regret sample haemolysed- sho contacted for repeat sample as previous sample had low potassiu
IK100063R 31/08/2007 SB	REGRET UNABLE TO ASSAY FOR HCG. SAMPLE DATED 2.5.07 AND VERY HAEMOLYSED.
IK330641L 21/08/2007 SB	Regret
IK340520R 12/02/2008 SB	Regret
IK340522L 12/02/2008 SB	Regret
IK427158D 03/04/2007 SB	regret as sample grossly haemolysed unsuitable for LFT analysis
IK455244H 23/05/2007 SB	SAMPLE FOR PHC STUDY GROSSLY HAEMOLYSED - PLEASE REPEAT
IK460345B 23/05/2007 SB	Sample grossly haemolysed
IK506859B 10/07/2007 SB	Regret sample very haemolysed. A repeat would be advisable. Oestradiol requested on this sampl
IK534067L 14/08/2007 SB	REGRET SAMPLE GROSSLY HAEMOLYSED- UNABLE TO ANALYSE SAMPLE FOR LFT'S NO
IK583757X 10/10/2007 SB	Sample analysed on 15/10/07 due to labelling error. Sample grossly haemolysed

Figure 3.2 Screen capture of pre-analytical data from 2012-2013 (pre-ICE implementation)



April 2012-April 2013			
IK514590X	ERROR	SB	REGRET UNABLE TO TEST FOR UES,LFTS OR CRP AS SAMPLE WAS RECEIVED UNLABELLED. UNA
IK514607T	ERROR	SB	REGRET UNABLE TO TEST FOR PTH AS SAMPLE WAS RECEIVED WITH INCOMPLETE PATIENT DEM
IK612712N	ERROR	SB	Specimen retained for spectrophotometry but ? test not requested. Please contact RHH duty biochemist if s
IK642379Y	ERROR	SB	URINE SAMPLE RECEIVED IN LAB UNLABELLED, UNABLE TO PERFORM REQUESTED TEST FOR AC
IK511341H	ERROR	SB	No EDTA sample received in lab, unable to perform requested test for PTH.
IK511342W	ERROR	SB	No urine sample received in lab with this request form, unable to perform requested test for ACR.
IK517445V	ERROR	SB	sample.(name only) Please send fully labelled SST(Gold) if still required. Unable to process for UE, LFT & L
IK519506S	ERROR	SB	Regret unable to analyse - sample insufficiently labelled. Random urine sample received for PCR. Patient's
IK511203V	ERROR	SB	Unable to process for UE, LFT, TSH & Lipids as incomplete demographics on sample. Please send fully labe
IK515428V	ERROR	SB	Unable to process for PTH as no sample recieved. Please send EDTA(Purple) if still required.
IK512941Q	ERROR	SB	Insufficient sample for analysis of Insulin (but patient not hypoglycaemic anyway). K Page (RHH 2308) KGH
IK513727V	ERROR	SB	REGRET, UNABLE TO PROCESS SAMPLE FOR URINE ALBUMIN CREATININ RATIO AS THE SAMPLE I
IK518468W	ERROR	SB	Sample insufficient for UE, LFT and CRP. Ward informed.
IK514789L	ERROR	SB	REGRET UNABLE TO TEST FOR PTH AS EDTA IS REQUIRED AND ONLY SERUM WAS RECEIVED IN C
IK518387W	ERROR	SB	PTH requested on request form, but no EDTA sample sent. R Marr PTH could not be done on haematology's
IK518388P	ERROR	SB	REGRET UNABLE TO TEST FOR PTH AS ONLY SERUM WAS RECEIVED IN CHEMISTRY AND EDTA IS
IK792908W	ERROR	SB	BICARBONATE TEST NOT AVAILABLE ON URINE.
IK511739X	ERROR	SB	Unable to analyse for UE, LFT and CRP due to specimen contamination prior to arrival in laboratory. Ward ir
IK519185L	ERROR	SB	REGRET UNABLE TO TEST FOR URINE ACR AS ONLY BLOOD SAMPLES WERE RECEIVED. GP INFC
IK518040K	ERROR	SB	Unable to process for ACR as no sample recieved. Please send white topped urine sample if still required. u

Between March 2007 and March 2008, a total of 2,055 pre-analytical errors (representing 0.49% errors) in total samples tested were recorded in LIMS (table 3.1), with a mean of 171 pre-analytical errors per month. The total number of samples received in the clinical chemistry laboratory from various requesting centres in and around Sheffield was 416,703 in the same period (table 3.1 and table 3.2). Between April 2012 and April 2013 a total of 903,814 samples were received (table 3.1 and 3.2) from the same sources for test requests (table 3.2 and figure 3.3), out of which 1,616 samples (representing 0.18% errors) were rejected as a result of one category of pre-analytical error or another, with a mean of 135 pre-analytical errors per month within the study period.

Hence, all clinical chemistry laboratory test requests entered into the LIMS, in addition to the documented pre-analytical errors from the clinical chemistry laboratory were accessible for comparison. Overall an absolute error reduction rate of 0.31% was achieved (table 3.1), following the introduction of electronic test requesting.

Table 3.1 Overall error rates and differences from pre- and post-Anglia-ICE study

	Pre - ICE (2007 - 2008)			Post - ICE (2012 - 2013)			
All centres in Sheffield	**Total Errors**	**Total Samples received**	**% Errors**	**Total Errors**	**Total Samples received**	**% Errors**	**% Difference**
	2,055	**416,703**	**0.49**	**1,616**	**903,814**	**0.18**	**0.31**
Chi-squared test (x^2)							
P <0.05							

Table 3.2 Comparison of pre-analytical errors and their frequencies in the pre-analytical phase of TTP, prior to and after implementation of Anglia-ICE electronic requesting

ERROR TYPE	PRE-ICE FREQUENCY (2007-2008)	%	POST-ICE FREQUENCY (2012-2013)	%	P- VALUE	SIGNIFICANCE
INCORPAT	212	10.3%	49	3.0%	1.53E-17	S*^
NOFLOX	87	4.2%	30	1.9%	4.70E-05	S*^
LEAKTRANS	35	1.7%	7	0.4%	0.000328502	S*^
NOPRESV	8	0.4%	0	0.0%	0.012041577	S*^
EXLIGHT	16	0.8%	26	1.6%	0.018861059	S*v
ICEERROR	0	0.0%	11	0.7%	0.00017989	S*v
INCORSAM	171	8.3%	167	10.3%	0.036256617	S*v
NOICE	17	0.8%	27	1.7%	0.019729926	S*v
OLDSAMP	25	1.2%	36	2.2%	0.017351079	S*v
TIMEDEL	0	0.0%	8	0.5%	0.001407849	S*v
UNREQ	13	0.6%	57	3.5%	1.94E-10	S*v
WRCONT	10	0.5%	35	2.2%	4.43E-06	S*v
WRPRES	16	0.8%	36	2.2%	0.000225719	S* v
BROKCENTI	4	0.2%	1	0.1%	0.278923528	NS
BSHAEM	31	1.5%	13	0.8%	0.05166242	NS
EXAIR	2	0.1%	0	0.0%	0.209684004	NS
EXMATCH	1	0.1%	0	0.0%	0.375133544	NS
EXTIME	1	0.1%	0	0.0%	0.375133544	NS
ILLEGIBL	2	0.1%	1	0.1%	0.709111404	NS
INCOMPL	186	9.1%	129	8.0%	0.251237783	NS
INSUFF	99	4.8%	97	6.0%	0.11289448	NS
LABERRO	26	1.3%	18	1.1%	0.675727716	NS
LOST	15	0.7%	9	0.6%	0.518520517	NS
NOEDTA	168	8.2%	159	9.8%	0.078935649	NS
NOSAMP	287	14.0%	233	14.4%	0.696382596	NS
SAMCLOT	6	0.3%	6	0.4%	0.675994078	NS
SAMCONT	24	1.2%	28	1.7%	0.150574085	NS
SINTEG	3	0.1%	7	0.4%	0.097477046	NS
SWAPDET	47	2.3%	32	2.0%	0.524694148	NS
TESTNAV	30	1.5%	31	1.9%	0.280717382	NS
UNCODED	83	4.0%	63	3.9%	0.828901941	NS
UNLABL	427	20.8%	300	18.6%	0.094699319	NS
WRTEST	3	0.1%	0	0.0%	0.124398148	NS
TOTAL NO OF ERRORS RECORDED	**2055**	**100.0%**	**1616**	**100.0%**		
TOTAL NUMBER OF SAMPLES RECEIVED	**416703**		**903814**			

Legend:

For Significance $p<0.05$

NS - No significant change in error rate

S*^ - Decrease in error frequency post Anglia-ICE implementation

S*v - Increase in error frequency post Anglia-ICE implementation

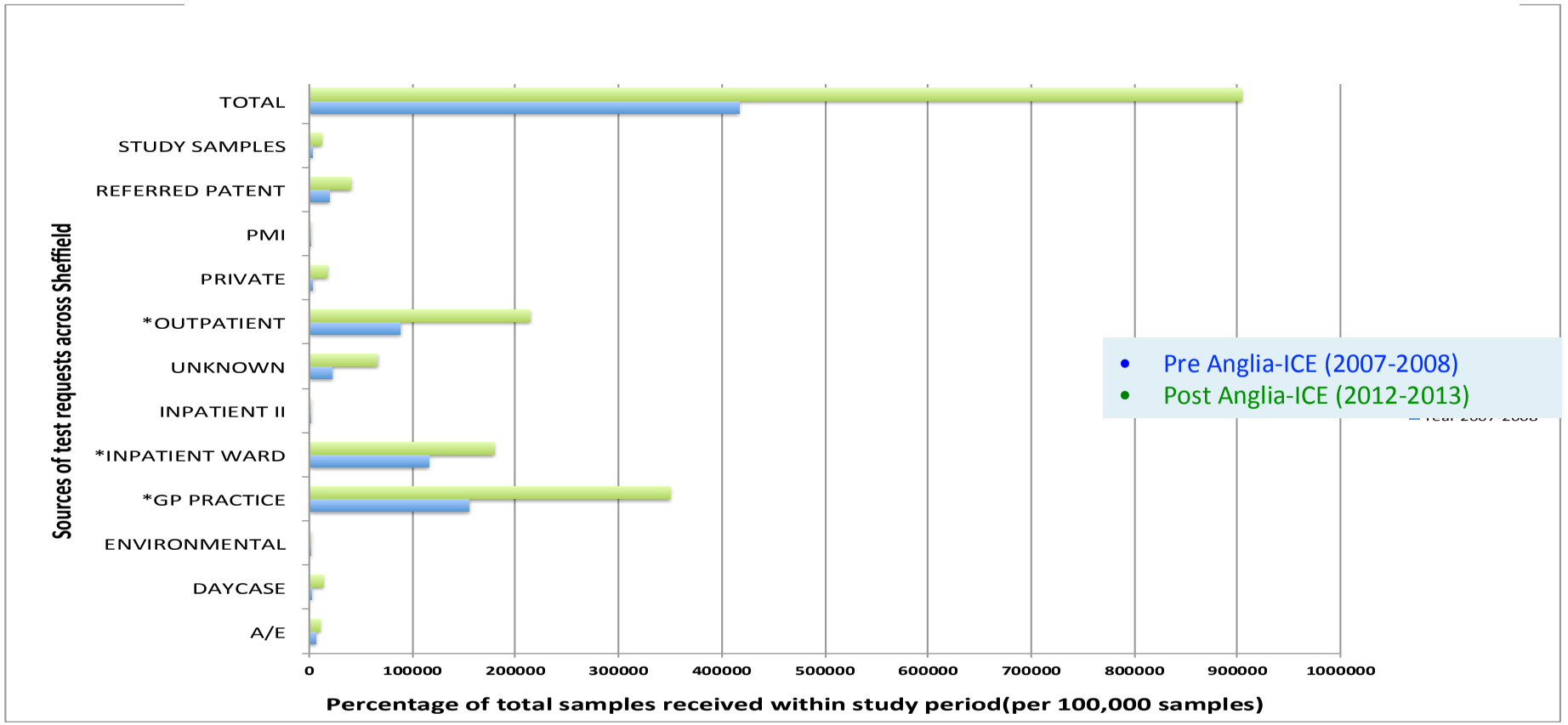
Table 3.3 Total number of samples received from requesting centres between the two periods under review.

SOURCE OF TEST REQUEST	Year 2007-2008	% of Total	Year 2012-2013	% of Total	Increase / Decrease in Total
*A/E	6357	1.526	10472	1.159	4115
*DAYCASE	2301	0.552	13649	1.510	11348
ENVIRONMENTAL	15	0.004	9	0.001	-6
**GP PRACTICE	154719	37.129	350041	38.729	195322
*INPATIENT WARD	115896	27.813	179414	19.851	63518
*INPATIENT II	238	0.057	305	0.034	67
UNKNOWN	22341	5.361	65901	7.291	43560
*OUTPATIENT	88409	21.216	214161	23.695	125752
PRIVATE	3493	0.838	17338	1.918	13845
PMI	1017	0.244	29	0.003	-988
REFERRED PATIENT	19215	4.611	40499	4.481	21284
STUDY SAMPLES	2702	0.648	11996	1.327	9294
TOTAL	416703		903814		487111

Legend

* Test request centres where Anglia-ICE had already been implemented in 2010.
** Centre with the most test requisition per year
A/E – Accident and Emergency department of STH NHS FT
PRIVATE – Private patients attending STH NHS FT
PMI - Private medical insurance

Figure 3.3 Total number of samples received from requesting centres between the two periods under review



Legend

% of total samples received in clinical chemistry laboratory in 2007-2008 (Pre-ICE Electronic Order entry)

% of total samples received in clinical chemistry laboratory in 2012- 2013 (Post-ICE Electronic Order entry)

During the conduct of the present studies, an electronic order entry (Anglia-ICE or COES) system had already been in place in STH NHS FT. The central features include printing of the patient's name and NHS identification number, the time and date of sampling and a short sampling instruction on each test tube label. The implementation also included standardized routines for ordering of tests and handling of test tube labels. The electronic order entry should have eliminated most of the investigated error-prone test request practices, but will not cover several of the important manual VBS practices surveyed in this thesis.

3.2 Coding of pre-analytical errors from LIMS

According to recommended practice, each sample rejected due to a pre-analytical error is registered into the LIMS database by the laboratory staff. It usually includes a standardized 'error coded comment'. Any explanatory or advisory comment is entered as free text to support the reason for rejection, if applicable. After the database search, the data was extracted from the LIMS and transferred into an excel spreadsheet for further statistical manipulation in order to classify or categorize the error. However a large percentage of the errors had been registered unto the LIMS database only as 'free texts comments' (in order to describe the nature of the pre-analytical errors) and not as ''coded comments,'' which should be the standard protocol. The recording of these pre-analytical errors as free text comments in the LIMS created a problem as it made the pre-statistical process of 'cleaning the data' very arduous. To get around this problem a system of coding was devised by the researcher (table 3.4). Thirty-three (33) error codes were generated and assigned to groups of generically similar pre-analytical error comments, in order to assign the errors into categories.

Table 3.4 Coding and categorisation of pre-analytical error in the Pre-analytical phase of TTP

	ERROR CODE	PRE-ANALYTICAL ERROR TYPE
1	**BROKCENTI**	Sample broken in centrifuge
2	**BSHAEM**	Haemolysed sample received in laboratory
3	**EXAIR**	Sample contains un-expelled air
4	**EXLIGHT**	Sample exposed to light
5	**EXMATCH**	Patient identity mismatched
6	**EXTIME**	Late arrival of 'timed sample' request
7	**ICEERROR**	Electronic order generated error (Anglia ice/COE)
8	**ILLEGIBL**	Patient's details illegible
9	**INCOMPL**	Incomplete patient's details
10	**INCORPAT**	Incorrect patient details /wrong patient sample
11	**INCORSAM**	Incorrect sample type
12	**INSUFF**	Insufficient sample received
13	**LABERRO**	Laboratory reception error
14	**LEAKTRANS**	Sample leaked in transit
15	**LOST**	Sample lost in transit/lost in laboratory
16	**NOEDTA**	No EDTA sample received
17	**NOFLOX**	No fluoride oxalate sample revived for glucose/ lactate request
18	**NOICE**	Sample not received on ice (e.g. ammonia request)
19	**NOPRESV**	Sample received without appropriate preservative
20	**NOSAMP**	No sample received / empty sample container
21	**OLDSAMP**	Sample received more than 24 hours (left on cells)
22	**SAMCLOT**	Sample arrived in laboratory clotted
23	**SAMCONT**	Sample received contaminated
24	**SINTEG**	Compromised sample integrity
25	**SWAPDET**	Swapped patient demographics
26	**TESTNAV**	Test not routinely available in laboratory
27	**TIMEDEL**	Delay in receiving timed sample in laboratory
28	**UNCODED**	Unspecified pre-analytical error type (e.g. no clinical details or duplicated requests)
29	**UNLABL**	Unlabelled sample received
30	**UNREQ**	Unrequested test received (no test requests)
31	**WRCONT**	Sample received in wrong container
32	**WRPRES**	Sample received in wrong preservative
33	**WRTEST**	Wrong test request received

For example, code UNLABL represents unlabeled sample errors; code INSUFF represents 'insufficient or inadequate sample volumes' etc. (table 3.4). The coded data was transferred to an Excel 2010 for Macintosh data sheet (Microsoft Corp., Redmond, WA) and then transposed to Statistical package for Macintosh, Version 23 (SPSS Inc., Chicago, IL). Calculations of specimens with errors were presented as percentages. Statistical differences in error frequencies between pre-electronic test requesting procedure and post-electronic requesting procedure were compared using a Chi-squared test. A p-value of less than 0.05 was considered statistically significant.

3.3 Results of LIMS Study

A descriptive analysis of the frequencies and percentages of the Pre-ICE and Post-ICE analytical errors and the total number of samples received for the study periods is provided in table 3.2. Samples for testing are collected from various STH NHS FT departments including accident and emergency department (A/E), in-patient wards, out-patient wards, specialist clinics, day-case units, phlebotomy units, private clinics, referrals and clinical trial (study samples) and from the majority of General Practice (GP) Surgeries spread across Sheffield. The largest numbers of test requests are received from the GP practices and from in-patient wards of both hospitals. Samples from the inpatient and outpatient wards are delivered to the clinical chemistry laboratory through the Pneumatic Tube System Transport (PTST) or hand delivered by the phlebotomists/hospital porters. Samples outside the hospitals (GP and Private Clinics and study samples etc.) are delivered by vans to the central receiving point in phlebotomy unit at stipulated times or delivered by pre-arranged taxis and dropped off at the laboratory. The highest numbers of requests were those received from GP practices during both periods of this study (table 3.3 and figure 3.3). 154,712 samples were received in 2007-

2008 representing 37.1% of the total samples received in that year. In 2012-2013 study years the request from the GP centres rose to 350,041 (38.7% of total samples received). Samples received from the inpatient wards in 2007-2008 were 115,896 (27.8% of total samples received), increasing to 197,414 (19.9%). Similarly, outpatient requests rose sharply from an initial 88,409 (21.2%) to 214,161 representing 23.7% of the total samples received for the 2012 - 2013 study period. The total numbers of samples received from the other centres are presented in table 3.3.

Figure 3.3 presents a bar chart of the percentages of the total number of samples received for both periods under study. Although more requests were received in 2012-2013 from most of the centres (excluding Environmental and private medical insurance (PMI), there appears to be an overall decrease in requests received from the A&E unit and inpatient wards of STH NHS FT as a percentage of the total numbers of samples received in the laboratory for testing, when both periods were compared. Overall GP surgeries, inpatient and outpatient wards show definitive increases in percentages between the two study periods.

Breakdown of retrospective data from LIMS revealed that, of the total pre-analytical sample errors received for the Pre-ICE period, 427 (20.8%) were recorded as unlabelled errors (UNLABL); 287 (14.0%) were reported as no sample received errors (NOSAMP**)**. Other results for the pre - and post-ICE test requesting periods are presented in table 3.2. There were significant reductions in frequencies for INCORPAT (incorrect patient details/ wrong patient sample), LEAKTRANS (sample leaked in transit), NOFLOX (no fluoride oxalate sample received for glucose/ lactate request) and NOPRESV (samples received with no preservative). Of particular importance is the

significant Post-ICE reduction in INCORPAT (incorrect patient details /wrong patient sample errors) where the researcher observed an absolute reduction in error rate, which appears to be directly linked to implementation of Anglia-ICE, as entry of data is a pre-requisite.

Further analysis of the data shows no significant changes in absolute terms for 18 of the pre-analytical error categories in the present study. Interestingly when the frequencies of these pre-analytical errors were calculated as a proportion (per every 100,000) of the total number of samples received from various requesting centres, pre- and post-implementation of Anglia ICE, an abrupt reduction in frequencies was observed post Anglia-ICE implementation for most error types, except WRPRES, WRCONT, SINTEG, ICEEROR and TIMEDEL (figure 3.4). However these apparent reductions in error rates failed to yield any significance ($p > 0.05$) when a chi-squared test was applied (Appendix VII). One theory underpinning this study was that the introduction and implementation of Anglia-ICE in STH would considerably reduce patient identification related errors and eliminate the requesting of tests that were not routinely available (TESTNAV) in the clinical chemistry laboratory. There were no statistical significant changes in relation to these errors. The most probable explanation for this result may be linked to the non-implementation of the electronic order systems by a majority of the requesting centre outside STH NHS FT e.g. GP Practices and private clinics, where most of the samples for biochemical testing are manually requested and are therefore prone to a multiplicity of human errors.

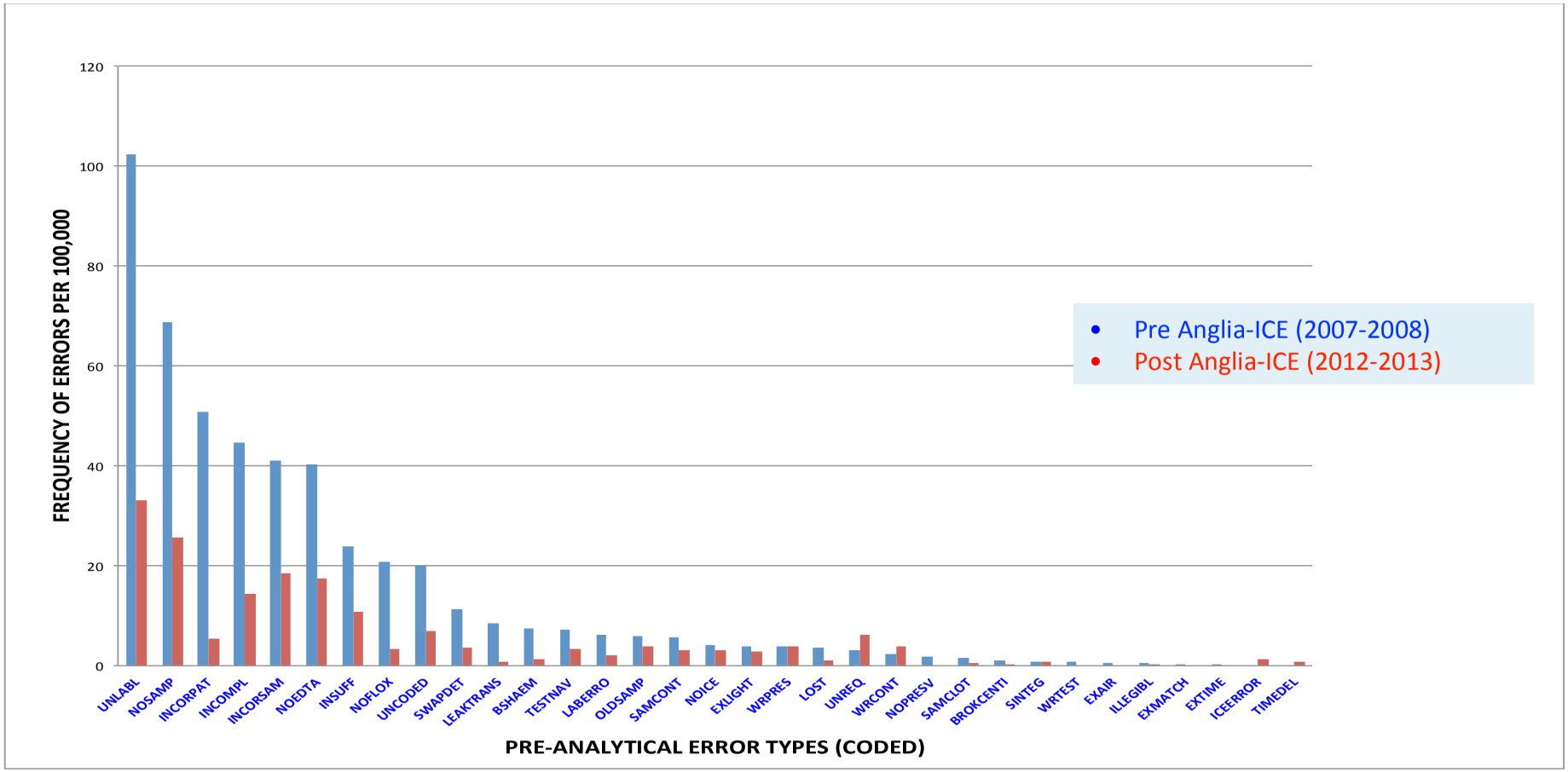


Figure 3.4 Error type as a fraction of the total samples received within the 2 study periods under review

3.4 Discussion – LIMS study results

Pre-analytical errors in the clinical chemistry laboratory have a high possibility of causing serious harm or fatalities to patients. In a study by Bonini *et al.*, (2002) a high frequency of laboratory errors resulted from the misidentification of samples such as illegible patient details, incomplete patient details, incorrect patient details /wrong patient sample (INCORPAT), and swapped patient demographics (SWAPDET). In a similar investigation by Valenstein *et al.*, (2006) involving monitoring of sample misidentification for over 5 weeks in pathology laboratories at 120 institutions, they observed that of the 6,705 errors reported, 4,852 (72%) errors were categorised. Of these, 55.5% were due to primary specimen labelling errors. Valenstein and co-workers estimated that such sample misidentification errors could result in as many as 160,900 adverse events per year (Valenstein *et al*, 2006). Consequently, it appears that accurate patient identification and verification of samples would address many of the reported sources of pre-analytical error and may considerably result in improved patient care and safety (Hill *et al.*, 2010).

Following the introduction of Anglia ICE system of electronic test ordering in 2010, there appears to be a gradual decrease in the 2012/2013 study period in some pre-analytical error incidences when compared with the 2007/ 2008 period. Thus there appears to be an absolute error reduction of 0.31% even though more samples were received during the post-Anglia-ICE period from all the requesting centres in Sheffield. The use of Anglia-ICE or similar computerised bar-coding systems to match specimens to patients has been shown to improve the accuracy of specimen labelling and patient identification in studies by others (Hayden *et al.*, 2008; Hill *et al.*, 2010).

Previously, a 3-year study by Hayden *et al.*, (2008) in a large oncology hospital (St. Jude Children's Research Hospital in Memphis, Tennessee, U.S.A), showed a significant decrease in the 'mislabelled sample' error rate from 0.03% to 0.005% after the implementation of COE systems combined with bar-coding systems. A similar COE system was also used by Hill *et al.,* (2010), in an emergency department of John Hopkins University School of Medicine Hospital and had been shown to significantly reduce clinical laboratory specimen identification error. In a cohort pre- and post-intervention study conducted within a 61-month period, with a 2-component structured intervention, with retrospective data, Hill and co-workers (2010) observed a reduction in the mislabelled specimen rate from 0.42% to 0.31% after the implementation of a computerised bar-code-based verification process. These results support this present study where an absolute error reduction rate of 0.31% was achieved, which is an improvement on that reported by Hill and co-workers.

Although the clinical chemistry laboratory's labelling errors have reduced with the introduction of Anglia ICE software and bar-code labelling in the phlebotomy units, in-patient and out-patient wards, the is not applicable to GP centres and private clinics across the city of Sheffield. These are the other sources of test requests, but were yet to implement the Anglia-ICE system this study was conducted. While it may be argued that the introduction of Anglia ICE may have been directly responsible for the reduction of some pre-analytical errors previously detailed in the results section, there is the potential that electronic order systems might also have no advantage at all in reducing some pre-analytical errors or may in the worse scenario, lead to an increase of other types of ordering errors not identified or reported to the clinical chemistry laboratory (Hill *et al.*, 2010). For example, errors such as SWAPDET (swapped patient

demographics) may be generated in an electronic order system when patients with similar surnames or first names occur next to each other on a computer screen or database and selecting the wrong patient by the requesting healthcare professional can be easily done. Analysis of data has also shown that Anglia-ICE has not been able to reduce a category of pre-analytical errors such as EXLIGHT (sample exposed to light), NOICE (sample not received on solid ice), OLDSAMP (sample received after more than 24 hours delay), TIMEDEL (delay in receiving timed sample in laboratory), WRCONT (sample received in wrong container) and WRPRES (sample received in wrong preservative).

In fact the errors (mentioned in previous paragraph) have increased in frequencies post-introduction of Anglia-ICE, because all these error types are usually associated with pre-analytical operation that directly involve manual procedures or requiring human intervention. Of notable concern is the increase in electronic order generated errors (ICEERROR). This is not unexpected as there were teething IT issues and technical problems which were commonplace, especially since the new system had been in use for less than 2 years and it is probable that this error category will reduce over the coming years. Thus a radical approach to reducing the occurrence of a majority of these errors that continue to rely on manual processing may involve frequent re-training/education programmes for service users by clinical chemistry laboratory professionals and experts (The Pathologist, 2015).

Chapter 4 Results II (questionnaire study)

4.1 Questionnaire study for evaluation of practice

A questionnaire survey of pre-analytical practice/procedures was conducted in STH NHS FT to capture the attitudes of staff of the phlebotomy unit towards current practice. 80 copies of anonymous questionnaires were sent out to respondents with 18 questions, including open-ended questions and sections for comments/suggestions. The response rate was 85% as 68 participants returned completed questionnaires.

The questions were designed as statements describing laboratory procedures and answers were offered as frequency of particular procedure performed in the respondent's ward or centralized phlebotomy unit on a three or six-grade Likert scale, testing self-reported frequency. For example questions 4 to 5 were graded as: **Yes = 1, No = 2, don't know =3; Questions 6,7, 10 to 17 were recorded as: Always = 1, Often = 2, Seldom = 3, Never = 4. Unanswered questions were recorded as 5 and comments/suggestions were recorded as 6**.

The questions were also divided in 4 sections, to include questions regarding training and routine procedures in phlebotomy practice (7 items), questions regarding patient identification, the handling of test requests and test tube labelling (5 items), questions concerning sampling, sample storage, and information search procedures (5 items) and finally questions relating to error/incident reporting (2 items). There were only two open-ended questions.

4.1.1 Employment, training and routine procedures in phlebotomy practice (Questions 1 – 5)

Of all the respondents (n = 68) that took part in the questionnaire survey only 13% (n=9) had been in employment for 5 years approximately, in the phlebotomy unit of STH NHS FT (figure 4.1). 3% (n=2) of the respondents had been in employment for between 10-22 years. The mean number of years in employment for all respondents is 9 years. 51% (n=35) of the respondents reported to have attended training in the last year (figure 4.1b), while a total of 43% (n=27) had been given refresher training in the previous 2-5 years. However 6% of the staff stated that they had not had the opportunity of attending any refresher training since they were first employed by the Trust. There was no correlation between the number of years in employment and years of training (figure 4.2). 53% (n=36) of all the respondents reported to carry out the VBS procedure every workday, 35% (n=24) of the respondents perform this duty every week, while 9% (n=6) of the staff perform this duty at least once a month. Only 3% (n=2) reported to perform VBS less often in relation to the options provided (figure 4.3).

88% (n=60) of the respondents stated that they were aware of documented information (printed manuals/SOPs/phlebotomy handbook and online laboratory VBS manual), to assist with their VBS duties, while 12% (n=12) of the staff was oblivious to this source of information (figure 4.4a). 91% (n=62) of the respondents reported that they were aware of the presence of undocumented information (such as posters and leaflets) in the phlebotomy unit, to assist with their VBS duties, while 8% (n=6) of the respondents simply did not know or were not aware that such sources of information exist (figure 4.4b).

Figure 4.1a Distribution of length of time in employment of staff in phlebotomy unit of STH NHS FT

Figure 4.1b Distribution of length of time of staff in recent VBS training in STH NHS FT phlebotomy unit

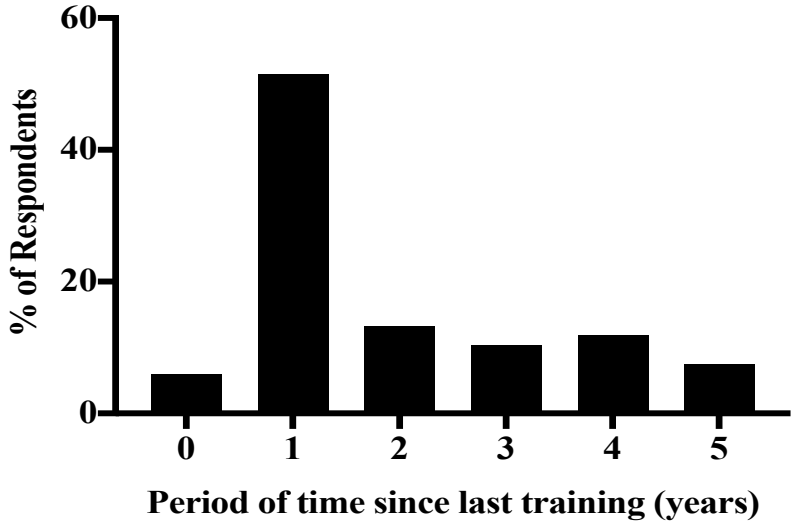
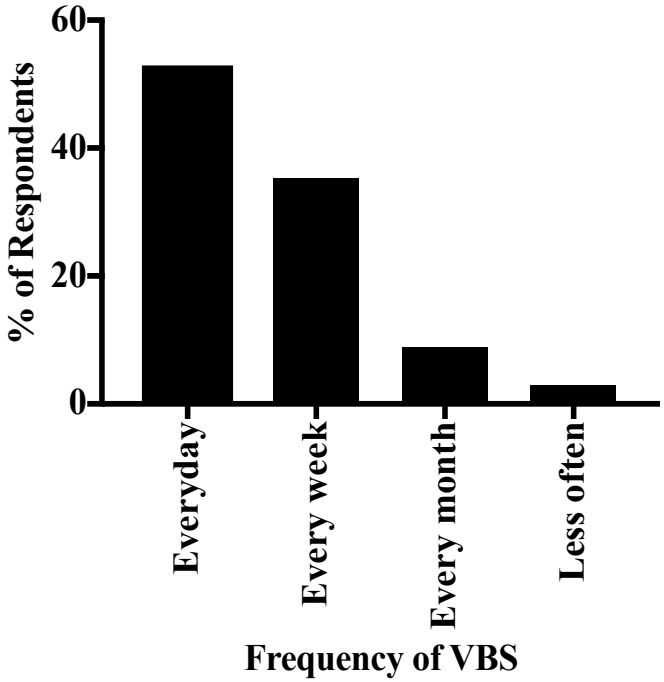


Figure 4.2 Correlation between length of service and years in VBS training

Figure 4.3 Percentage of phlebtomy staff carrying out VBS in wards/units of STH NHS FT



52% (n=35) of all the respondents stated that they would be interested in receiving further training in VBS and sample handling, 35% (n=24) of the staff were not interested in seeking further training, while 13% (n=9) have not considered whether they would be interested or not in taking up the opportunity for further training (figure 4.5a). 62% (n=42) of respondents indicated an interest in receiving information about VBS techniques, 22% (n=15) were not interested, while 13% (n=9) of the respondents were unsure (figure 4.5b). 3% did not respond with any answer.

Figure 4.4a Percentage of staff with awareness of documented routines for VBS in phlebotomy unit in STH NHS FT

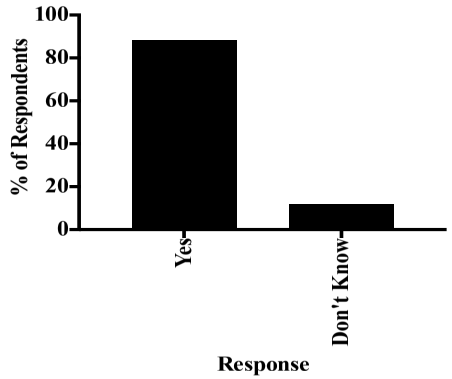


Figure 4.4b Percentage of staff with awareness of undocumented routines for VBS in phlebotomy unit in STH NHS FT

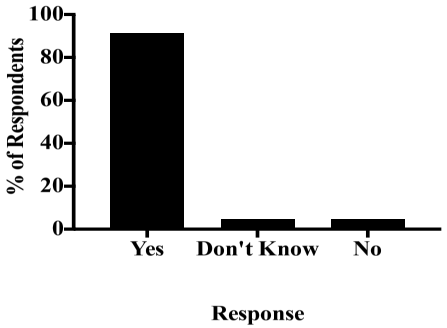


Fig 4.5a Percentage of staff signifying interest in receiving further training in phlebotomy practise in STH NHS FT

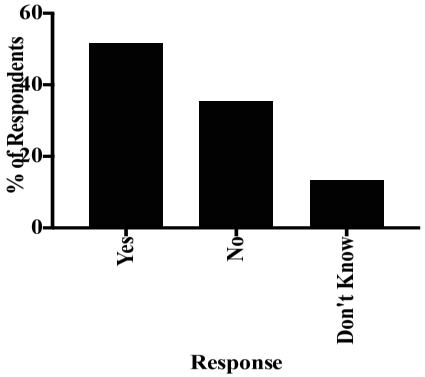
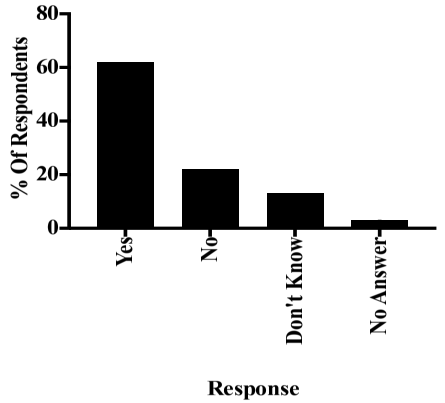


Figure 4.5b Percentage of staff signifying interest in receiving further training in phlebotomy practise in STH NHS FT



4.1.2 Patient Identification (PID) processes undertaken by phlebotomists (Question 6)

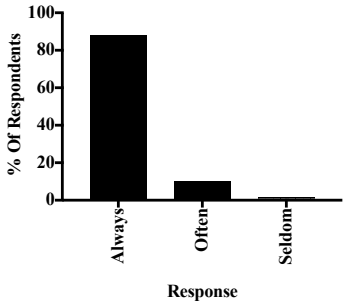
In the questionnaire survey, 88% of the respondents reported that they always follow the procedure of asking the patient to state his/her name and surname in order to identify the patient (figure 4.6a). 10% of the respondents reported to only 'often follow this procedure'. In addition to asking the patients to state their names only 7% of the respondents have considered verifying patient's identification from past knowledge, while 84% of the respondents in the survey reported to never use previous acquaintance with the patient as a process of identifying patients (figure 4.6b). About 25% of the respondents stated that they 'always checked the wristbands of in-patients' (patients on admission on the wards). 13% of the respondents seldom checked wristbands for patient identification, while 41% have never bothered to check at all (figure 4.6c).

31% of the respondents reported to seldom ask the patient's family/relative or carer for the patient name and identification number (figure 4.6d). 49% of the respondents reported never to use this means for patient identification, while about 5% reported to 'often or always ask a patient's relative' as a means for identifying their patients before the VBS procedure. 10% of the participants did not respond to the question in section 6 (d).

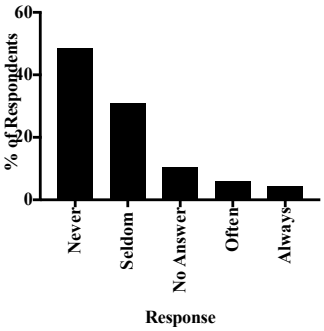
65% of the respondents reported to never use the patient health card for identification purposes (figure 4.6e); 22% of the respondents did not respond to this question at all.

Figure 4.6 (a-e) Staff approaches to patient identification procedures before VBS

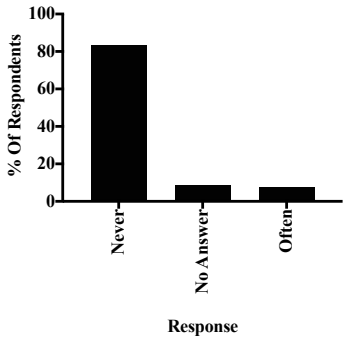
Q6a. How often do you check patient ID by asking for their names?



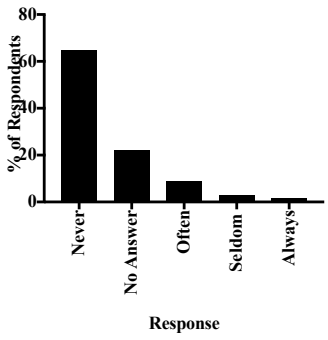
Q6d. How often do you check patient's identification by asking their family member?



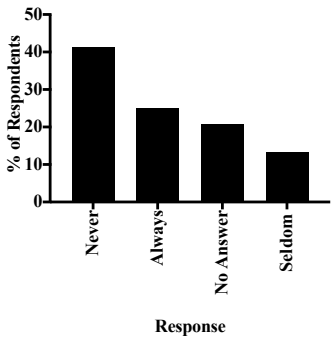
Q6b. Since I know the patient I do not need to check PID-how often do you do this?



Q6e. How often do you check patient's ID during VBS by checking their healthcare card?



Q6c. How often do you check patient's wristband identification?



79% of the respondents returned no comment to the question when asked to comment whether the respondents would consider checking the identity of patients by other means different from the options provided in questions 6(a-e) before performing VBS.

Only 21% of respondents made the following three common observations below:

1. 'I sometimes asked for translators for patients who could not communicate in English language'
2. 'In addition to question 6a above, I always ask the patient to state their DOB, NHS or hospital number, GP practice they attend and home address'
3. 'I always ask for the patient to confirm their DOB, NHS or hospital number and home address as stated in the patient demographics'

4.1.3 Managing sample test requests

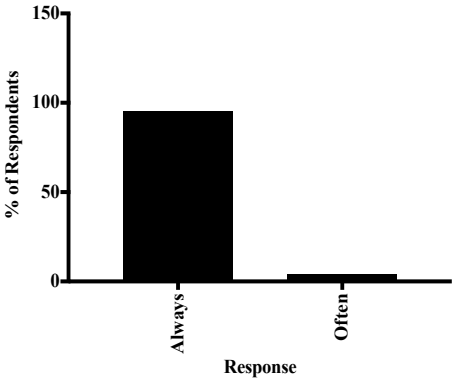
96% of the respondents reported to always follow the procedure of comparing the patient's identification details with information provided on the test request form (figure 4.7a), while only 4% of the total respondents stated to often perform this procedure.

Of all the respondents, 53% reported to always use test requests that another colleague had completed (figure 4.7b), while 23% of the respondents reported to never use test requests that another colleague has completed. 69% of the respondents reported to always check information on the test request, especially if another colleague has completed it, while 13% of the respondents stated to often perform this check. 7% of the respondents stated to never perform this check (figure 4.7c).

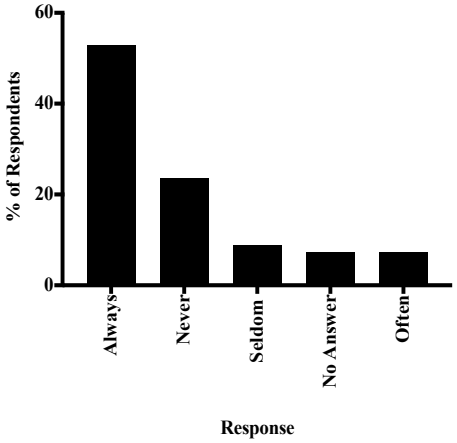
With regards to questions around the entering sampling time on the test request, 29% of respondents stated to always adjust the sampling time if the marked time differed by more than 30 minutes from the actual sampling collection time, while 31% responded to never adjust sampling time even if there are variations (figure 4.7d). To seldom adjust the sampling time, if the marked time differed by more than 30 minutes was reported by 16% of the respondents. 46% of all respondents reported to always sign the test requests, 21% seldom performed this task, while 26% never sign the test requests at all (figure 4.7e).

Figure 4.7 (a-e) Staff approaches to test request procedures

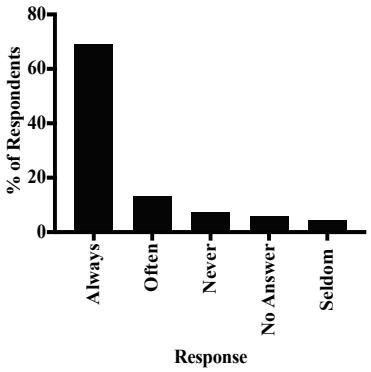
Q7a. How often do you compare patient's ID with information on test requests?



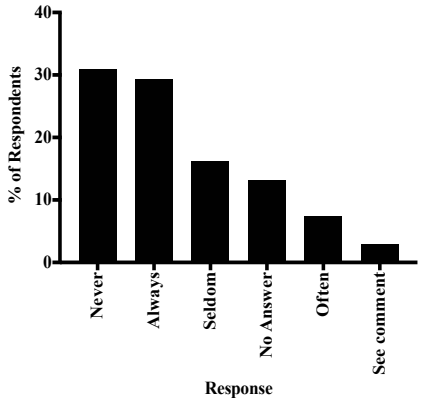
Q7b. How often do you use the test request that another member has completed?



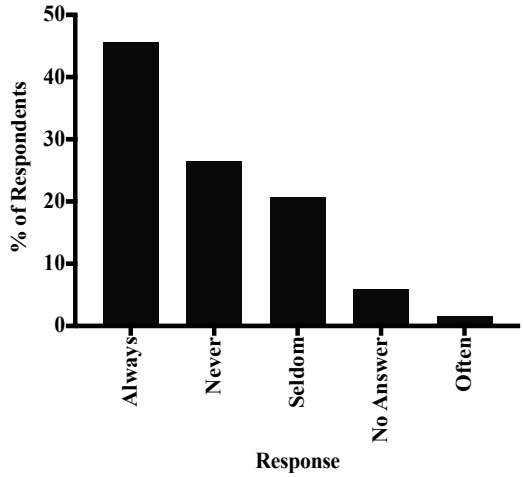
Q7c. How often do you check information on a test request that another staff has completed?



Q7d. How often do you adjust time of VBS sampling on request form?



Q7e. How often do you sign a test request form?



4.1.4 Responsibility for marking sampling time on sample/request forms

According to the survey statistics for this section, 49% of the respondents reported to never allow other colleagues to mark the sampling time on test requests that they were responsible for (figure 4.8). 47% reported to occasionally let another colleague mark the sampling time while only 4% of the respondents would allow another colleague to mark the sampling time on a daily basis.

4.1.5 Marking sampling time on sample/request forms

Of the respondents, 75% reported to marking sampling time on the test request/samples, 0-30 minutes after drawing the blood sample (figure 4.9). A small percentage (6%) reported to marking sampling time 0-30 minutes before sampling, while 7% have never bothered marking sampling time at all.

4.1.6 Vacutainer tube labeling (Question 10)

56% of the respondents stated to never label the tubes before approaching the patient, while 7% reported to often/seldom label the tubes before approaching the patient (figure 4.10a). 16% of respondents stated to always label the vacutainer tubes alongside the patient before blood sampling (figure 4.10b); 24% of respondents stated to seldom carry out the tube labeling procedure alongside the patient before blood sampling, while 37% of the respondents reported to never label the tubes alongside the patients, immediately before sampling. Another 24% did not respond to this question (figure 4.10b). 71% of the respondents reported to always label the vacutainer tubes themselves alongside the patient, immediately after sampling, while 4% of the respondents never perform this tube labeling procedure (figure 4.10c).

Figure 4.8 Staff responses regarding marking of sampling time by colleagues during VBS

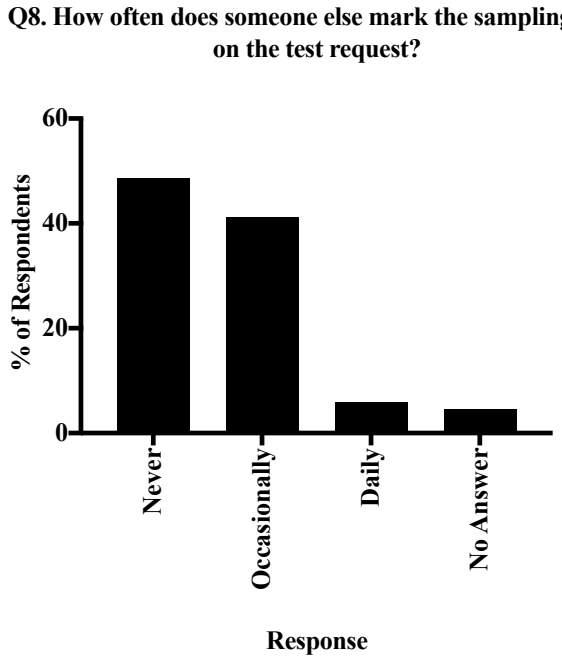


Figure 4.9 Staff responses regarding sampling time during VBS

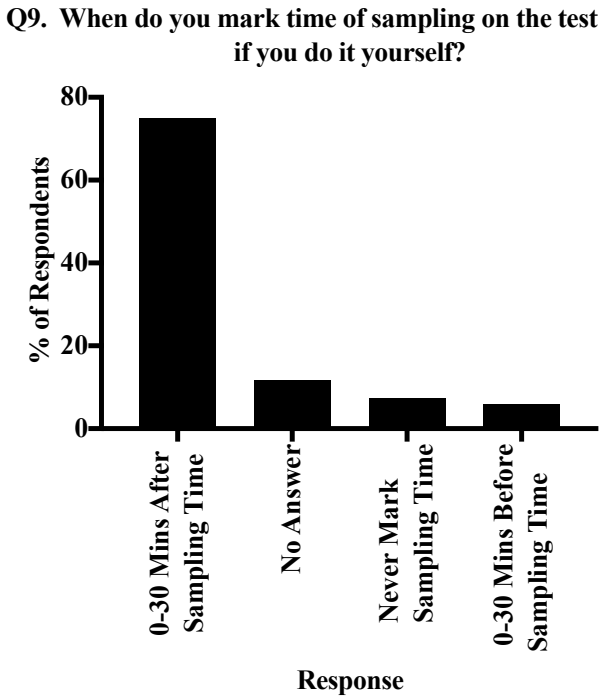
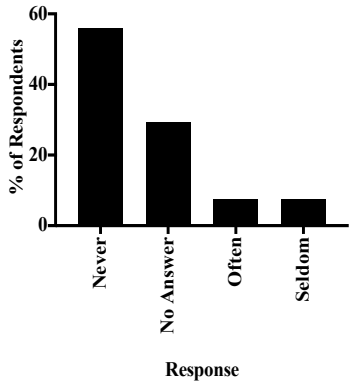
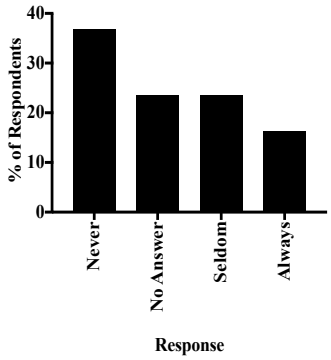


Figure 4.10(a-f) Staff responses regarding sample tube labelling during VBS

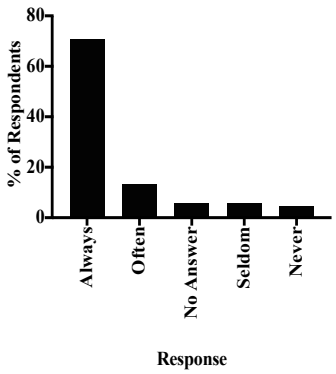
Q10a. When or where do you label the vacutainer sample tube. Is it before you approach the patient



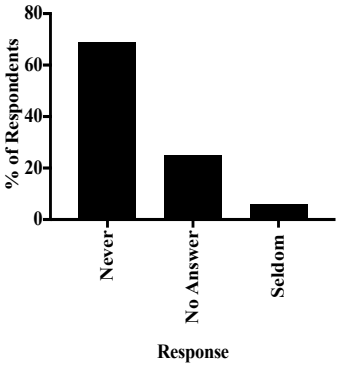
Q10b. When or where do you label the vacutainer sample tube. Is it alongside the the patient, immediately before sampling?



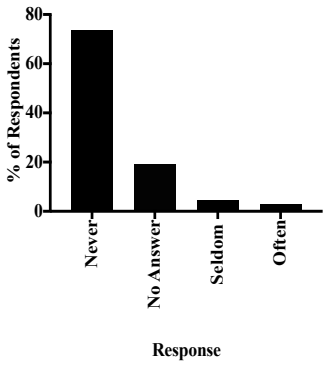
Q10c. When or where do you label the vacutainer sample tube. Is it alongside the patient, immediately after sampling?



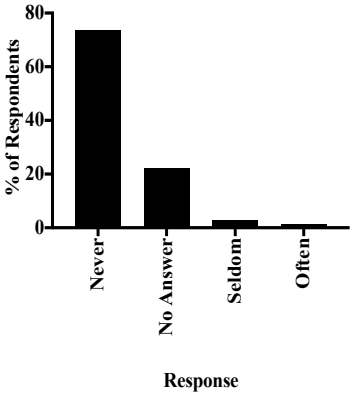
Q10d. When or where do you label the vacutainer sample tube. Is it at a later occasion after VBS?



Q10e. When or where do you label the vacutainer sample tube. Does another staff member label the tube before you perform VBS?



Q10f. When or where do you label the vacutainer sample tube. Does another staff member label the tube after you have performed VBS?



Only 6% of the respondents reported to seldom label the tubes at a later occasion, different from the options provided (figure 4.10d). 74% of all the respondents reported to never allow another colleague to label the vacutainer tubes either before or after blood sampling, while less than 5% of the respondents reported to seldom allow another colleague to label the tubes (figure 4.10e and 4.10f).

4.1.7 Patient preparation, venous stasis, and venipuncture (Question 11, 12 and 13)

54% of the respondents reported not to check the time of patient's rest, prior to blood sampling. Most of the respondents commenced sampling whenever they felt that the patient was ready (figure 4.11). 35% reported to allow 0-5 minutes before sampling, while 4% allowed 6-10 minutes before sampling. None of the respondents in this study considered the other options provided (Appendix V).

A significant number of the respondents (71%) reported to always remove the tourniquet after blood sampling (figure 4.12c); 34% reported to keeping the stasis on, for as long as necessary, especially where there may be difficulty in sampling (figure 4.12d). 53% of the respondents reported to never remove the tourniquet before the first sample is drawn, while 3-10% stated to always or seldom release stasis before first draw. 28% and 24% respectively of the respondents reported to always or seldom remove venous stasis during sampling (figure 4.12b). Only 34% of respondents reported to always release the tourniquet as soon as practicable. 30% of the participants did not respond to any of the other options provided.

Figure 4.11. Staff responses regarding patient preparation before VBS

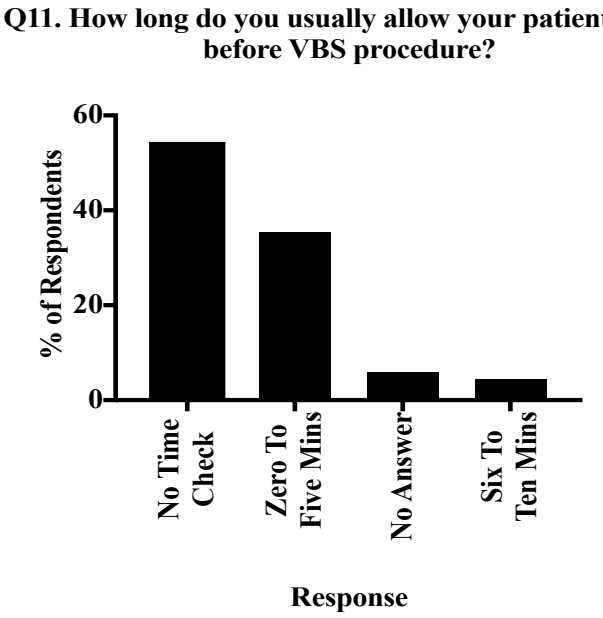


Figure 4.12a. Staff responses regarding use of stasis during VBS

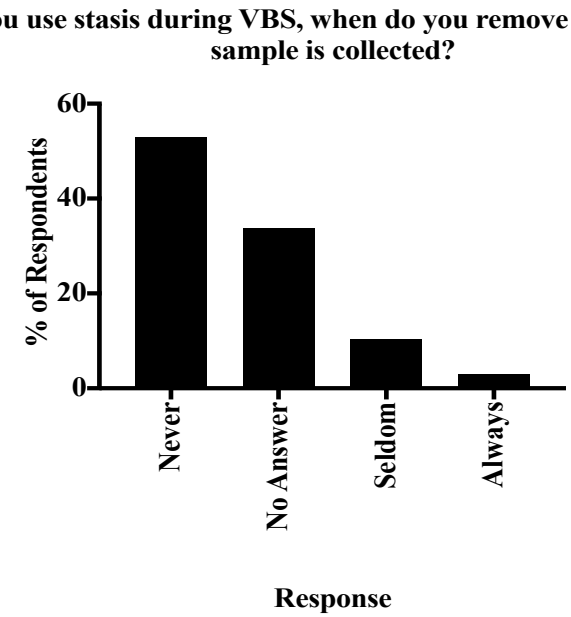
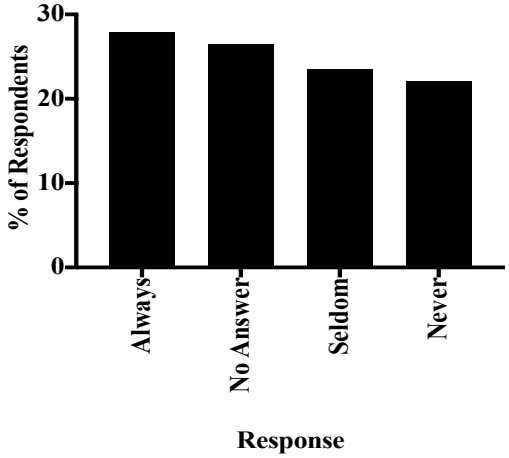
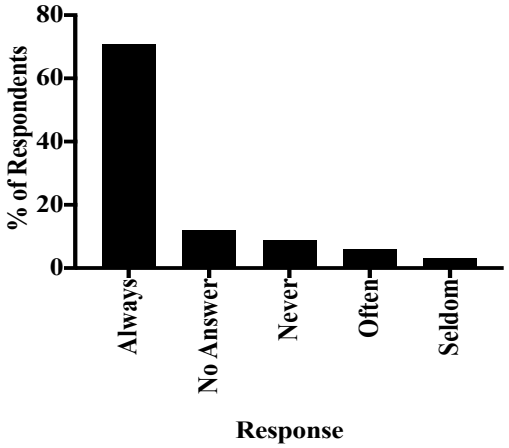


Figure 4.12(b-d). Staff responses regarding use of stasis during VBS

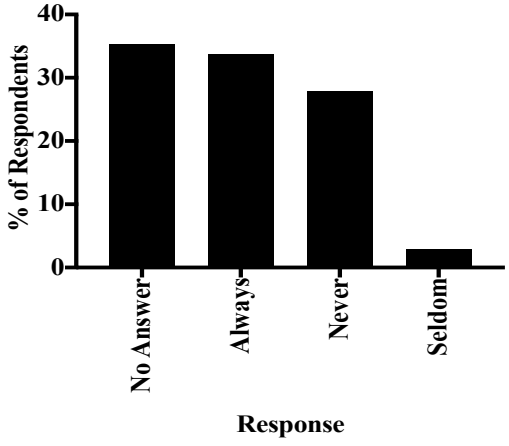
Q12b. If you use stasis during VBS, when do you remove it? During VB sampling?



Q12c. If you use stasis during VBS, when do you remove it? After sampling is completed?



Q12d. If you use stasis during VBS, when do you remove it? Keep stasis on for as long as necessary

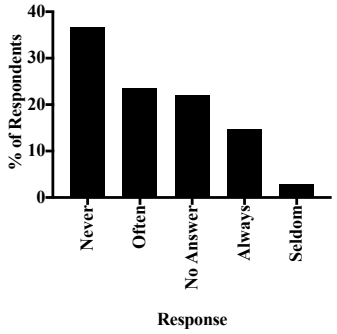


32% of the respondents reported to always use the online laboratory manual, 21% reported to often use the online manual, while 12% stated that they seldom use the online manual when unsure about a pre-analytical procedure (figure 4.13b).

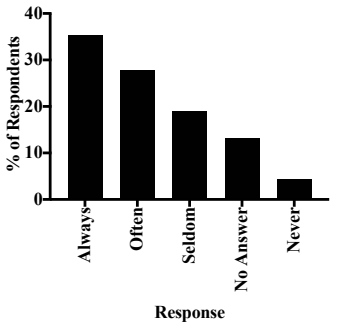
Only 15% of the respondents reported to always use the print version of the manual, while 24% of them reported to often use the print version of the handbook (figure 4.13a). As high as 52% of the respondents reported to call the clinical chemistry laboratory for information regarding VBS procedure and sample handling, while 13% and 25% stated that they seldom or often call the clinical chemistry laboratory for advice (figure 4.13c). 35% and 28% of respondents stated to always or often ask another colleague for VBS information respectively (figure 4.13d). A few, 10% of the respondents, reported to seek the assistance of medically qualified personnel or consult the phlebotomy handbook, when responding to the question in the survey on information search procedure – *'aside from the options provided, by which other means should you collect samples if you are unsure of how a sample should be collected'* (fig 4.13e).

Figure 4.13(a-e). Staff responses regarding access to the laboratory handbook

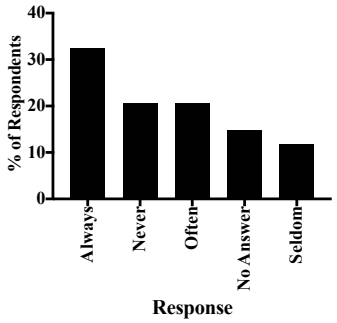
Q13a. What do you do if you are not sure of how a sample should be collected? Do you check the print version of the lab handbook?



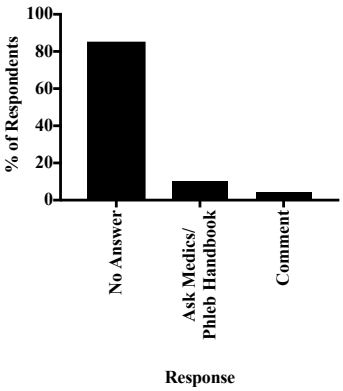
Q13d. What do you do if you are not sure of how a sample should be collected? Do you ask another colleague?



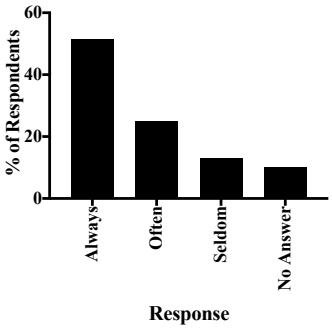
Q13b. What do you do if you are not sure of how a sample should be collected? Do you look up version of the lab. handbook on the STH intranet?



Q13e. What do you do if you are not sure of how a sample should be collected? By other means apart from the previous options provided?



Q13c. What do you do if you are not sure of how a sample should be collected? Do you call the clinical chemistry laboratory?



4.1.8 Sample handling procedures (Questions 14 and 15)

To always carry out the practice of inverting vacutainer tubes containing additives or anticoagulants several times after filling with blood sample, was reported by 84% of the respondents, while 7% of them reported to 'often perform this practice' (figure 4.14a). 2% and 11% reported to always or often use an automatic vacutainer tube inverter to ensure proper tube inversion and mixing of blood, while 74% of the staff reported to never using this device (figure 4.14b).

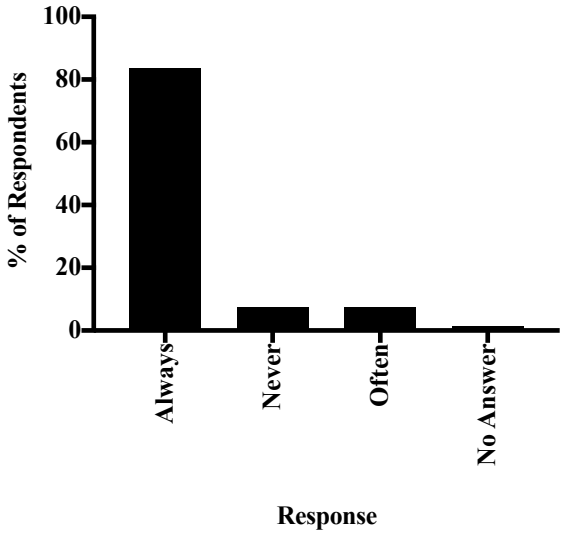
50% of the respondents reported to using a vacutainer tube rack or stand for vertical tube storage, while 34% stated to never use the device (figure 4.15a). 68% of all the respondents reported never to put the vacutainer tubes in their laboratory coat pockets. Similarly 63% stated never to store the samples in the refrigerator after VBS (figure 4.15d). 59% of the respondents stated to never store the samples lying on the phlebotomy work bench/station, while 4% have reported to often leave the samples on the workbench (figure 4.15c).

Only 49% of the participants recorded comments to question 15(e). The most common comments are reproduced below:

1. 'I place the vacutainer tubes in a specimen pouch ready to be delivered to the chemistry laboratory.'
2. 'We do not store the vacutainer sample tubes in the ward; we bag them and send them to the laboratory via the pneumatic transport system.'
3. 'After VBS, samples are placed in racks on the phlebotomist's trolley ready to be delivered to the clinical chemistry laboratory.'

Figure 4.14(a-b). Staff responses regarding sample handling during VBS

Q14a. How often do you invert each test tube containing anticoagulants or other additives post VBS and before filling the next tube?



Q14b. How often do you use an automated test tube inverter to ensure proper mixing of sample placed in tubes containing anticoagulants or other additives?

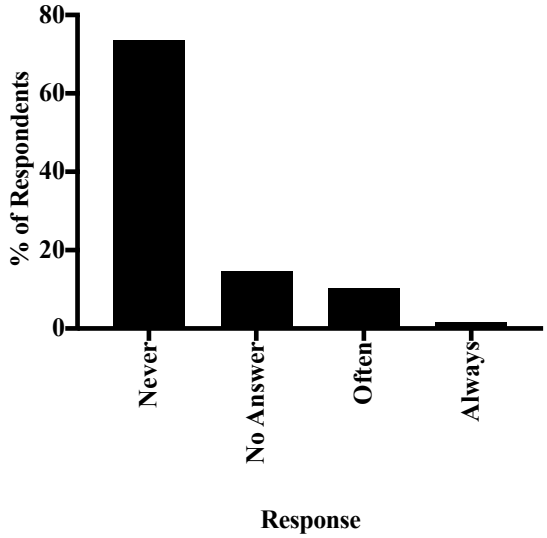
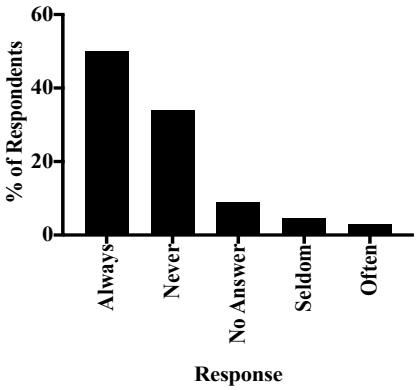
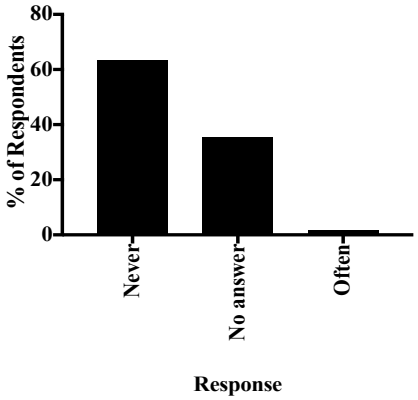


Figure 4.15(a-e). Staff responses regarding sample storage after VBS

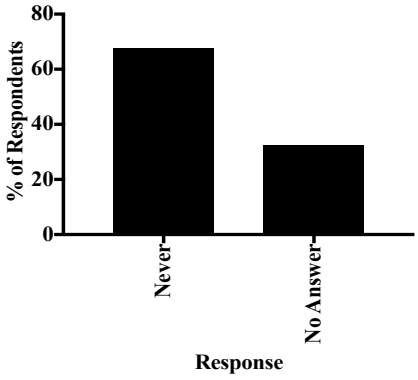
Q15a. How do you store vacutainer tubes after VBS? Do you store them in racks?



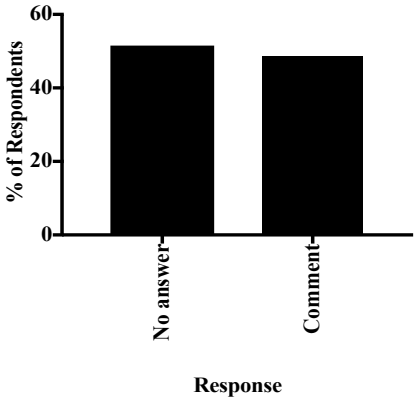
Q15d. How do you store vacutainer tubes after VBS? Do you store them in fridge racks prior to transport to laboratory?



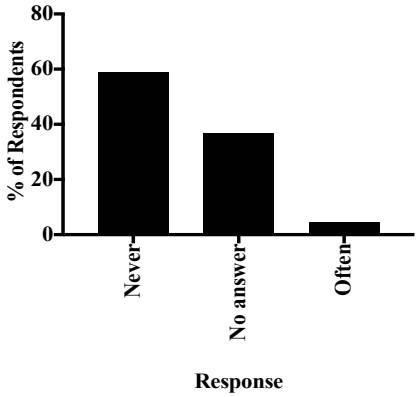
Q15b. How do you store vacutainer tubes after VBS? Put them in lab coat pockets until later?



Q15e. How do you store vacutainer tubes after VBS? By other means? (Please state).



Q15c. How do you store vacutainer tubes after VBS? Do you lay them on the work bench?



4.1.9 Incident reporting in phlebotomy and staff suggestions (Questions 16 and 17)

Of all respondents surveyed in the phlebotomy unit, 94% (n=64) reported to have never filed an incident report relating to a VBS procedure. Only 3% of respondents have filed four pre-analytical error-related incidents and just 2% have filed either one or two error incidents regarding the VBS procedure (figure 4.16a).

77% of all the respondents stated to have never written any error reports since they had been employed by the Trust, while 24% of them did not provide answers to this question in section 16b of the questionnaire survey (Appendix V). 93% of the respondents did not respond to question 16c, while 7% of them stated that a senior member of staff (rather than themselves) had the responsibility of reporting any pre-analytical error event or incident.

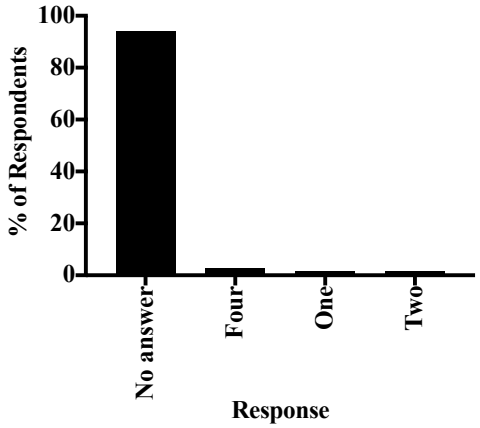
81% of the respondents did not give any plausible reason(s) for refraining from filing an incident/error report when asked in questions 17a-d (figure 4.17a). 35% of the respondents stated that the unit head was responsible for filing or reporting all pre-analytical errors relating to VBS; 18% are not in agreement with this view, while 47% did not respond with any answer (figure 4.17e). None of the respondents provided answers to question 17f, when asked if they were concerned about possible consequences if they refrained from filing an error report.

The three most common reasons/comments reported by 18% of all the respondents for not filing or reporting previous errors were:

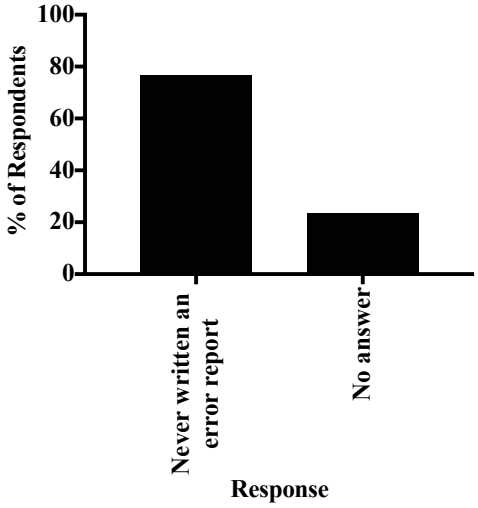
1. 'I have never had any reason to file an incident/error report'.
2. 'I was not aware that there is a form for reporting errors'.
3. 'I was never informed that I had to file error reports'.

Figure 4.16(a-c). Staff responses regarding error reporting in phlebotomy practice

Q16a. How many VBS errors or incidents in VBS have you filed in this unit?



Q16b. Have you ever written any error report?



Q16c. Does another member of staff write the error reports on your behalf?

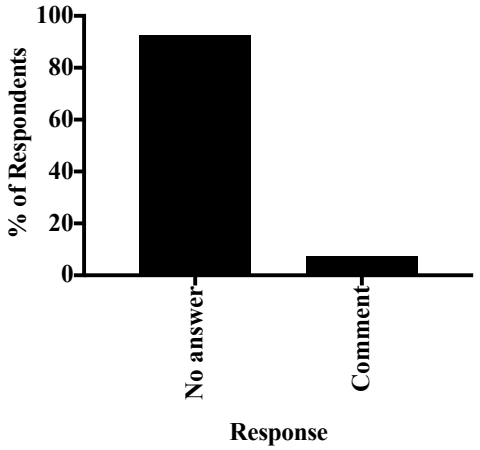
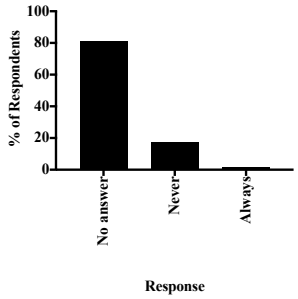
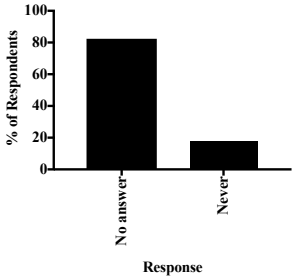


Figure 4.17(a-g). Staff responses regarding error reporting responsibilities in phlebotomy practice

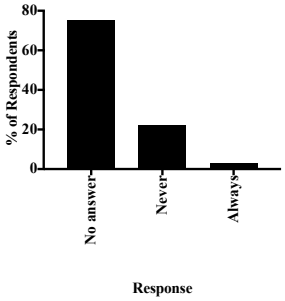
Q17a. What is your reason for refraining from filing an error report?
I did not have enough time?



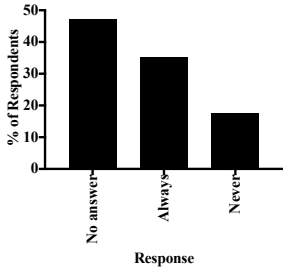
Q17d. What is your reason for refraining from filing an error report?
None of my colleagues completes an error report.



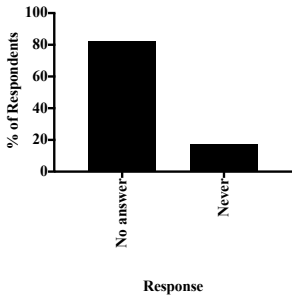
Q17b. What is your reason for refraining from filling an error report?
I do not know how to fill an error report?



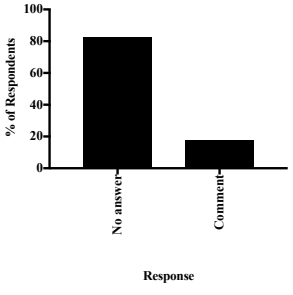
Q17e. What is your reason for refraining from filing an error report?
Is it a responsibility of the unit head?



Q17c. What is your reason for refraining from filling an error report?
The process is cumbersome, so I am not bothered.



Q17g. Do have any other reason(s) apart from the ones suggested
for refraining from filing an error report?



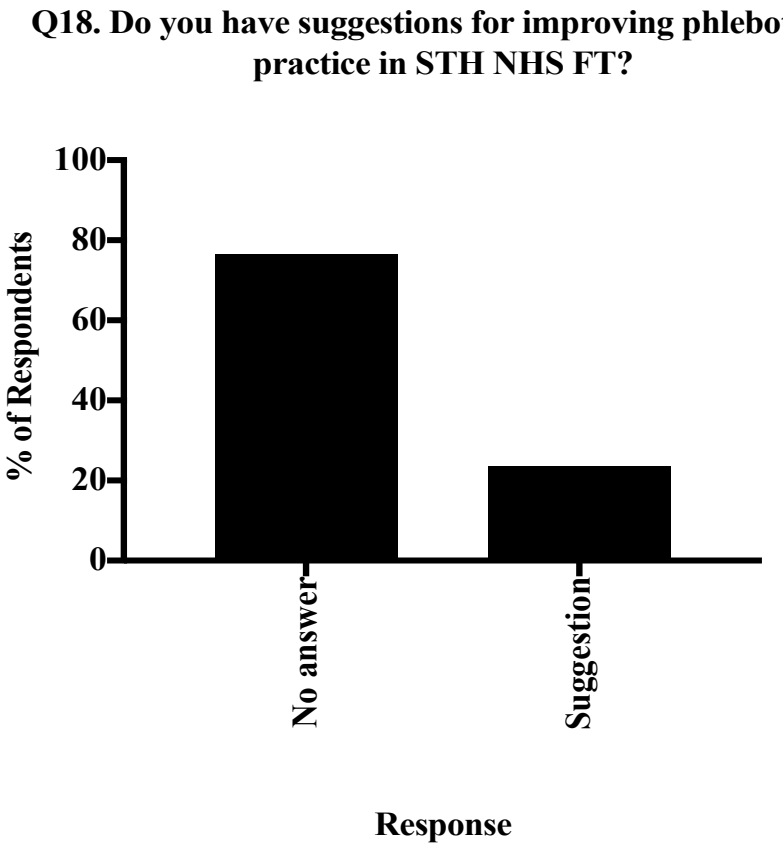
4.2 Respondents comments/suggestions for improving phlebotomy service (Question 18)

Of all respondents in this questionnaire survey, only 24% (n=16) responded with suggestions on how the services in the phlebotomy unit, especially VBS and sample handling procedures, could be improved.

The main suggestions provided are given below:

1. We need a more efficient pneumatic tube transport system. The current system breaks down too frequently.
2. There is a need for current and frequent in-house VBS training for staff to improve service to patients.
3. I would appreciate re-fresher training/updates every quarter to broaden our VBS knowledge and practical skills base.
4. Staff need training visits to all STH NHS FT clinical laboratory departments to see how these blood samples we collect are processed.
5. Permanent phlebotomy staff should be encouraged to visit or rotate through specialist clinics and wards in STH NHS FT to compare notes and improve their experience.

Figure 4.18 Staff responses regarding suggestions to improve phlebotomy practice in STH NHS FT



4.3 Discussion on questionnaire study regarding phlebotomist practice

Reducing pre-analytical errors in the clinical chemistry laboratory is still considered to be one of the greatest challenges to biomedical scientists and other professionals in laboratory medicine (Simundic and Lippi, 2012). A large percentage of pre-analytical errors are often outside the direct control of the clinical chemistry laboratory (Simundic, 2015). Most laboratories still focus solely on analytical quality (Plebani and Piva, 2010), but the pre-analytical phase is still poorly standardised as there are numerous local, national and international guidelines that exist about best practice in the pre-analytical phase of TTP, but these are not often implemented or checked (Lippi *et al*., 2005; Soderber *et al*., 2009). Misidentification of patients is still a major source of pre-analytical errors (Lippi *et al.*, 2006; Wallin, 2008; Lippi *et al.*, 2009; Sölderberg, 2009; Woodworth and Pyle, 2013), and this is largely as a result of non-compliance with local and national guidelines in place (Plebani, 2012).

Phlebotomy staff involved with sample collection, are unaware that, what seem to be ‘small errors’ in their practice, can have an impact on sample quality and processing and consequently the clinical chemistry laboratory’s ability to produce accurate results. The resulting ‘domino effect’ may have dire consequences on patient safety. Suppose a sampling error occurs and is not detected at the start of the TTP, the further the erroneous sample advances through the analytical process, the greater the impact on laboratory efficiency (Chalwa *et al.*, 2010; Sciacovelli *et al.*, 2011), laboratory cost (Green, 2013) and ultimately patient care (The Pathologist, 2015).

Members of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) working group, at a recent meeting in Portugal in 2015, are of the opinion that there is a lack of understanding of the consequences of pre-analytical errors (The Pathologist, 2015) as there is a disconnection between where the error occurs and where its impact is seen. All health professionals must know more about what the pre-analytical error risks are and their effects on test results. There still exists inadequate training for phlebotomists and other healthcare professionals on VBS procedures as evidenced by this study.

Clinical chemistry laboratories need to take more responsibility to try to minimize the errors especially in the pre-analytical phase of the TTP where they occur. Healthcare professionals in the hospital setting generally have very limited knowledge of the pre-analytical phase and the impact it has on the TTP. They are of the opinion that the analytical phase is the most error prone stage. There is therefore a need to be more pragmatic and move away from this way of thinking that in order to reduce pre-analytical errors in the TTP, biomedical scientists and laboratory professionals must work closely with other healthcare professionals and support staff such as phlebotomists to provide the necessary training and education needed.

The IBMS, the UK professional body for biomedical science and the ISO 15189 (2012) standard, define the minimum criteria (table 4.3) that must be in place on the sample tube for receipt and identification of specimens for laboratory testing. The phlebotomist must identify the patient by asking for their full names, date of birth (DOB). Their NHS or hospital number should be checked (CLSI, 2007; IBMS, 2016). Every person registered with the NHS in England and Wales has their own

unique NHS number made up of 10 digits appearing in a 3-3-4 format (IBMS, 2016). Other parts of the UK use the Health and Care number system (Northern Ireland) or the Community Health Index (CHI) number (Scotland).

In the questionnaire survey, 88% of the respondents on the survey reported that they always follow this procedure described above in identifying the patient. This is paramount, to avoid mix up of patients with similar or the same surnames/forenames, which may have dire consequences, leading to patient harm or in some instances, fatalities (Kalra *et al*., 2013; Plebani, 2015). 10% of the respondents reported to only often follow this procedure. Sample and request form information, which can be in paper or electronic format (Anglia-ICE), must be compatible (IBMS, 2015, 2016). The SOP for sample acceptance by the clinical biochemistry laboratory must define locally agreed and minimum acceptable identification criteria and the course of action to be followed when these criteria are not satisfied (IBMS, 2015).

The SOP must be in accordance with national guidance and information given by other sources such as the Health and Care Professions Council (HCPC), the Royal College of Pathologists (RCP) and the International Organization for Standardization standard (ISO 15189:2012), which promotes global harmonization of clinical practices. Laboratory professionals, regulatory authorities, and accreditation bodies to ensure competence use ISO 15189. Samples or request forms received without the minimum essential identification criteria may be rejected, not processed and appropriate coded comments recorded on the LIMS stating the reason for rejection.

Table 4.3 IBMS professional guidance document for the receipt and identification of samples (adapted from IBMS, 2016).

	Essential	Desirable
Patient's Sample	1. NHS, CHI or Health and Care number* 2. Patient's full names 3. DOB and Hospital number	1. Date and time** 2. Nature of specimen, including qualifying details, e.g. site of sampling
Request Forms (Electronic or Paper)	1. NHS, CHI or Health and Care number* 2. Patients full names 3. DOB and Hospital number 4. Gender 5. Patient location and destination of report 6. Patient's consultant, GP or name of requesting healthcare professional 7. Details of investigations required	1. Relevant clinical detail including medication if applicable 2. Date and time specimen was collected** 3. Patient's address and post code 4. Requesting healthcare professional's contact details

*The use of NHS (or CHI or Health Care number) on paper and electronic patient records is mandatory as required by the NHS Operating Framework (2008/2009). NHS /CHI/ Health Care number thus becomes the primary patient identifier (IBMS, 2016)

** Date and time collected is usually essential for clinical biochemistry samples.

Considering the findings in this questionnaire survey, in light of the sample acceptance requirements, e.g. if 10% of the respondents only 'often' follow standard procedure there is a likelihood that the samples with these error types such as swapped patient demographics (SWAPDET), incorrect patient details /wrong patient sample (INCORPAT) or incomplete patient's details (INCOMPL) to be rejected – indicating that frequent re-training/re-certification of phlebotomy unit staff on essential labelling protocol is required for correct patient identification in order to prevent the samples being rejected. The findings relating to identification of patients before VBS procedures agree with previous findings, demonstrating some serious shortcomings, and indicates that there is need to improve practice. A previous study reported critical sample misidentification errors in the clinical chemistry laboratory

(Bonini *et al.*, 2002). A separate study in the USA estimated that sample misidentification incidents resulted in 160,000 adverse events every year (Valenstein *et al.,* 2006). In another study in a large Thailand hospital clinical pathology laboratory it was established that critical patient identification errors occurred in approximately 1 out of 1200 test requested (Wiwanitkit, 2001). No adverse events relating to sample misidentification or any other type of pre-analytical errors was reported in STH before or during the period of this study.

It is interesting to note that majority of the respondents in the survey reported to never use previous acquaintances with the patient as a process of identifying patients. This finding is supported by a previous study (Wallin, 2008). This statistic is encouraging but still leaves much room for improvement to achieve practice that is fit for purpose. Söderberg (2009) observed that only 41% of respondents reported to never use previous knowledge as a means of identifying patients in a previous study of pre-analytical errors in a primary health care in Sweden. Only 7% of the respondents from this study have considered verifying patient's identification from past knowledge.

Using previous acquaintances or past knowledge of patients as a means of identification poses a risk of misidentification of patients (Wallin *et al.*, 2007; Söderberg *et al.*, 2009). Correct patient identification could also be enhanced by using a photo ID system, as practised in some countries such as Sweden (Söderberg *et al.*, 2009). The photo ID system is not currently in use in the UK. Valenstein and co-workers (2006) found in a previous study undertaken in 120 American pathology laboratories that errors in patient identification, before specimen collection, is responsible for up to 25% of all pre-analytical errors (Valenstein *et al.*, 2006).

Mistakes in patient identification often occur during manual tasks. Using electronic technologies such as barcodes, radiofrequency identification and wristbands should reduce pre-analytical errors compared with manual (Lau *et al.*, 2000; Dzik, 2007). Wristbands have the patient's name and identification number, and sometimes have a barcode. Other studies have reported error rates of 0.3-11% for identification wristbands, mostly comprising of missing or incomplete wristbands, and wrong wristband on the patient (Howanitz *et al.*, 2002; Wallin *et al.*, 2007; Söderberg *et al.*, 2009; Hoffmeister and De Moura, 2015). A quarter of the respondents stated that they always checked the wristbands of in-patients. This is good practice and is in line with the policy governing patient sample and request form identification (IBMS, 2016). However a large percentage of the phlebotomy staff are not following the recommended standard procedure and are not using wristbands for identification of patients.

In this study, nearly half of the respondents never bothered to check wristbands for the purpose of patient identification, this is poor practice and may lead to incorrect identification of the patient (Howanitz *et al.*, 2002) and may cause harm to the patient. A number of healthcare facilities in some countries including the USA, Sweden, and the UK have developed the barcoded wristbands to assist in patient identification and verification (Wallin *et al.*, 2007; Sölderberg, 2009). Although previous studies (Howanitz, 2005; Lippi *et al.*, 2006, Lippi *et al.*, 2009) have established that barcoded wristbands have significantly reduced patient misidentification in hospital wards and clinics, this approach is still inadequate in drastically reducing incidental patient mismatch or total misidentifications of patients in a high turnover phlebotomy service (Lippi *et al.*, 2006, Lippi *et al.*, 2009) such as STH NHS FT.

A third of the respondents reported to seldom ask the patient's family/relative or care provider for their name and identification number. Although close to half of the respondents (49%) reported never to use this means for identifying their patients before the VBS procedure there is a need for further education and training to improve service delivery and reduce errors arising from misidentification. Proper patient identification is particularly valuable when performing VBS on young children, the elderly or adult patients with reduced mental capacity or dementia. In these cases a healthcare professional, relative or guardian should identify patients that are unable to speak or identify themselves.

As such many hospitals now employ translators for non English-speaking patients in order to correctly identify the patient. Frequent re-education and monitoring of phlebotomy staff would help reduce pre-analytical identification errors and ensure greater compliance. More than a two-thirds of the respondents reported never to use the patient health card for identification purposes; 22% of the respondents did not respond to the question at all. These responses were not unexpected since the health card system is not used in most hospitals across the UK, including STH NHS FT, where this study was carried out. The healthcare card introduced in some countries such as Sweden, contains name, address and identification number, but no photograph, and should therefore never be used for identification purposes (Sölderberg, 2009).

4.3.1 Patient preparation prior to phlebotomy

According to recommended practice (CSLI, 2007, 2008), the phlebotomist should ensure that the patient is comfortable and if appropriate should verify whether the

patient is fasting (for at least 12 hours or overnight as necessary for some chemistry analytes such as glucose and lipids); what medications are being taken or have been discontinued as required (Haverstick and Groszbach, 2014). The patient should be seated or in a supine position, since the body position causes changes in plasma volume that influence the test results, and should be in this state of rest for about 15 minutes (Kiechle, 2013; WHO, 2014) before blood is collected. Diurnal and positional variations (Haverstick *et al.*, 2009), affect other analytes such as cortisol, adrenocorticotropin, iron and lipid, which should be considered by the phlebotomist. More than half of the respondents reported not to check the time of the patient's rest prior to blood sampling. Most of the respondents commenced sampling whenever they felt that the patient was ready. Failure to allow time for patient rest for about 15 minutes is undesirable practice (Kiechle, 2013; WHO, 2014).

Previous findings (Kiechle, 2013; Söderberg, 2009) suggest that insufficient patient rest may increase the risk of post-analytical errors by complicating the use of reference limits when managing the patient. Although a very small percentage (5%) of phlebotomy staff in the current survey appear to be working more in line with the guidelines (by allowing 6-10 minutes patient rest before sampling), none of the respondents in this study considered the other options (11-15 minutes, or more than 15 minutes), which are in line with recommended procedure, indicating that more education is needed to alert staff on the importance of patient rest before VBS. This is another important area of pre-analytical phase of the TTP that needs improvement in order to reduce errors. However in everyday practice, allowing adequate "rest time" for patients may not be achievable due to pressures of number of people coming through the service. For a moderately staffed phlebotomy unit the average waiting

time between patients is about 10 minutes (Mijailovic *et al.*, 2014). It is also possible to argue that due to extended waiting times on extremely busy specialist clinic days; most patients waiting in the queue would have attained the ideal rest time prior to VBS procedure.

The responses recorded for venous stasis from this present survey are varied and are not in line with recommended practice (CSLI, 2007, 2008; WHO, 2014). The tourniquet should be applied approximately three to four inches above the venepuncture site and venous stasis should be on the arm no longer than one minute (CSLI, 2007, 2008). A good rule of thumb to determine the one-minute tourniquet time is to remove the tourniquet when blood starts to flow into the first tube of blood being drawn. Only a quarter of respondents reported to always release the tourniquet as soon as practicable. A significant number of the respondents reported to removing tourniquet after blood sampling and a third of the respondents reported to keeping the stasis on, for as long as necessary, especially where there may be difficulty in sampling.

Prolonged venous stasis should be avoided since this may result in clinically significant effects on some plasma analytes (Haverstick *et al.*, 2009; Lippi *et al*., 2009; Haverstick and Groszbach, 2014), causing haemoconcentration and haemolysis. According to Haverstick and Groszbach (2014) haemolysis can result in the spurious elevation of such analytes as potassium, iron, magnesium, aspartate, phosphate and lactate dehydrogenase. In their study Lippi *et al.* (2005*)*, established that potassium, calcium, and albumin showed clinically significant differences after 1 minute of venous stasis. A few of the participants did not respond to any of the

options provided. These varied responses from the phlebotomy unit staff suggest that respondents appear to be unsure about how to properly use a tourniquet during VBS. Incorrect venous stasis could lead to pre-analytic errors such as 'haemolysed sample received in laboratory' (BSHAEM). Therefore there exists a gap in the VBS training that needs attention.

4.3.2 The handling of test requests

Before any VBS procedure, the patient's details comprising of their full names, DOB and unique NHS number must always be compared with the corresponding information on the test request (paper or electronic) forms (IBMS, 2016; CLSI, 2016; ISO 15189, 2012). Strict adherence to this practice decreases the risk associated with test requests containing erroneous information (Solderberg, 2009). A few of the respondents were not consistent in performing this task according to recommended guidelines, and non-conformity to this practice has previously been reported as an important source of pre-analytical error (Plebani and Piva, 2010; Plebani, 2012), resulting in sample rejection (Dale and Novis, 2002; Lippi *et al*., 2009; Plebani, 2012; Plebani and Piva, 2015). Failure to check test request forms has also been linked to higher test request error frequencies (Plebani, 2006, 2007, 2009, 2010).

The practice of using test requests that another colleague has completed may increase the risks associated with erroneous test requests (Wagar *et al.*, 2006; Wallin *et al.*, 2008; Söderbeg, 2009). More than half of the respondents surveyed reported to always use test requests that another colleague has completed. This result is in line with previous work by Söderberg in 2009. He reported that 89% of the participants use test request completed by another colleague in a questionnaire survey of sources of pre-analytical error in primary health care. This may lead to higher error frequencies with

the possible adverse consequences for patients (Valenstein *et al.*, 2006; Plebani, 2015). 23% of the respondents reported to never use test requests that another colleague has completed. Based on this high proportion of staff using partial or completed test request paper work, which another colleague has completed, it is evident that more training is needed to improve practice in this area, in order to reduce associated risks with erroneous test requesting (Wallin *et al.*, 2008; Söderbeg, 2009; Plebani, 2012). 69% of the respondents reported to always check information on the test request especially if another colleague has completed it, while 13% of the respondents only often perform this check. This data indicates that a minority of the staff (18%) are not complying with the recommended guidelines, which could lead to the risk of an erroneous test request, as corroborated by previous reports (Valenstein *et al.*, 2006; Kirchner *et al.*, 2007).

With regards to the question around the sampling time on the test request, 29% of the respondents stated to always adjust the time, if the marked time differed by more than 30 minutes from the actual sampling time. The date and time the sample was collected is essential for biochemistry samples (IBMS, 2016; ISO 15189 Standard, 2012). Time of sampling is crucial for time-specific assays such as ammonia, calcium, glucose and the Oral Glucose Tolerance Test (OGTT) (Haverstick *et al.*, 2009; Harverstick and Groszbach, 2014), and for analytes with circadian variation e.g. cortisol, insulin and serum iron (Harverstick and Groszbach, 2014), therapeutic drug monitoring samples e.g. digoxin, cardiac enzymes (Harverstick and Groszbach, 2014) and antibiotic assays. It is thus alarming to find that 31% of the respondents reported to never adjust the sampling time on the request forms if it is needed. This result appears to be in line with previous studies, which indicate that not adjusting the

sampling time may be a source of some clinically significant pre-analytical error (Wallin *et al.*, 2008; Söderbeg, 2009; Plebani, 2012) and may be responsible for the increase in time-related pre-analytical errors e.g. 0.5% increase in errors due to delay in receiving sample in laboratory (TIMEDEL) and 1.7% sample not received on ice (NOICE) in Post-ICE electronic requesting (Table 3.1). More VBS training and education is required to further reduce this error frequency (Plebani and Carraro, 2007; Plebani, 2007).

Close to half of all respondents reported to always sign the test requests, while about a quarter of them were not conforming to established standards by not signing the test request at all. Signing test requests is an important aspect of the pre-analytical stage of the TTP as it can help in the audit process (Lippi *et al.*, 2009; Lippi and Plebani, 2009; Bilic-Zulle *et al.*, 2010) when errors are reported (i.e. incident reporting). Signing test requests therefore represents an important area for improving patient safety (Howanitz, 2005) and must be encouraged through further training and education at STH NHS FT.

4.3.3 Responsibility for marking sampling time on sample/request forms

According to the survey statistics for this section, up to half of the respondents reported to never allow other colleagues to mark the sampling time on test requests that they were responsible for. This is in line with standard VBS procedure (Kiechle, 2013) as it signifies ownership and responsibility (Wu *et al.*, 1997; National Audit Office, 2005). To occasionally let another colleague mark the sampling time on the request form and vacutainer tube was reported by 47% of the respondents. This indicates that personally marking the sample time on the test request by the

phlebotomist during VBS is an aspect that needs considerable improvement (CLSI, 2007; Wallin *et al.*, 2007; Söderberg *et al.*, 2009). Sampling time in VBS can have a huge advantage in prioritising assays in the clinical chemistry laboratory (especially time specific assays such as glucose or cardiac enzymes).

Results from this current survey indicate that the majority of the respondents reported to marking sampling time on the test request/samples, 0-30 minutes after drawing the blood sample. However, around a quarter of the respondents did not respond to the questions or have were not following standard procedures regarding marking sampling time. Close attention must be paid to recording time of sampling during VBS (Billic-Zulle *et al.*, 2010). Failure to observe and mark sampling time may lead to the rejection of the samples and another replacement sample being requested, which would certainly impact on the turnaround time (Lippi *et al.*, 2006; Haverstick and Groszbach, 2014) for some analytes (ammonia, bicarbonate, electrolytes and glucose), whose concentration in plasma/serum might significantly change over a short period of time (Howanitz, 2005; Lippi *et al.*, 2009). In the event that the sample is delivered for analysis it may lead to the generation of an erroneous result due to sample deterioration over time, caused by analyte instability. Serious consequences to the patient may result from such pre-analytical errors of not marking sampling time on blood samples. More frequent training is needed to improve this aspect of phlebotomy practice.

4.3.4 Vacutainer tube labelling

The test requester must ensure that samples are correctly labelled and request forms are completed to agreed standards (IBMS, 2016). Unlabelled vacutainer tubes, test request forms and other phlebotomy equipment or consumables must be taken to the

patient's side prior to any VBS procedure (Kiechle, 2013; WHO, 2014). According to recommended guidelines vacutainer tubes should always be labelled immediately alongside the patient (CLSI, 2010; WHO, 2014) after VBS, to avoid mislabelling or 'unlabelled sample' errors (Wallin *et al.*, 2009; Kiechle, 2013; WHO, 2014). A significant number of the respondents reported to always label the vacutainer tubes themselves alongside the patient, immediately after sampling. This is in line with recommended practices (CLSI, 2007, 2008, 2010; WHO, 2014; IBMS, 2016).

About a quarter of the respondents did not respond to this question, while a small number of staff recorded varying responses that seem to suggest that they were unsure about following recommended standard procedures available for VBS. This indicates unacceptable practice and associated with increased risks of the wrong patient's blood in the labelled vacutainer tube (CLSI, 2007; Wallin *et al.*, 2008; Soderberg *et al.*, 2009; Harverstick and Groszbach, 2014). The results from the pre-analytical data in this study indicate that errors such as incorrect patient details /wrong patient sample (INCORPAT), incomplete patient's details (INCOMPL) and swapped patient demographics (SWAPDET) are common in the laboratory and may be associated with incorrect vacutainer tube labelling.

It is important to correctly identify the patient so that the blood sample is collected from the correct patient into the correctly labelled container (Lippi *et al.*, 2006; Kiechle, 2013; WHO 2010). In cases where an inadequately labelled sample is received from a patient who is not easily accessible for a repeat (e.g. cerebrospinal sample), then the sample may be processed at the discretion of senior staff in the clinical chemistry laboratory, in accordance with local protocols (STH NHS FT

clinical chemistry laboratory SOP). The report should show a clear disclaimer detailing the shortcomings of the sample and/or request and alerting the requesting practitioner to take responsibility for the results, and for any action taken as a result of the report (IBMS, 2016). A large percentage of the staff reported that they never ask another colleague to label the vacutainer test tubes before or after sampling, but will always label the vacutainer tubes themselves, in line with SOPs (Kiechle, 2013). Nevertheless this result suggests that the remaining number of the respondents will ask another colleague to label a vacutainer tube, either before or after sampling. Such practice will increases the risk of unlabelled, mislabelling or sample mismatches (EXMATCH, SWAPDET), and are important sources of pre-analytical errors in the clinical chemistry laboratory (Plebani and Carraro, 2007; Plebani, 2007; Sciacovelli and Plebani, 2009).

Mislabelled tubes or tubes with incomplete patient demographics may result in adverse events (Kalra, 2004; Valenstein *et al*, 2006) and in some cases, fatalities. Drawing blood from the wrong patient, or labelling the correct patient's sample with a different patient's label can undoubtedly contribute to pre-analytical errors in the laboratory (CLSI, 2008; IBMS, 2016). The vacutainer tube labelling procedures adopted by staff as reported in the questionnaire survey clearly demonstrates an association with a significant risk (CSLI, 2010; ISO 15189; 2012; IBMS, 2015), resulting from mislabelling / inadequate labelling of vacutainer tubes, and represents a significant area of patient safety improvement (Kalra, 2004; Plebani, 2009) that needs to be addressed.

4.3.5 Online laboratory manual and information search

The online laboratory manual is available through the STH NHS FT intranet (http://STH NHS FTweb/LabMed_nhs/Handbook). It is a source of accurate information on test requesting, VBS procedures, and sample handling. Online laboratory manuals should be considered the preferred source of information for VBS procedures, since they can be updated periodically. However in this present survey only a third of the phlebotomy staff use this online resource regularly. One explanation for the low reported use of the online manual may include complicated access to the manual (Söderberg, 2009) via the intranet server. It is of utmost importance that VBS instructions are regularly updated and easily accessible since pre-analytical information from laboratories changes over time (Blechner *et al.*, 2006, Georgiou *et al.,* 2007). User information should be underpinned by laboratory SOPs and standards (IBMS, 2016).

The online manual must easily be accessible, be user friendly, and the users must be aware of its existence. Consultants, registrars and house officers, nursing and other healthcare professionals working in the hospitals must be familiar with and understand the rationale of laboratory procedures and standards. There should be clear written guidelines for those who obtain blood samples from a patient on behalf of the requesting practitioner (IBMS, 2016). Although a large percentage of the staff stated that they were aware of the availability of documented information (printed and on-line versions of the laboratory handbook) to assist with VBS procedure, only 15% of the respondents have used the printed version of the handbook on a regular basis. The probable explanation for the low number of staff using the printed version of the on-line manual may be due in part to the dynamics surrounding the job such as

staff shortage and the cumbersome nature of updating paper-based laboratory manuals, which may lead to inaccurate or obsolete information (Blechner *et al.*, 2006), some of which may jeopardize the safety of patients. The results in this part of the questionnaire survey show that information search procedures in the phlebotomy unit are in need of improvement.

4.3.6 Specimen handling procedures

Based on international recommendations (Valenstein *et al.*, 2006; CLSI, 2010; IBMS, 2016), vacutainer tubes containing additives such as anticoagulants (EDTA and lithium heparin) or enzyme inhibitors (fluoride-oxalate) should be gently inverted after sampling to mix with the blood. In this way clotting of the blood is prevented. A majority of the phlebotomy staff (n=57) reported to always perform this procedure. This adherence to high-quality practice may be responsible for the very low frequencies of clotted sample errors (below 0.5%), received in the clinical biochemistry laboratory department between the two periods under survey. However a few respondents (n=11) do not adequately mix blood samples after VBS. Some authors have reported that inadequate inversion of vacutainer tubes may have some pre-analytical effects in clinical chemistry laboratory testing (Kiechle, 2013; Harverstick and Groszbach, 2014). Only a small number (n=8) reported to always or often use an automatic vacutainer tube inverter to ensure proper tube inversion and mixing of blood.

The inverter device is not routinely available in all the units and phlebotomy workstations, which may explain why a larger percentage of the staff have reported to never use the device. Not having this device does not appear to have any

disadvantageous effects on the majority of biochemical test requests that utilize serum samples in clinical chemistry but may have effects on a number of biochemical requests that utilize plasma samples such as glucose and parathyroid hormones (Ashwood and Bruns, 2008). Results also show that half of the respondents (n=34) reported the acceptable practice of using a vacutainer tube stand for vertical tube storage. Vertical storage of test tubes is recommended for proper coagulation of serum samples used in clinical chemistry (CLSI, 2010). The survey results indicate that half of the respondents are not following recommended practice.

Although none of the respondents reported to storing test tubes 'lying horizontally' on a workbench top or on other surfaces in line with recommendation, there is an urgent need for laboratory professionals to raise awareness of the pre-analytical issues arising from sample handling in VBS procedures through continuous training and education (The Pathologist, 2015) and move towards upholding international standards. More than half of all the respondents reported to never put the vacutainer tubes in their laboratory coat pockets or store them in the refrigerator after VBS, which still suggests that a high percentage of staff do this indicating a low level of compliance and therefore more education of staff is needed.

4.3.7 Incident/error reporting in phlebotomy

A significantly high number of respondents surveyed in the phlebotomy unit (n=64), reported to have never filed an incident report relating to VBS procedure. According to the survey only a handful of the phlebotomy staff stated to have filed either one or two error incidents regarding VBS procedure. These numbers are very low indeed. Two previous studies indicate that some hospitals have reported low frequencies of

pre-analytical incident reporting (Söderberg *et al.,* 2009; Söderberg, 2009). Söderberg and co-workers (2009) found out that 69% of the phlebotomy staff in a public health centre reported that they had never filed an incident or error report. In this present survey, 77% (n=52) of all the respondents have never written any error reports since they have were employed by the Trust. A possible reason for the low incident reporting frequencies could be that the significance of an error in the VBS process may not be considered at the time of blood sampling (Söderberg, 2009). However, it is arguable that most respondents are likely to be familiar with an incident in VBS (Söderberg, 2009) that would require a report, considering that the average time in employment is about 9 years. About 20% of the respondents have indicated, among other factors, that lack of time and the complicated process of error reporting currently in place, may have contributed to the reasons for the majority of the staff refraining from filing an error report. Pre-analytic phase incident reporting is a means to achieve increased patient safety (IOM, 2000).

Patient safety and care could be improved by continuously applying useful information gained from incident reporting to improve pre-analytical practices in the clinical chemistry laboratory (National Quality Forum, 2009). A high percentage of the staff did not give any plausible reason(s) for not filing an incident/error report. 35% of all the respondents stated that the section or unit leaders are assigned the responsibility of recording pre-analytical an incident/error. All the respondents (n=68) appear unconcerned about possible consequences that may arise from not reporting error incidents. The relatively low incident reporting frequencies among the respondents may arise because they have not been given the opportunity to be involved in the process of incident or error reporting. Therefore, when designing

strategies for increased incident reporting, it is important to consider the barriers and opinions reported by the staff (Lippi *et al.*, 2009; Lippi and Plebani, 2009; Söderberg, 2009; Billic-Zulle *et al.*, 2010). Considering these aspects, increased reporting of pre-analytical incidents regarding phlebotomy practice in STH NHS FT NHS should be intensified through continuous education and training, specifically defining whose responsibility it is to report or file errors.

4.3.8 Staff opinions and suggestions

The staffs desire to increase and develop their competence should be considered a valuable resource when attempting to improve the VBS procedure. The healthcare system is going through challenging times as a result of reorganizations, spending cuts to some services and staff shortages. The implementation of any change must embrace the opinions and suggestions of frontline staffs such as phlebotomists and nurses who perform VBS on a daily basis. Educational efforts in VBS must be designed to improve quality, reduce the most common pre-analytical errors in TTP, and ensure patient safety at all times.

5 General Discussion

5.1 General considerations from this study

Most procedures in the pre-analytical stage of the TTP rely heavily on human involvement and are therefore prone to human error. Unfortunately human errors are currently likely to increase, with the decrease in staffing levels in most UK NHS Trusts over the recent years and 'insufficient funding for technological solutions leaving healthcare years behind other industries' (European Federation of Clinical Chemistry and Laboratory Medicine, EFLM in the Pathologist, 2015). Before the implementation of the electronic request system - Anglia-ICE, specimen labelling was a manual process of visually comparing the identity on the stamped labels usually comprising 4 patient identifiers, with the identification details on the patient's wristband (described in Chapters 1 and 3). The information on the vacutainer test tube and the request form was then entered into the laboratory computers in the clinical chemistry department, and subsequently transferred to the LIMS. If the sample was rejected, a comment was added describing the reason for its unsuitability for testing.

The electronic-requesting system (Anglia-ICE) was implemented in 2010, allowing users of the laboratory service to print out pre-completed VBS/ test request order forms. The system was initially trialled in the acute unit of the STH NHS FT and gradually rolled out to all inpatient and outpatient wards, but has not yet been extended to GP surgeries or private clinics. The move to electronic requesting was necessitated by the gradual increase in the number of samples received in the clinical chemistry department. A total of 903,814 samples were received in 2012/2013, which is double the number of samples received in 2007/2008 (416,703 samples). The direct

implication of this surge is an increased workload on the clinical chemistry laboratory as well as longer turn-around-time to process samples, since a substantial proportion of the pre-analytical phase involves manual procedures.

The clinical chemistry laboratory, through the LIMS system, keeps a record of each sample analysed in the laboratory as part of the standard quality assurance management. The system also keeps a record of how many samples were rejected due to one specific error type (e.g. haemolysis, insufficient sample or sample lost in transit) or a combination of errors such as sample identification errors. The total number of samples received, the total number of samples with pre-analytical errors from all the requesting centres pre and post-implementation of Anglia ICE were recorded. On each of these occasions, the discovery of the pre-analytical error depends on the detection by the test-ordering healthcare professional, the phlebotomist who performs VBS, the medical laboratory assistant or the biomedical scientist that an anomaly has occurred. If the error is not detected the consequences could be serious.

The primary source of most samples received in the laboratory in 2007/2008 was from GP surgeries across Sheffield, outpatient and inpatient wards of STH NHS FT. These three centres also delivered most of the samples to the clinical chemistry laboratory in 2012/2013. However despite the number of samples increasing by 487,111 in the 4-5 year period, fewer samples were rejected for pre-analytical errors in 2012/2013, following the introduction of Anglia-ICE system. It is possible that a high percentage of these errors pre- and post-Anglia ICE may be linked to samples received from GP surgeries and private clinics, which have not had the Anglia-ICE system implemented during this period of this study. Therefore, targeting these

centres for future pre-analytical error reduction strategies is important. The questionnaire study involved the phlebotomy units of inpatient and outpatient wards of STH NHS FT only (both centres deliver about 45% of the total samples to the clinical chemistry laboratory. The decision to exclude phlebotomy units of GP practice centres and A&E departments is predicated on the difficulties that may arise from bureaucratic bottlenecks that are usually encountered when trying to evaluate practice in such environments.

5.2 Findings from this study

This present study involved an investigation of the LIMS and assessment of pre-analytical errors to compare two separate time periods before and after the implementation of Anglia-ICE. The study also investigated whether the introduction of the electronic test requesting system played a key role in reducing the occurrences of pre-analytical errors. This study also included a survey of pre-analytical procedures in the phlebotomy units of STH NHS FT, to identify the potential sources of these errors and whether phlebotomy practices contributed to pre-analytical error reduction in the clinical chemistry laboratory.

The specific aims were:

- To investigate, categorise and determine the frequencies of pre-analytical errors in the TTP.
- To conduct a survey of pre-analytical procedures by phlebotomy staff to identify key error prone steps in the TTP.
- To draw any conclusions from phlebotomy staff practice and specific errors (e.g. haemolysis or labelling errors) identified in the TTP.
- To engage with experts and seek advice to improve phlebotomy practice in STH NHS FT and to communicate the outcomes from the study to service users with the aim of improving the service and promote patient safety.

Of all the published procedures on the reduction of pre-analytical errors in the TTP, the methodologies described by Söldreberg (2009) and Hill *et al*., (2010) relate closely to the study design in this present research. Both previous studies investigated separate aspects of pre-analytical errors in the laboratory. While Sölderberg (2009) investigated sources of pre-analytical errors in primary health care in Sweden, Hill and co workers (2010) investigated the reduction of labelling errors by introduction of an electronic ordering system in the emergency department of John Hopkins University School of Medicine Hospital, USA. The results of this present study concurred with the separate findings from both these previous studies. There were 3 key findings from this study:

Firstly, the results show a definitive decrease in the occurrence of specific pre-analytical errors following the implementation of the Anglia-ICE system in 2010. It is likely that Anglia-ICE has contributed to the decreased pre-analytical error rates. The implementation of electronic requisitioning of laboratory samples has certainly significantly reduced the rate of one error-prone manual test requesting procedure that is related to patient identification - incorrect patient details (INCORPAT). Overall an absolute pre-analytical error reduction rate of 0.31% was attained and the result agrees with previous findings of Hill *et al.*, (2010) who achieved a 0.31% reduction in institutional sample labelling error rate. Although it has been argued that introduction of new and advanced technology such as electronic test ordering combined with sample bar-coding systems (Valenstein *et al.*, 2006) can go far in reducing patient identification errors, it is certainly also the case that electronic systems will increase other types of ordering errors (Hill *et al.*, 2010) not detected or reported to the laboratory such as electronic order generated errors, no-test request errors and unspecified pre-analytical error types. For illustration, it is fairly easy to select the

wrong patient's details from two different patients with very similar surnames and their names appear closely together on the computer screen of an electronic order system. There is therefore a need for continuous evaluation of practice and monitoring (Sölderberg, 2009) by experts in clinical chemistry laboratory practice.

Secondly, a number of patient identification and test ordering errors were still recorded in the LIMS post Anglia-ICE implementation (e.g. patient's details illegible, incomplete patient details, swapped patient demographics, test not routinely available in laboratory, unspecified pre-analytical error type, unlabelled sample received, unrequested test received, wrong test request received - indicating that the electronic test ordering alone is not sufficient for a reliable error-free pre-analytical procedure. Nonetheless the implementation of Anglia-ICE technology is still the way forward to reduce errors associated with manual paper-based test requests.

Thirdly, there appears to be considerable underreporting of pre-analytical errors in the phlebotomy units of STH NHS FT, where this study was carried out. Underreporting or filing of pre-analytical incidents can lead to clinically important errors (Kolovos *et al.*, 2008). Results show that more than 95% of phlebotomy staff had never filed an error incident regarding the VBS procedure. These findings are supported by results from a previous study by Söderberg (2009), where 69% of respondents in the investigated primary health care setting in Sweden, stated to have never filed an incident report regarding VBS practice. Shortage of time and the complicated process of error reporting currently in place have been voiced as possible reasons for most of the VBS staff refraining from filing an error report. Other reasons for a lack of compliance are fear of punishment, a lack of perceived benefits and the assumption that error reporting is the Manager's duty (Bates *et al.*, 1995; Kalra *et al.*, 2013). This

contrasts with practice that exists in the clinical chemistry laboratory, where error reporting by staff is greatly encouraged.

Therefore, it is crucial to douse the blame and shame culture that surrounds staff, causing them to keep vital evidence or information about errors away from other colleagues or senior members of staff (Darosa and Pugh, 2012). Increased reporting of pre-analytical incidents regarding phlebotomy practices in STH NHS FT should be intensified through continuous education and training, specifically defining whose responsibility it is to report or file errors. Education about errors and their preventability may result in approaches to decrease errors and improve quality, and prevention that can better happen through learning about mistakes and near misses (Kalra *et al.*, 2013).

The finding of undesirable practices within the questionnaire survey largely reflect the lack of standardised procedures in place for VBS, including sample handling, storage and transport. Although there is a copy of a controlled documentation for VBS in the quality management system software on the intranet server of STH NHS FT, staff still relied mainly on uncontrolled documents (such as leaflets kept in the unit), asking other colleagues about standard procedures relating to VBS or calling the laboratory for information when they are confronted with any challenging aspect of their practice. Hence improvements are needed to deliver an excellent service to users.

5.3 Is there a relationship between the LISM study and staff responses in the questionnaire survey?

Evidence of possible linkage between the two parts of the separate studies (i.e. the pre-analytical error frequency statistics from LIMS and the phlebotomy staff questionnaire survey) exists. High frequencies of unlabelled tubes, mislabelled tubes, incorrect sample tubes and incomplete patient demographics on sample tubes have been identified through the LIMS database, which directly supports the results in the questionnaire survey relating to patient identification procedures and vacutainer tube labelling. A high percentage of the respondents were not following the recommended standard procedure for identification of patients. In the questionnaire study, nearly half of the respondents never checked wristbands for patient identification; this is undesirable practice and may lead to improper identification of the patient. Correct patient identification and correct tube labelling are undoubtedly the most crucial procedures in laboratory medicine. Hence, there is a need to prioritize efforts to ensure compliance by staff with standardized patient identification practices.

The demonstration that occurrence of vacutainer tubes labelling errors increased post Anglia-ICE, raises some concerns. Results from the questionnaire survey show low compliance with recommended practice. According to recommended guidelines, vacutainer tubes should always be labelled immediately alongside the patient (CLSI, 2010; WHO, 2014) after VBS to avoid labelling errors (Wallin *et al.*, 2009; Kiechle, 2013; WHO, 2014). A high percentage of the respondents reported to always label the vacutainer tubes alongside the patient after VBS procedure, however a considerable number did not, but reported to label the sample tubes alongside the patient, before VBS procedure. This is not in line with recommended practices (CLSI,

2007, 2008, 2010; WHO, 2014; IBMS, 2016). About a third of the total numbers of respondents were unsure about which standard procedure was available for vacutainer tube labelling in VBS. This indicates unacceptable practice and associated with increased risks of the wrong patient's blood in the labelled vacutainer tube (CLSI, 2007; Soderberg *et al.*, 2009; Harverstick and Groszbach, 2014, IBMS, 2016).

The questionnaire survey also revealed that close to 30% of the phlebotomy staff will ask another colleague to label a vacutainer tube, either before or after sampling, a practice which increases the risk of unlabelled, mislabelling or sample mismatches and are important sources of pre-analytical errors (Plebani and Carraro, 2007; Plebani, 2007; Sciacovelli and Plebani, 2009). These findings appear to be the result of a combination of factors relating to staff shortages and time pressures on the service. Therefore there is a need for adequate staffing to maintain VBS standards (Lippi *et. al.,* 2006), which provides appropriate of expertise (Ashikiran *et. al*., 2011). Mislabelled tubes or tubes with incomplete patient demographics may result in adverse events (Kalra, 2004; Valenstein *et al*, 2006) and in some cases, fatalities. Drawing blood from the wrong patient, or labelling the correct patient's sample with a different patient's label can undoubtedly contribute to pre-analytical errors in the laboratory (CLSI, 2008; IBMS, 2016).

The vacutainer tube labelling procedures adopted by staff, as reported in the questionnaire survey clearly demonstrates an association with a significant risk (CSLI, 2010; ISO 15189; 2012; IBMS; 2015), resulting from mislabelling/ inadequate labelling of vacutainer tubes, and represents a significant area for patient safety improvement (Kalra, 2004; Plebani, 2009) that needs to be addressed.

Results from this present study also show a decrease in the error frequencies of haemolysed sample events during VBS procedures, but this decrease was not statistically significant. Therefore there appears to be was no established correlation between the reduction in the number of haemolysed samples (observed post Anglia-ICE) and VBS practices (including extent of staff training or length of practice). While the reduction in haemolysed sample errors cannot also be directly linked to implementation of Anglia-ICE, it may be down to improvements in good VBS practices and optimized transport conditions (including the use of the pneumatic tube transport system (Fernadez, *et al.*, 2006)), for sample delivery to the clinical chemistry laboratory in STH NHS FT. It may be worthwhile to consider a future study that would directly link sample haemolysis to time of stasis (use of tourniquet) during VBS.

Common errors can also be made in the transportation of phlebotomy samples, thus it is important that the clinical chemistry laboratory and phlebotomy staff are made aware of the optimum time and transport conditions, especially for blood samples. The occurrences of other errors such as sample received contaminated, sample received in wrong container and sample received in wrong preservative, may be avoided by implementing good practices. These include strictly adhering to the correct order of draw, not drawing the blood sample immediately after catheter insertion, and never collecting from an infusion line.

5.4 Limitations of study

One of the limitations of this present study was the relatively small sample size of 68 respondents involved in the questionnaire survey. This study was conducted in the phlebotomy units of the inpatient and outpatient wards of STH NHS FT only. A larger sample size (including the phlebotomy units of A&E, GP surgeries and private clinics) would probably produce improved outcomes.

Another constraint to this study is that the research methodology was restricted to a questionnaire study only. Although the anonymity offered by the questionnaire approach may well have yielded more open responses from respondents, a mixed methodology to include direct observational studies combined with structured interviews could have offered more participant involvement (Polit and Beck, 2014)

This study is the first inquiry linking VBS practices in phlebotomy to retrospective LIMS pre-analytical data by comparing two separate periods pre- and post electronic order requesting in an NHS hospital, which meant that there were very few published studies available for reference purposes or to compare results of findings, although there were a number of published articles on electronic order requesting, which relates to this present study and these are cited in this thesis.

It is important to emphasize that the data presented in this study represent only those pre-analytical errors that were identified by laboratory personnel and recorded in LIMS. Nonetheless, an electronic test requisition system can introduce new source(s) of error not readily detectable by laboratory staff. There is no knowledge of how many pre-analytical sample errors went undetected or unreported. No harm or injury

were linked to any patient as a direct result of a pre-analytical event during the period of this study.

Lastly, there were some difficulties encountered with the returns of completed questionnaires. Several participants took over two months to return their completed questionnaires.

5.5 Recommendations for practice in STH NHS FT

Based on the findings from the questionnaire survey the following recommendations for practice in STH NHS FT (See appendix XVI) were identified:

- The development of a vigorous incident reporting and error filing system. This reporting can be a valuable data collection tool for designing approaches for future VBS training.
- A thorough review of all pre-analytical procedures in the TTP, with specific focus on manual tasks involving patient identification and vacutainer test tube labelling.
- Focus on frequent training and competency assessment to involve all phlebotomy staff performing VBS procedures.
- Development of a standardized coding system for entry of all categories of pre-analytical errors in LIMS.

5.6 Recommendation for future research

- Extend the questionnaire survey to include other requesting centres such as GP surgeries, and private clinics to increase sample size.
- Future studies should consider mixed methodologies such as questionnaire survey combined with observational studies, face-to-face interviews for better staff participation experience.
- Future studies should involve NHS hospitals in other regions of the UK to compare outcomes between pathology laboratories to improve pre-analytical practice and subsequently reduce or eliminate pre-analytical errors in the clinical chemistry laboratory.

Findings from this study will be submitted for publication in a scientific journal and will be presented at scientific meetings such as the IBMS congress to share and promote good practice in clinical chemistry. A service evaluation report, based on the findings from this study and included in appendix XVI of this thesis, has already been submitted to the Clinical Effectiveness Unit (CEU) of STH NHS FT for consideration.

The outputs of the research will be extremely beneficial not only in terms of consolidating the implementation of the outcomes but also in the transferability of findings to other pathology departments. To facilitate this, a website (http://preanalytics.omegapl.com) has been commissioned to discuss the outcomes of the research as well as create a forum to discuss issues relating to pre-analytical testing.

5.7 Conclusion

In general, improvements to clinical chemistry laboratory services require periodic objective evaluation of practices (Shaw, 2003), procedures, staff and organizations against valid and unambiguous standards, to identify and implement appropriate changes. Most pre-analytical errors detected in the clinical chemistry laboratory are avoidable. By strengthening the education of healthcare professionals (doctors, nurses, phlebotomists and clinical support staff) about pre-analytical quality and establishing a comprehensive system of quality in the pre-analytical phase that entails systematic monitoring of non-conformance (EFLM in The Pathologist, 2015), desired outcomes of reduction in errors can be achieved.

Continual local observational studies with error frequency assessment and risk analysis of pre-analytical practice errors, combined with direct feedback, discussions and reflection amongst involved personnel, seems to be the most efficient strategy for sustained good pre-analytical practices.

Overall the key steps to improve the pre-analytical phase are standardization of VBS procedures, education, re-training, clear definition of responsibilities and fluid communication with phlebotomy staff, development of new technologies and automation, all of which require continuous funding and monitoring. Continuous professional development and further training in VBS should be encouraged among staff and support staff in the phlebotomy unit. The loop will not be complete without continuous feedback from the users of the laboratory service - we can only improve the phases of laboratory services that we can measure.

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Sheffield Hallam University

Secretary and Registrar's Directorate
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Appendix I

GT/RDSC
3 February 2014

Tel no: 0114 225 4047
E-mail: g.taylor@shu.ac.uk

Mr BA Sholademi
173 Honeysuckle Road
Sheffield
S5 6FF

Dear Mr Sholademi

Application for Approval of Research Project and Supervisory Team

Your application for approval of research programme was considered by the Chair of the Research Degrees Sub-Committee on 29 January 2014 and I am pleased to inform you that it was approved. Please find attached rapporteurs' comments for your information.

The next stage for you will be the Approval of the Examiners and Doctorate Project Report title for Award of the Doctorate in Professional Studies. These details should be proposed on form DPS3 by your Director of Studies, and submitted to the Graduate Studies Team at least 4 months in advance of submission of your doctoral project report. In your case we would expect to receive a DPS3 no later than 30 April 2018, you will no doubt wish to discuss this with your Director of Studies.

If you have any queries, please contact Student Systems and Records (Research Degrees) based at City Campus, using the contact details above.

Yours sincerely

pp

Secretary
Research Degrees Sub-Committee

cc Director of Studies
Head of Programme Area (Research Degrees)
Research Administrator

Enc

Appendix II

Sheffield Hallam University | Centre for Health and Social Care Research

03062014

Dear Mr Sholademi,

This letter relates to your research proposal:

TITLE: Reducing pre-analytical errors in clinical chemistry through effective communication with service users.

This proposal was submitted to the Faculty Research Ethics Committee for ethics and scientific review in October 2013. It has been reviewed by two independent reviewers and has been passed as satisfactory on 11th October 2013. You will need to ensure you have all other necessary permission in place before proceeding, for example, from the Research Governance office of any sites outside the University where your research will take place. This letter can be used as evidence that the proposal has been reviewed ethically and scientifically within Sheffield Hallam University.

Good luck with your project.

Peter Allmark

Dr Peter Allmark
On behalf of the Faculty Research Ethics Committee
Faculty of Health and Well-being
Sheffield Hallam University
32 Collegiate Crescent
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Appendix III

5683- Identification and Reduction of Pre-analytical Errors in Clinical Chemistry - approved as SE

Dear Benjamin,

Project 5683- Identification and Reduction of Pre-analytical Errors in Clinical Chemistry has been approved as service evaluation. Please use this number when corresponding with me.

It has been be included on the Directorate's Clinical Audit and Effectiveness Programme to ensure that the project's progress can be monitored throughout all the stages of the cycle. The project is now on the programme as a locally managed project. Any project that is progressing as planned with be issued a green colour status, any with a minor problem – hoping to resolve - is issued an amber status and any which has a significant problem will be issued a red status. Please remember to keep me informed of your project status at all times. The progress of projects is reported regularly to the Trust Clinical Audit and Effectiveness Committee (CEC) and Directorate meetings. If you let me know of any problems, I will try to resolve them in a timely fashion to prevent any escalation procedures.

It was expected that on completion of the project you will submit a final written report in the STHFT CEU format. Please find attached the report template and separate guidance. The same headings should be used when you prepare a presentation. This is not only built into the terms and conditions of the Clinical Audit Policy but the report is also used as evidence of compliance for the NHS Litigation Authority Level 2 assessment. The report is used as evidence for:

- Care Quality Commission (CQC) Essential Standards for Quality and Safety
- CQC Engagement in Clinical Audit Performance Indicator
- NHSLA and Information Governance Standards
- Department of Health Quality Accounts
- Providing assurances to the Trust Board
- NHS Sheffield Commissioner contractual obligations
- Meeting NICE guidance (all types)
- NCAPOP programme

The Trust actively encourages that all project findings are disseminated within your Directorate/Speciality groups, along with stakeholders, to agree and monitor action plans following any recommendations for change. All audits require this formal report (a presentation is not appropriate since it does not outline all the relevant points in the report such as the action plan). An audit cannot be closed on the programme unless the action plan has been implemented.

If you need to discuss this email further with me then I am available Monday to Thursday.

Kind regards,

Christine

APPENDIX IV

Service Manager
NGH
Sheffield
10/07/2014

Identification and Reduction of Pre-analytical Errors in Clinical Chemistry Staff Questionnaire

YOUR OPINION MAKES A DIFFERENCE

Dear Sir/Madam,

The Clinical Chemistry team at the Sheffield Teaching Hospitals are constantly looking for ways to improve the service delivered. One of the ways we do this is by asking you about the service that you work in. Your feedback is very important to us. We ensure that we take a note of all comments received and use them to help us improve. We would be grateful if you could complete the following questionnaire giving us your opinions.

The questionnaire is completely anonymous and will only take you about 10 minutes to complete. You do not have to take part if you don't want to. Your answers will be used to help us to improve our services.

This questionnaire concerns the collection and handling of venous blood samples for clinical chemistry analysis. You will be asked to complete a ***series of*** yes/no questions. You will also be asked ***how often you*** carry out a task in a specified manner. Please select the most suitable alternative from the choices given. This means that you should not mark an answer between two alternatives. Finally I will ask for your opinion and suggestions. Mark your answers by placing a tick in the box (☐) beside the most suitable alternative. If you wish to change an answer, fill in the incorrectly marked box completely (■)

Please do not write your name on this questionnaire.

Please return your completed questionnaire in the boxes provided in the phlebotomy reception

May I take this opportunity to thank-you in advance for completing this questionnaire.

If you have any questions about this survey please ask to speak to Benjamin Sholademi.

Signed

Project Lead

Please turn over

APPENDIX V

The Questionnaire

The questionnaire proposed for this project will address phlebotomy practices in STH. The development of the questionnaire has be undertaken in discussion with experts in questionnaire design and validated. The discussions also involved experts in clinical chemistry department and the phlebotomy unit: Phlebotomists, Medical Laboratory Assistants and Biomedical Scientists. Relevant literature and international guidelines regarding the development of questionnaires has also informed the design and content of the questionnaire.
The return of a completed questionnaire (paper or electronic versions) will be taken as consent[§] to participate in the study

Data collected will be pooled to provide an overview of training and phlebotomy practices in STH and identify areas for improvement.

[§]*This proviso has been included in the questionnaire to satisfy ethical requirement.*

The following section contains questions regarding training and routine procedures in phlebotomy practice.

1b) How long have you been employed in *your current* unit? …….year(s)…….. month(s)

2) How long ago was your most recent phlebotomy training?

A) 5years ☐ B) 4years ☐ C) 3 years ☐ D) 2 years ☐ E) < 2 years ☐

3) How often do you carry out venous blood sampling?

A) Every workday ☐ C) Every week ☐

B) Every month ☐ D) Less often ☐ E) Never ☐

4a) Does your unit have documented routines for the handling of venous blood samples?

A) ☐ Yes B) ☐ No C) ☐ Don't know

4b) Does your unit have undocumented information such as posters regarding common sample requirements and the order of draw for venous blood sampling?

A) ☐ Yes B) ☐ No C) ☐ Don't know

5a) Would you be interested in receiving further training in phlebotomy and the handling of blood samples in your unit?

A) ☐ Yes B) ☐ No C) ☐ Don't know

5b) Would you be interested in receiving information about blood sampling techniques?

A) ☐ Yes B) ☐ No C) ☐ Don't know

The following questions concern patient identification, the handling of test requests and test tube labeling.
*(It is important for you to mark **one** alternative for **each** row in the following section.)*

6) How often and how do you check patient identification when collecting blood samples?

	Always	**Often**	**Seldom**	**Never**
a) By asking the patient to state his/her name and surname	A ☐	B ☐	C ☐	D ☐
b) Since I already know the patient, I don' t have to check this	A ☐	B ☐	C ☐	D ☐
c) By checking the identification wristband	A ☐	B ☐	C ☐	D ☐
d) By asking the patient's family	A ☐	B ☐	C ☐	D ☐
e) By checking the patient's health care card	A ☐	B ☐	C ☐	D ☐
f) By other means (please state below)				

7) How often do you perform the following tasks?

	Always	**Often**	**Seldom**	**Never**
a) Compare the patient's name and Hospital number with the information on the test request	A ☐	B ☐	C ☐	D ☐
b) Use test requests that somebody else has completed	A ☐	B ☐	C ☐	D ☐
c) Check the information on the test request, if somebody else has completed it	A ☐	B ☐	C ☐	D ☐
d) Adjust time of sampling on the request, if the marked time differs with more than 30 min from the actual sampling time?	A ☐	B ☐	C ☐	D ☐
e) Sign the test request	A ☐	B ☐	C ☐	D ☐

8) How often does someone else mark the sampling time on the test request?

A) Daily ☐ B) Weekly ☐ C) Monthly ☐ D) Occasionally ☐ E) Never ☐

9) When do you mark the time of sampling on the test request, if you do it yourself?

I never mark time of sampling	A ☐
More than 30 min before sampling	B ☐
0-30 min before sampling	C ☐
0-30 min after sampling	D ☐
More than 30 min after sampling	E ☐

10) When or where do you label the test tube?

	Always	**Often**	**Seldom**	**Never**
a) Before I approach the patient	A ☐	B ☐	C ☐	D ☐
b) Alongside the patient, immediately before sampling	A ☐	B ☐	C ☐	D ☐
c) Alongside the patient, immediately after sampling	A ☐	B ☐	C ☐	D ☐
d) At a later occasion	A ☐	B ☐	C ☐	D ☐
e) A different person labels the test tube before sampling	A ☐	B ☐	C ☐	D ☐
f) A different person labels the test tube after sampling	A ☐	B ☐	C ☐	D ☐

The following questions concern sampling, sample storage, and information search procedures.

(*It is important that you mark **one** alternative for **each** row in the following section*.)

11) How long do you usually allow your patient to rest (supine or sitting) prior to venous blood sampling?

A) Not at all ☐	B) 0-5 min ☐	C) 6-10 min ☐	D) 11-15 min ☐	E) More than 15 min ☐
F) I do not check the time ☐				

12) If you use stasis (tourniquet) when performing venous sampling, when do you remove it?

	Always	**Often**	**Seldom**	**Never**
a) Before the first sample is collected	A ☐	B ☐	C ☐	D ☐
b) During sampling	A ☐	B ☐	C ☐	D ☐
c) After sampling is completed	A ☐	B ☐	C ☐	D ☐
d) I keep the stasis for as long as necessary if there is difficulty in sampling.	A ☐	B ☐	C ☐	D ☐
e) Other reasons (please state)				

13) What do you do if you are not sure of how a sample should be collected?

	Always	**Often**	**Seldom**	**Never**
a) I check the print version of the sample handling manual issued in the laboratory (available in the unit)	A ☐	B ☐	C ☐	D ☐
b) I look up the online laboratory handbook available on STH intranet	A ☐	B ☐	C ☐	D ☐
c) I call the clinical chemistry laboratory	A ☐	B ☐	C ☐	D ☐
d) I ask a colleague	A ☐	B ☐	C ☐	D ☐
e) By other means (please state)				

14) How often do you carry out the following tasks?

	Always	Often	Seldom	Never
a) Invert each test tube with anticoagulants/ additives several times immediately before the next tube is filled?	A ☐	B ☐	C ☐	D ☐
b) Use an automated test tube inverter	A ☐	B ☐	C ☐	D ☐

15) How do you store the test tubes immediately after sampling?

	Always	Often	Seldom	Never
a) I put them into test tube racks on the workbench	A ☐	B ☐	C ☐	D ☐
b) I put them in the pocket of my uniform	A ☐	B ☐	C ☐	D ☐
c) I lay them on the work bench	A ☐	B ☐	C ☐	D ☐
d) I keep them in the fridge	A ☐	B ☐	C ☐	D ☐
e) By other means (please state)				

These final questions concern error (incident) reporting, ranking and suggestions

(*It is important that you to mark **one** alternative for **each** row in the following section*)

16) Approximately, how many error reports have you filed after observing or making an error in venous blood sampling?

A) Number of times (please indicate)……

B) I have never written any error reports ☐

C) Another member of staff reports on my behalf ☐

17) If you have refrained from filing an error log/report: What was/were the reason/reasons?

(Please complete the questions below even if you have never filed any report)

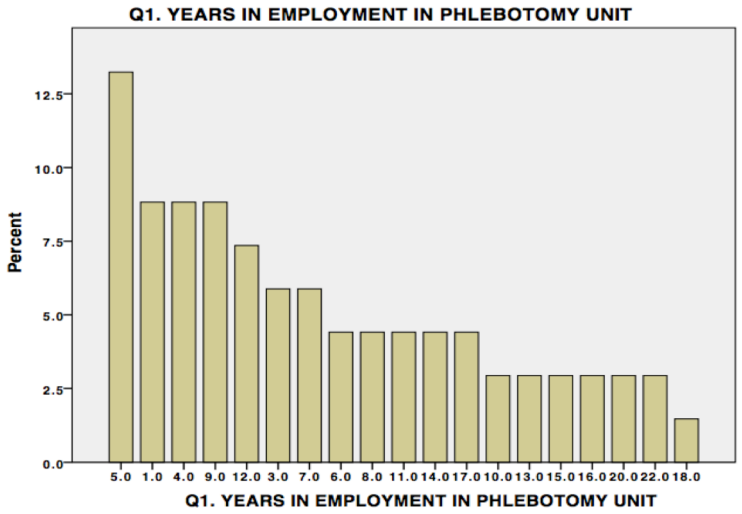
	Always	Often	Seldom	Never
a) I did not have enough time	A ☐	B ☐	C ☐	D ☐
b) I do not know how to fill an error log	A ☐	B ☐	C ☐	D ☐
c) I am not bothered, procedure is too cumbersome	A ☐	B ☐	C ☐	D ☐
d) Nobody else fills error logs/report	A ☐	B ☐	C ☐	D ☐
e) The section/unit head takes responsibility of filling error log/report	A ☐	B ☐	C ☐	D ☐
f) I am concerned about possible consequences (please specify below)				
g) Any other reason(s)				

18) Do you have any suggestions for how the collection and handling of venous blood samples could be improved in your unit/section?

Thank you for completing the questionnaire!

Please place the questionnaire in the enclosed anonymous returning envelope

Appendix VI
SPSS Analysis from Questionnaire Study

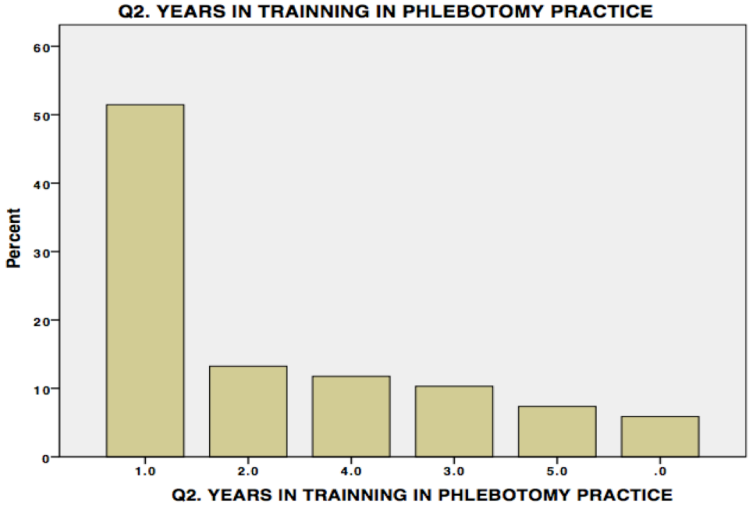


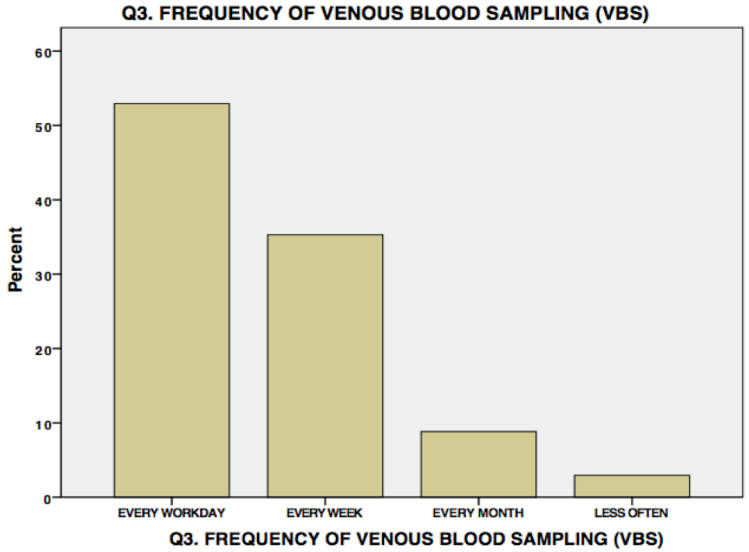
Q1. YEARS IN EMPLOYMENT IN PHLEBOTOMY UNIT

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	5.0	9	13.2	13.2	13.2
	1.0	6	8.8	8.8	22.1
	4.0	6	8.8	8.8	30.9
	9.0	6	8.8	8.8	39.7
	12.0	5	7.4	7.4	47.1
	3.0	4	5.9	5.9	52.9
	7.0	4	5.9	5.9	58.8
	6.0	3	4.4	4.4	63.2
	8.0	3	4.4	4.4	67.6
	11.0	3	4.4	4.4	72.1
	14.0	3	4.4	4.4	76.5
	17.0	3	4.4	4.4	80.9
	10.0	2	2.9	2.9	83.8
	13.0	2	2.9	2.9	86.8
	15.0	2	2.9	2.9	89.7
	16.0	2	2.9	2.9	92.6
	20.0	2	2.9	2.9	95.6
	22.0	2	2.9	2.9	98.5
	18.0	1	1.5	1.5	100.0
	Total	68	100.0	100.0	

Q2. YEARS IN TRAINNING IN PHLEBOTOMY PRACTICE

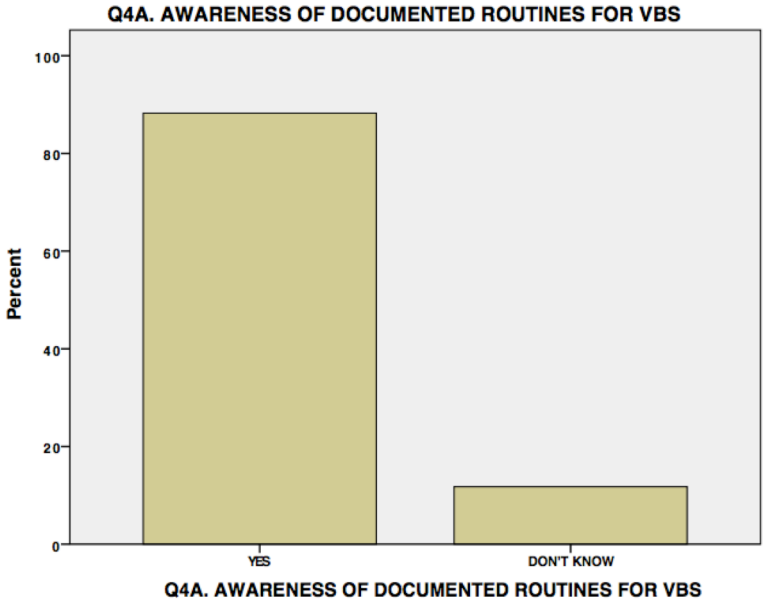
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.0	35	51.5	51.5	51.5
	2.0	9	13.2	13.2	64.7
	4.0	8	11.8	11.8	76.5
	3.0	7	10.3	10.3	86.8
	5.0	5	7.4	7.4	94.1
	.0	4	5.9	5.9	100.0
	Total	68	100.0	100.0	





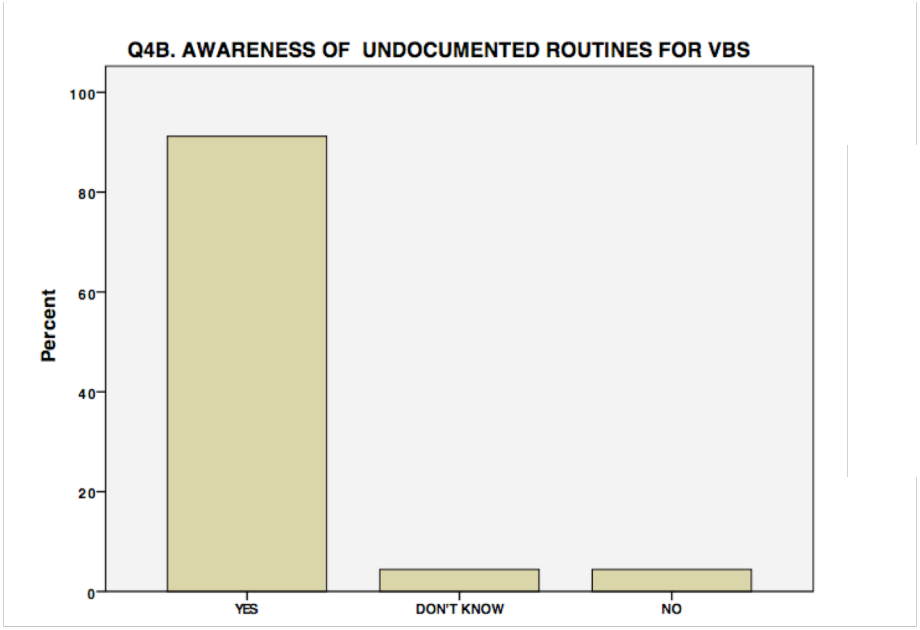
Q3. FREQUENCY OF VENOUS BLOOD SAMPLING (VBS)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	EVERY WORKDAY	36	52.9	52.9	52.9
	EVERY WEEK	24	35.3	35.3	88.2
	EVERY MONTH	6	8.8	8.8	97.1
	LESS OFTEN	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



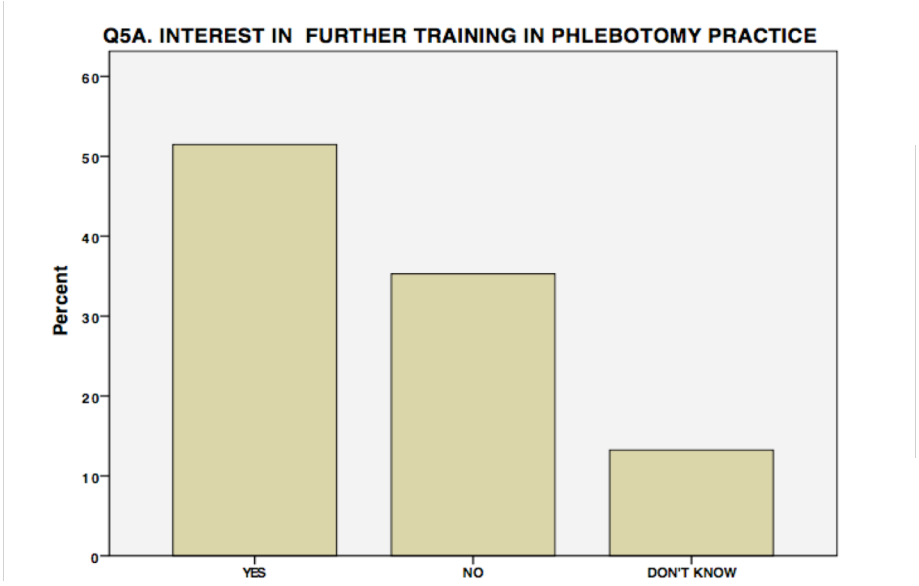
Q4A. AWARENESS OF DOCUMENTED ROUTINES FOR VBS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	YES	60	88.2	88.2	88.2
	DON'T KNOW	8	11.8	11.8	100.0
	Total	68	100.0	100.0	



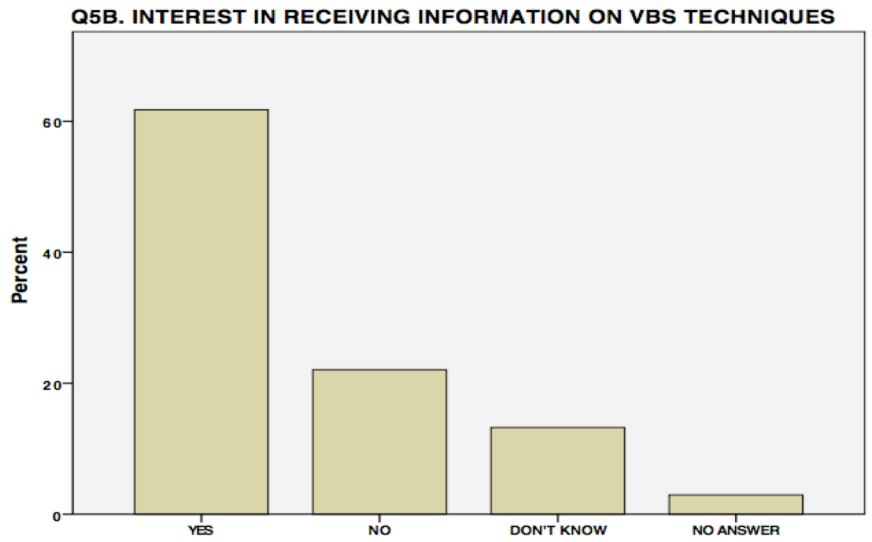
Q4B. AWARENESS OF UNDOCUMENTED ROUTINES FOR VBS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	YES	62	91.2	91.2	91.2
	DON'T KNOW	3	4.4	4.4	95.6
	NO	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



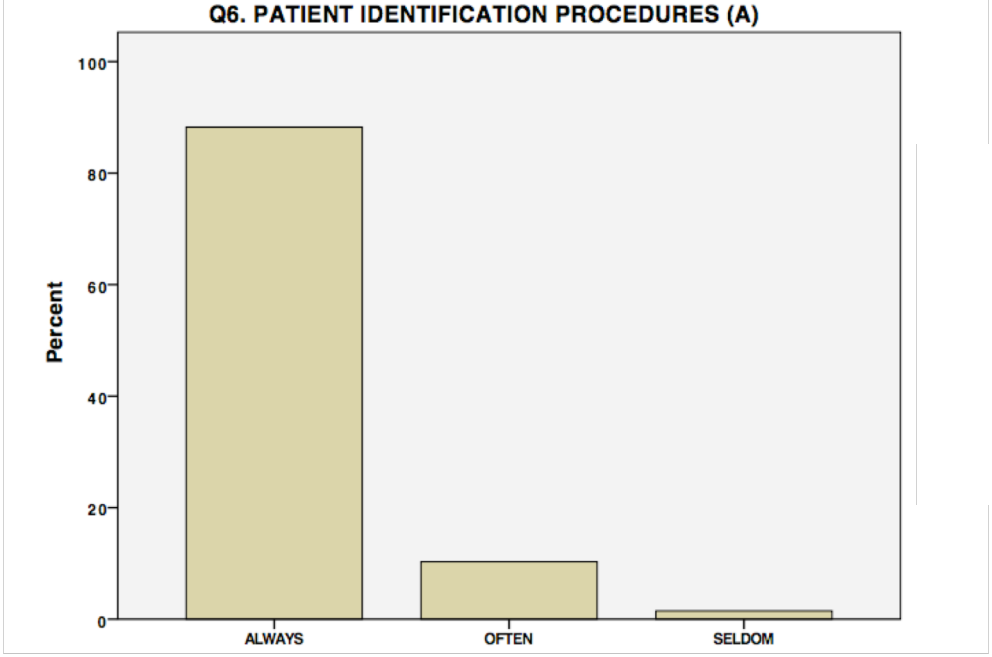
Q5A. INTEREST IN FURTHER TRAINING IN PHLEBOTOMY PRACTICE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	YES	35	51.5	51.5	51.5
	NO	24	35.3	35.3	86.8
	DON'T KNOW	9	13.2	13.2	100.0
	Total	68	100.0	100.0	



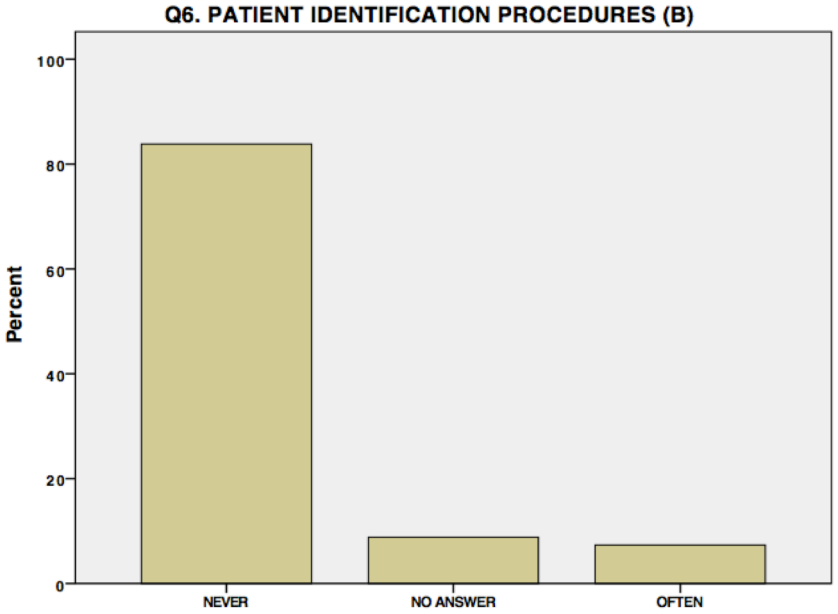
Q5B. INTEREST IN RECEIVING INFORMATION ON VBS TECHNIQUES

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	YES	42	61.8	61.8	61.8
	NO	15	22.1	22.1	83.8
	DON'T KNOW	9	13.2	13.2	97.1
	NO ANSWER	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



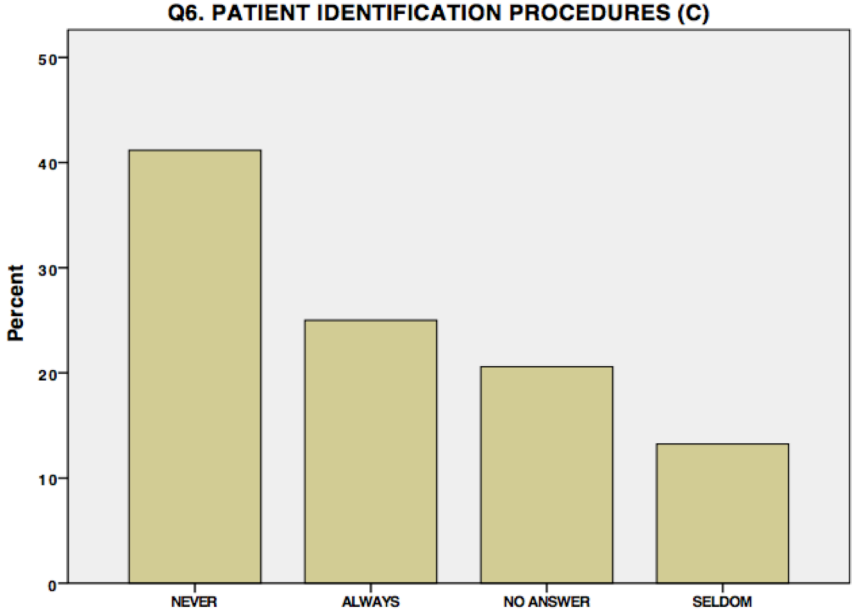
Q6. PATIENT IDENTIFICATION PROCEDURES (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	60	88.2	88.2	88.2
	OFTEN	7	10.3	10.3	98.5
	SELDOM	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



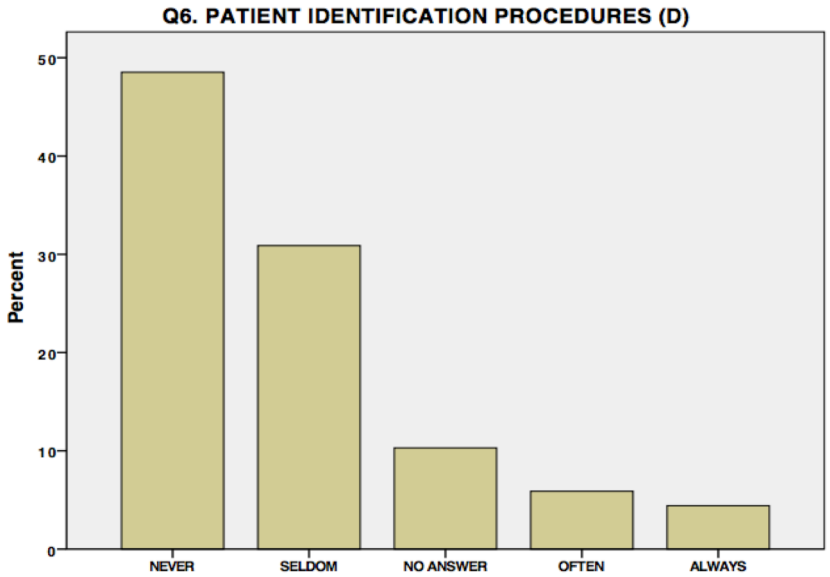
Q6. PATIENT IDENTIFICATION PROCEDURES (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	57	83.8	83.8	83.8
	NO ANSWER	6	8.8	8.8	92.6
	OFTEN	5	7.4	7.4	100.0
	Total	68	100.0	100.0	



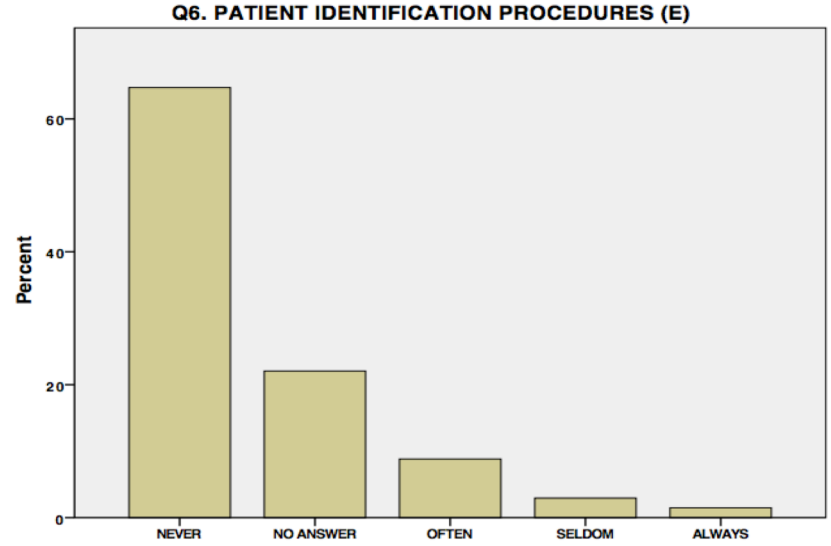
Q6. PATIENT IDENTIFICATION PROCEDURES (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	28	41.2	41.2	41.2
	ALWAYS	17	25.0	25.0	66.2
	NO ANSWER	14	20.6	20.6	86.8
	SELDOM	9	13.2	13.2	100.0
	Total	68	100.0	100.0	



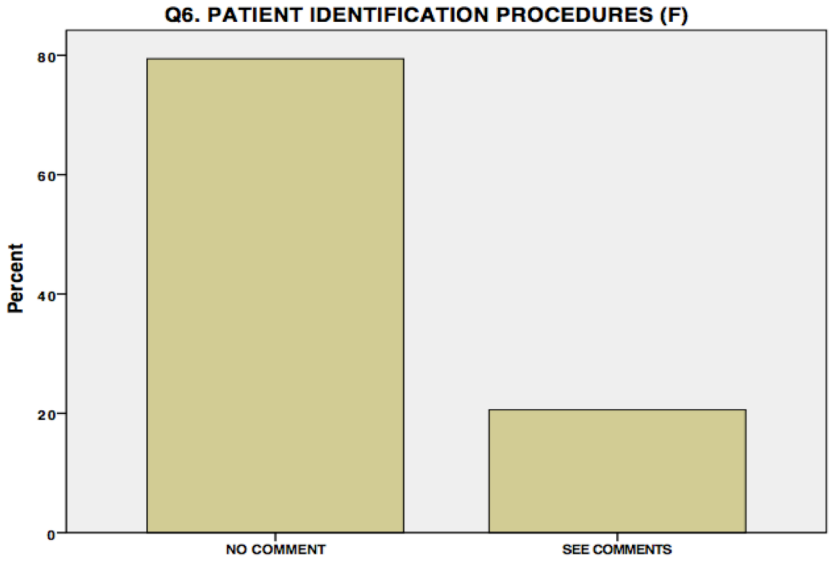
Q6. PATIENT IDENTIFICATION PROCEDURES (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	33	48.5	48.5	48.5
	SELDOM	21	30.9	30.9	79.4
	NO ANSWER	7	10.3	10.3	89.7
	OFTEN	4	5.9	5.9	95.6
	ALWAYS	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



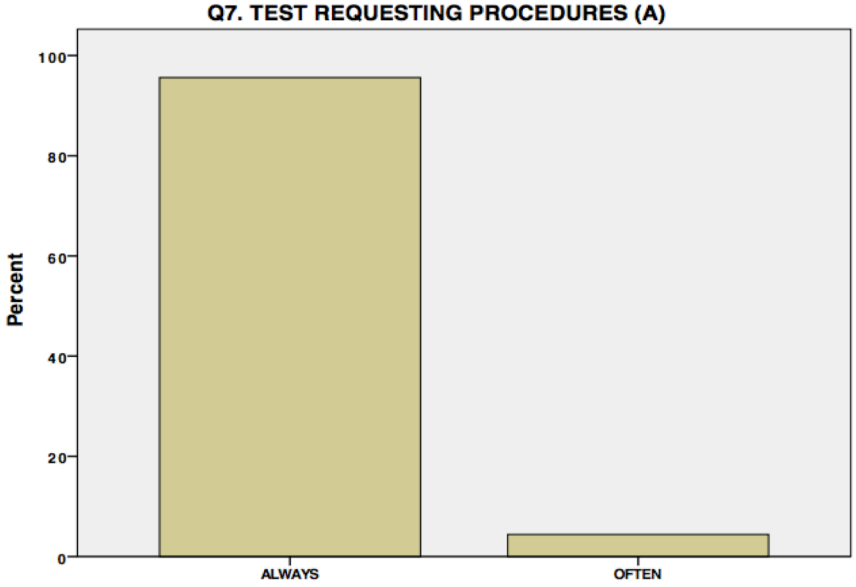
Q6. PATIENT IDENTIFICATION PROCEDURES (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	44	64.7	64.7	64.7
	NO ANSWER	15	22.1	22.1	86.8
	OFTEN	6	8.8	8.8	95.6
	SELDOM	2	2.9	2.9	98.5
	ALWAYS	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



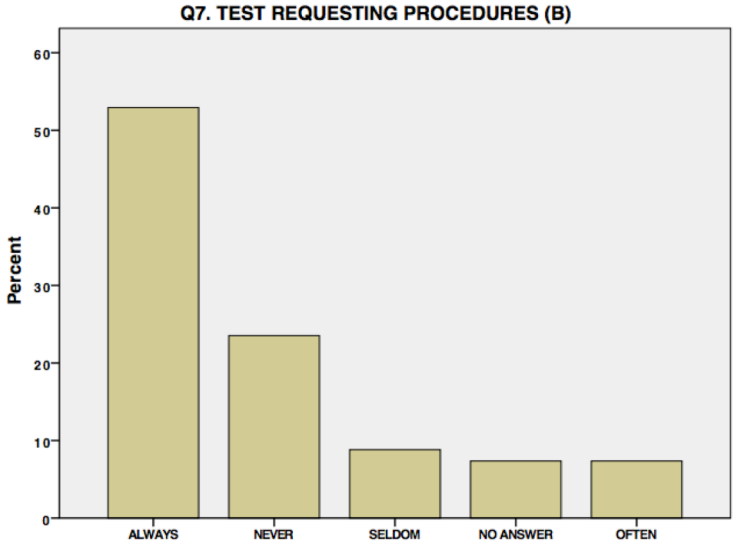
Q6. PATIENT IDENTIFICATION PROCEDURES (F)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO COMMENT	54	79.4	79.4	79.4
	SEE COMMENTS	14	20.6	20.6	100.0
	Total	68	100.0	100.0	



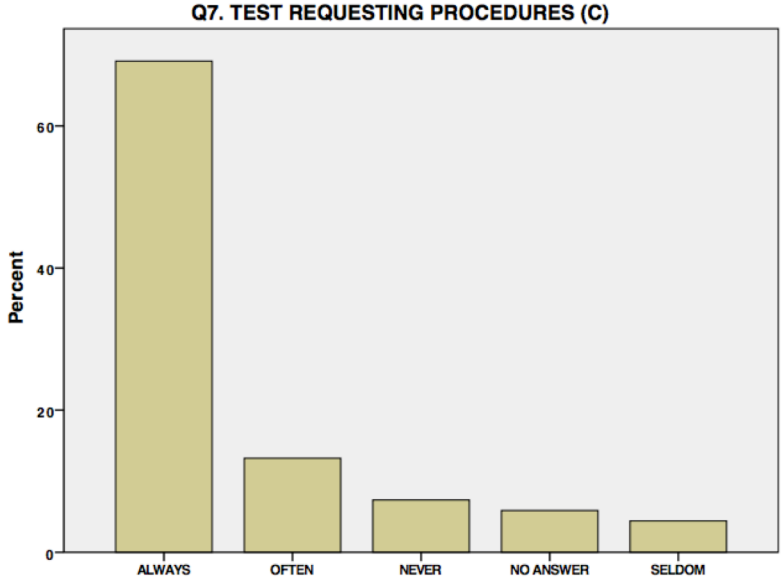
Q7. TEST REQUESTING PROCEDURES (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	65	95.6	95.6	95.6
	OFTEN	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



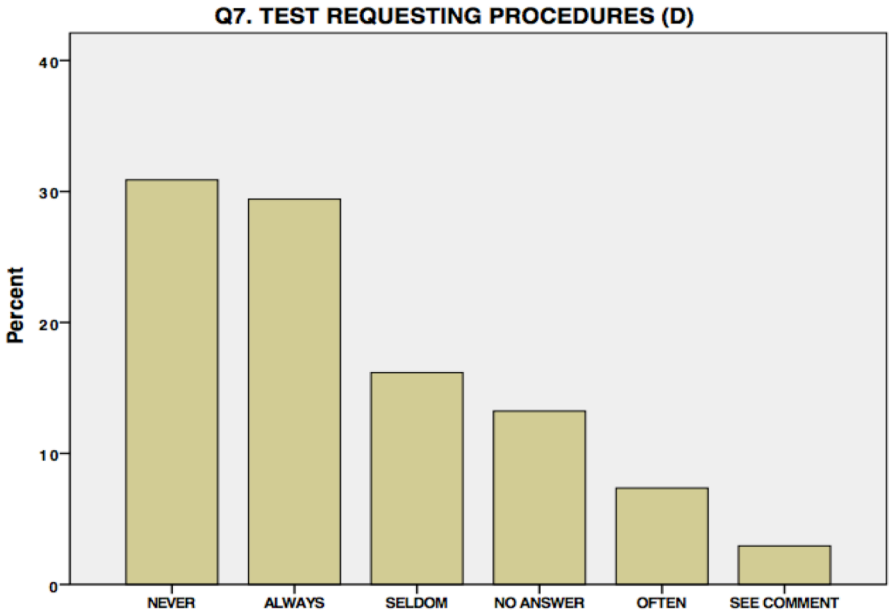
Q7. TEST REQUESTING PROCEDURES (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	36	52.9	52.9	52.9
	NEVER	16	23.5	23.5	76.5
	SELDOM	6	8.8	8.8	85.3
	NO ANSWER	5	7.4	7.4	92.6
	OFTEN	5	7.4	7.4	100.0
	Total	68	100.0	100.0	



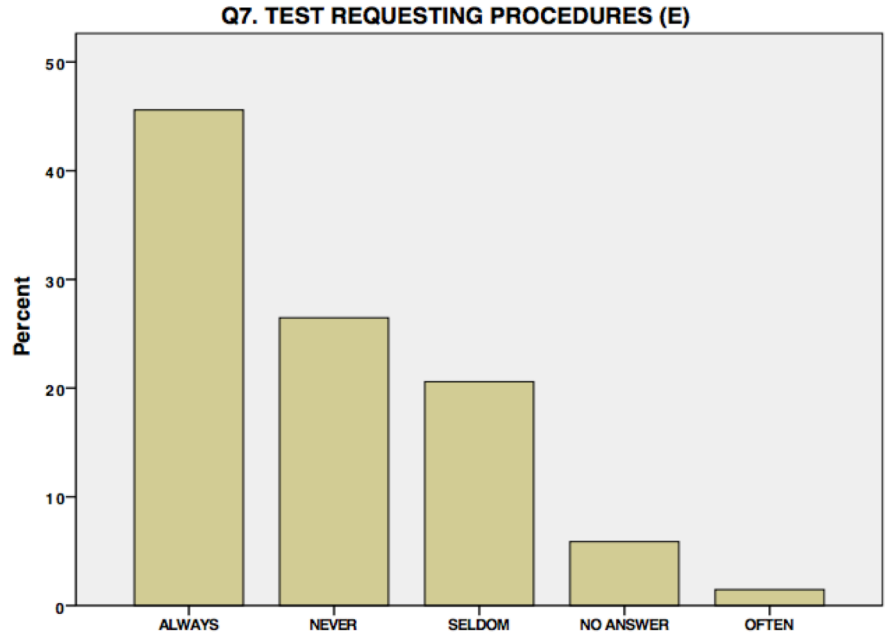
Q7. TEST REQUESTING PROCEDURES (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	47	69.1	69.1	69.1
	OFTEN	9	13.2	13.2	82.4
	NEVER	5	7.4	7.4	89.7
	NO ANSWER	4	5.9	5.9	95.6
	SELDOM	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



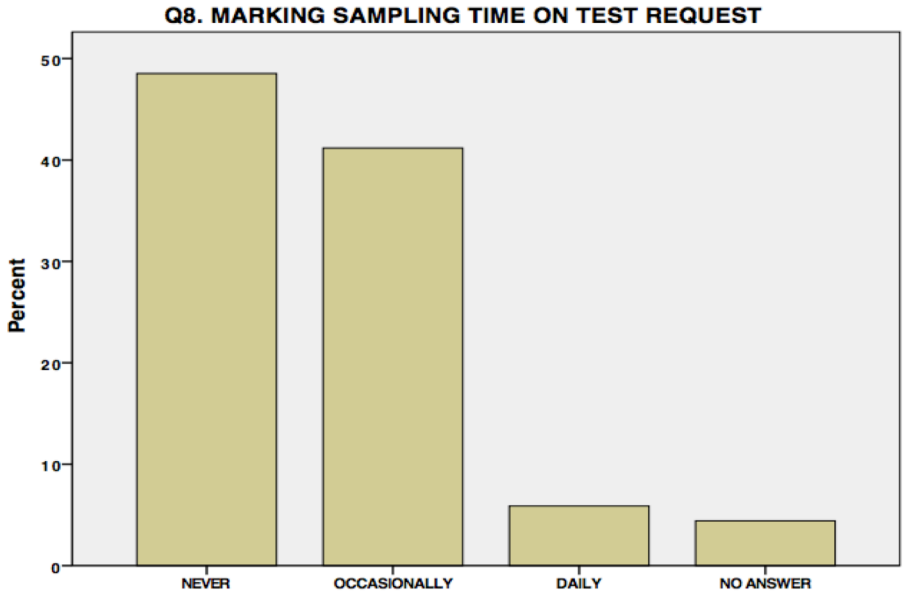
Q7. TEST REQUESTING PROCEDURES (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	21	30.9	30.9	30.9
	ALWAYS	20	29.4	29.4	60.3
	SELDOM	11	16.2	16.2	76.5
	NO ANSWER	9	13.2	13.2	89.7
	OFTEN	5	7.4	7.4	97.1
	SEE COMMENT	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



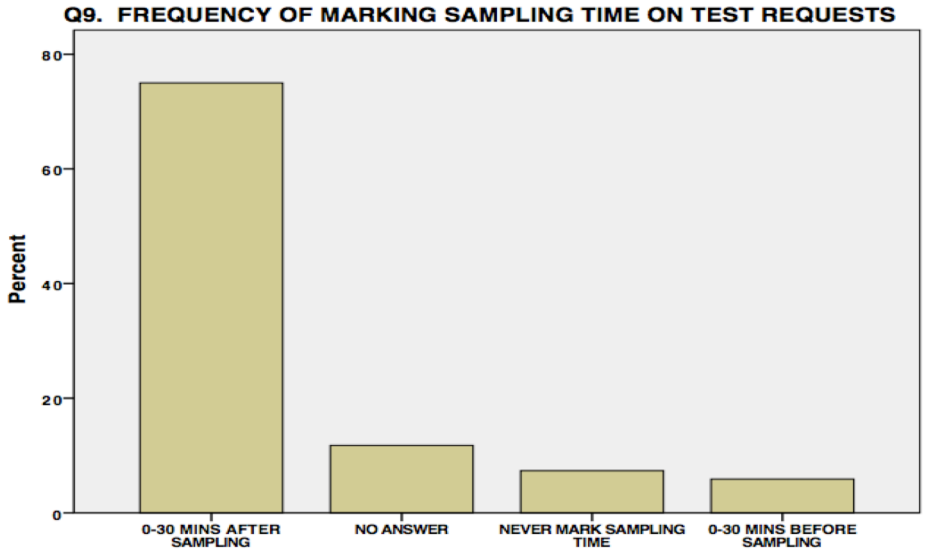
Q7. TEST REQUESTING PROCEDURES (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	31	45.6	45.6	45.6
	NEVER	18	26.5	26.5	72.1
	SELDOM	14	20.6	20.6	92.6
	NO ANSWER	4	5.9	5.9	98.5
	OFTEN	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



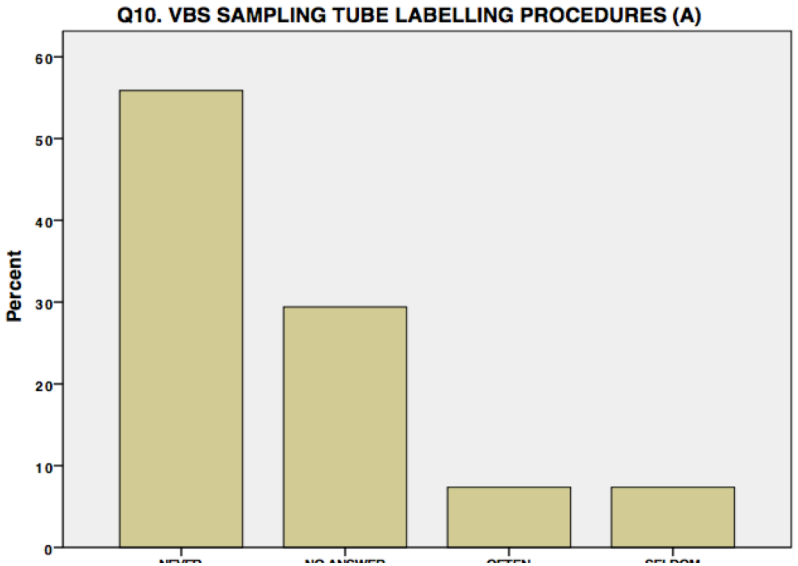
Q8. MARKING SAMPLING TIME ON TEST REQUEST

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	33	48.5	48.5	48.5
	OCCASIONALLY	28	41.2	41.2	89.7
	DAILY	4	5.9	5.9	95.6
	NO ANSWER	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



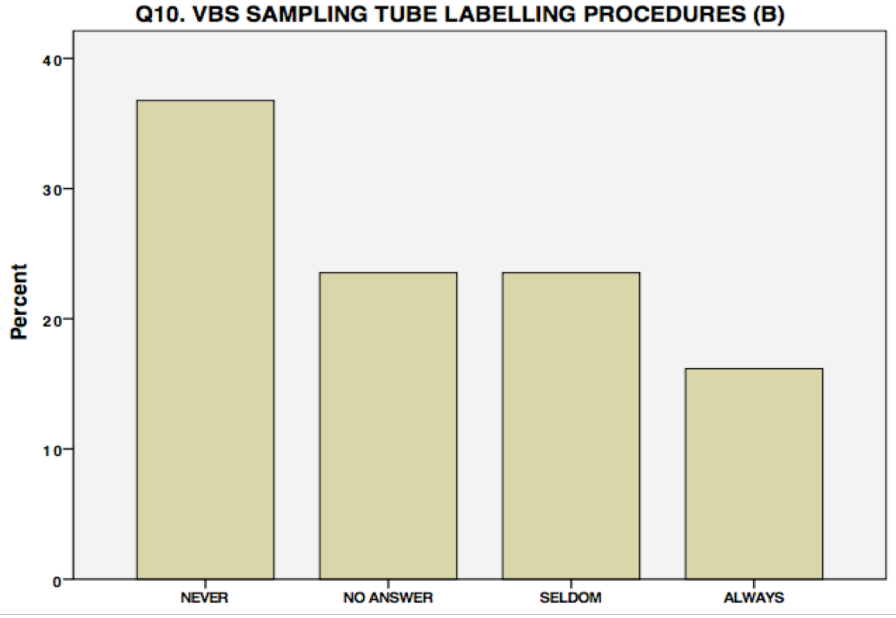
Q9. FREQUENCY OF MARKING SAMPLING TIME ON TEST REQUESTS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0-30 MINS AFTER SAMPLING	51	75.0	75.0	75.0
	NO ANSWER	8	11.8	11.8	86.8
	NEVER MARK SAMPLING TIME	5	7.4	7.4	94.1
	0-30 MINS BEFORE SAMPLING	4	5.9	5.9	100.0
	Total	68	100.0	100.0	



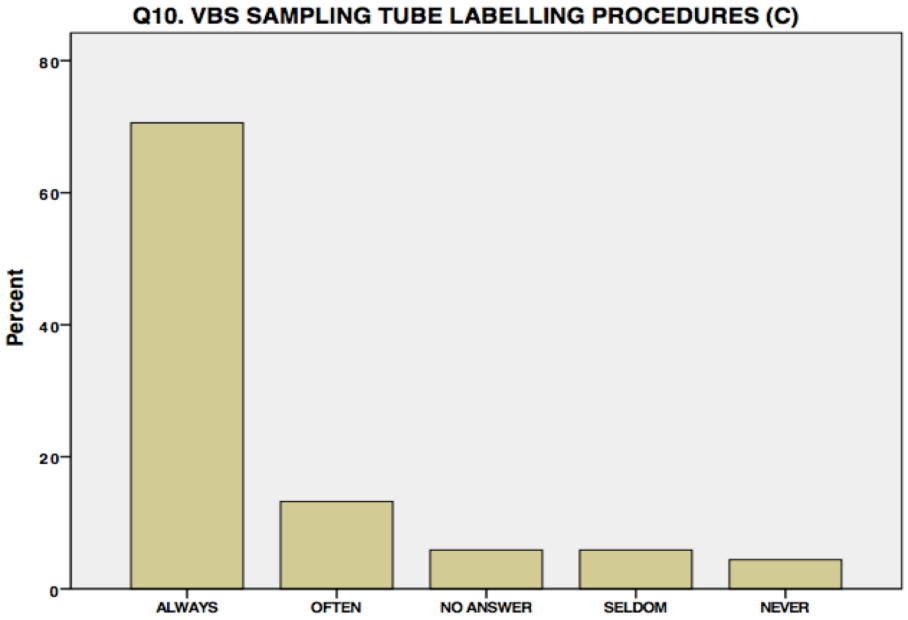
Q10. VBS SAMPLING TUBE LABELLING PROCEDURES (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	38	55.9	55.9	55.9
	NO ANSWER	20	29.4	29.4	85.3
	OFTEN	5	7.4	7.4	92.6
	SELDOM	5	7.4	7.4	100.0
	Total	68	100.0	100.0	



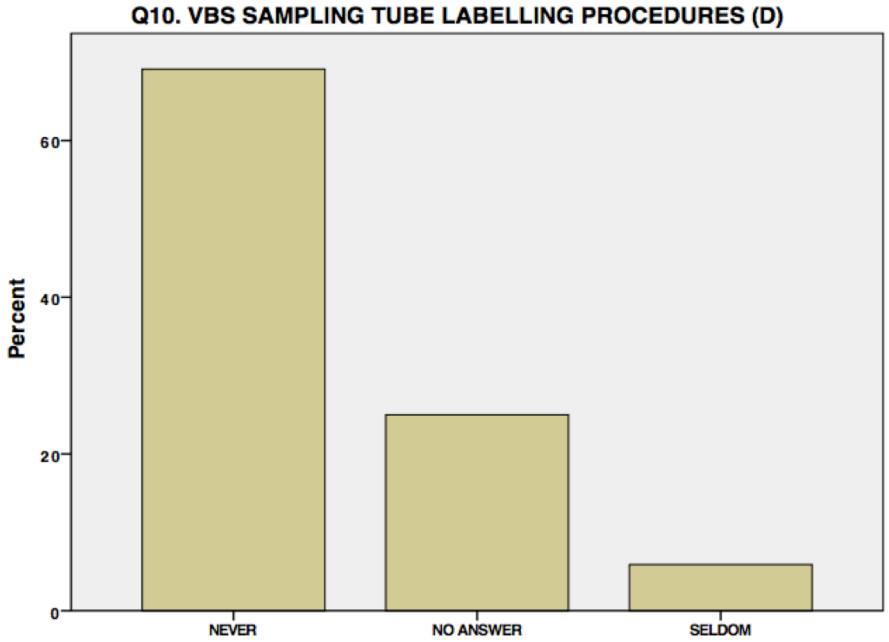
Q10. VBS SAMPLING TUBE LABELLING PROCEDURES (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	25	36.8	36.8	36.8
	NO ANSWER	16	23.5	23.5	60.3
	SELDOM	16	23.5	23.5	83.8
	ALWAYS	11	16.2	16.2	100.0
	Total	68	100.0	100.0	



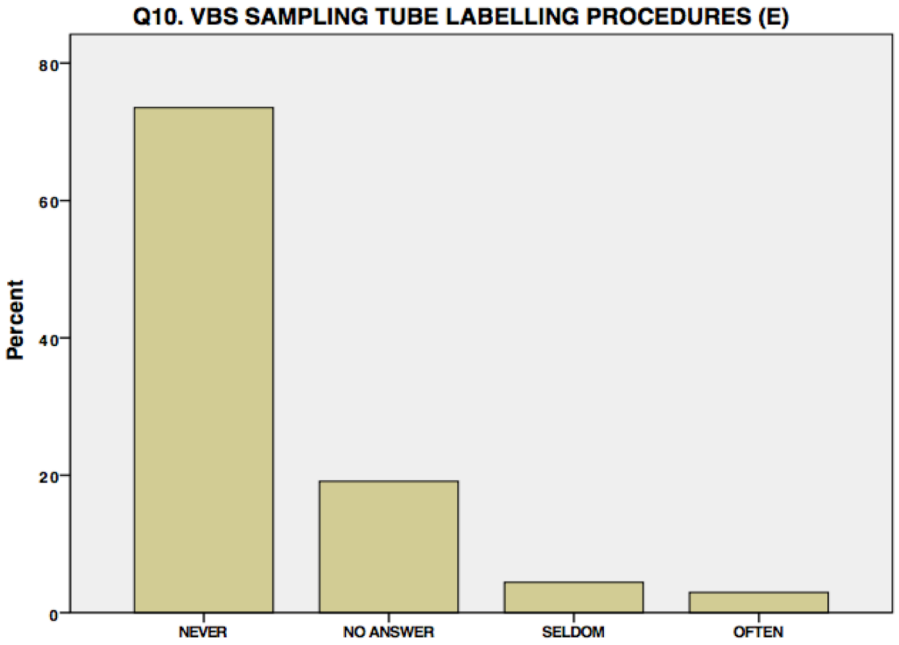
Q10. VBS SAMPLING TUBE LABELLING PROCEDURES (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	48	70.6	70.6	70.6
	OFTEN	9	13.2	13.2	83.8
	NO ANSWER	4	5.9	5.9	89.7
	SELDOM	4	5.9	5.9	95.6
	NEVER	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



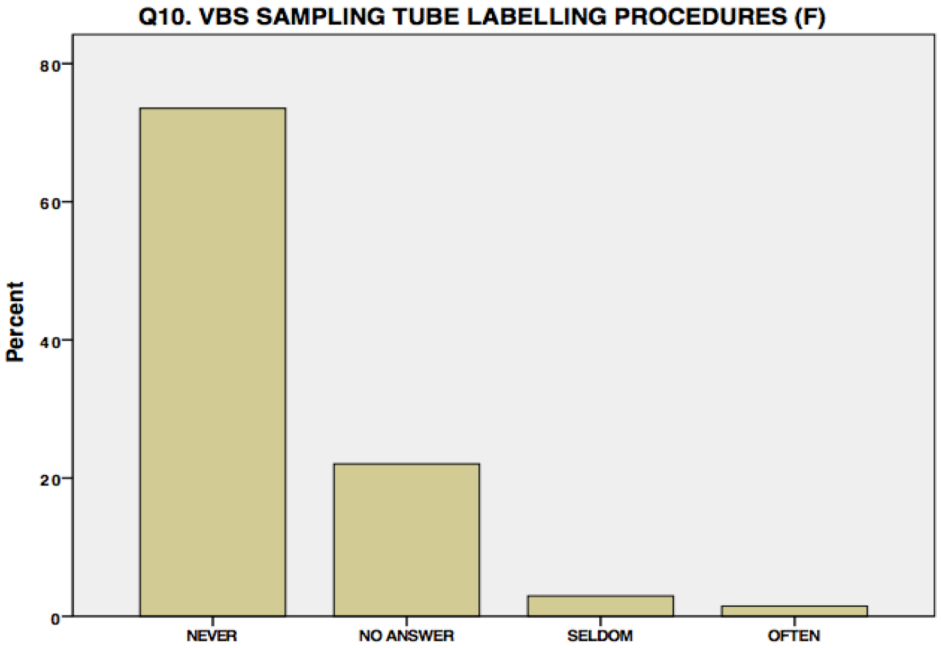
Q10. VBS SAMPLING TUBE LABELLING PROCEDURES (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	47	69.1	69.1	69.1
	NO ANSWER	17	25.0	25.0	94.1
	SELDOM	4	5.9	5.9	100.0
	Total	68	100.0	100.0	



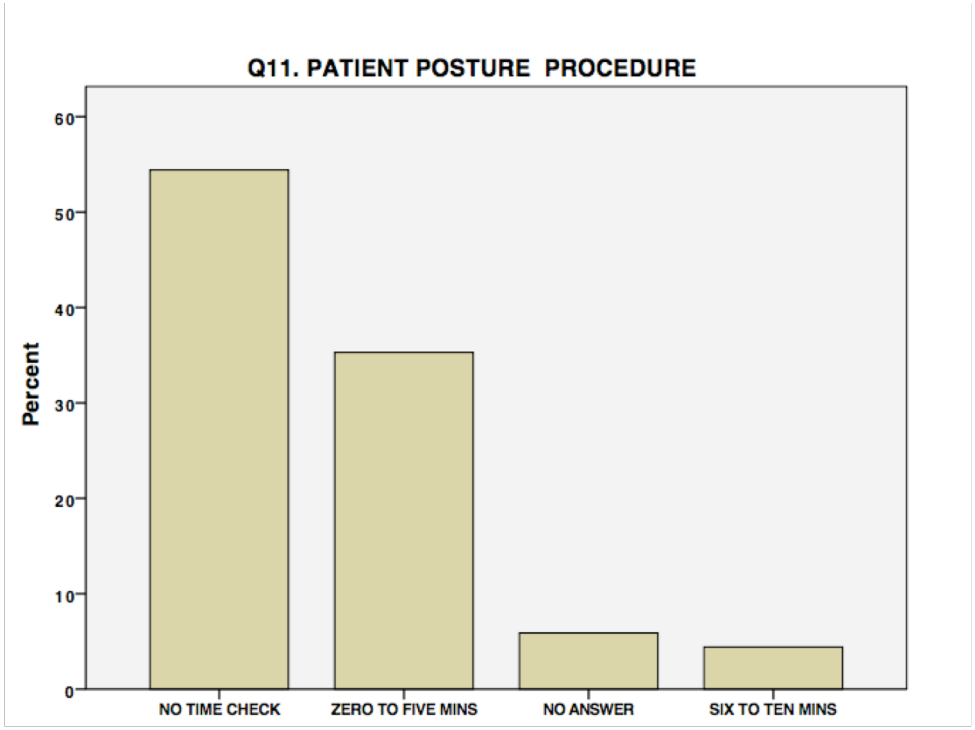
Q10. VBS SAMPLING TUBE LABELLING PROCEDURES (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	50	73.5	73.5	73.5
	NO ANSWER	13	19.1	19.1	92.6
	SELDOM	3	4.4	4.4	97.1
	OFTEN	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



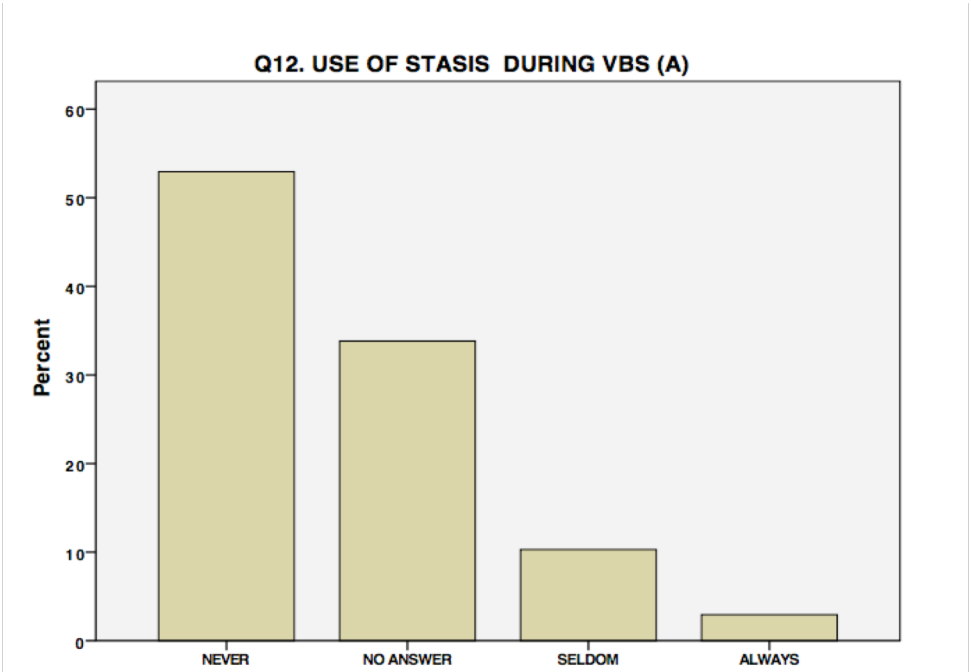
Q10. VBS SAMPLING TUBE LABELLING PROCEDURES (F)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	50	73.5	73.5	73.5
	NO ANSWER	15	22.1	22.1	95.6
	SELDOM	2	2.9	2.9	98.5
	OFTEN	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



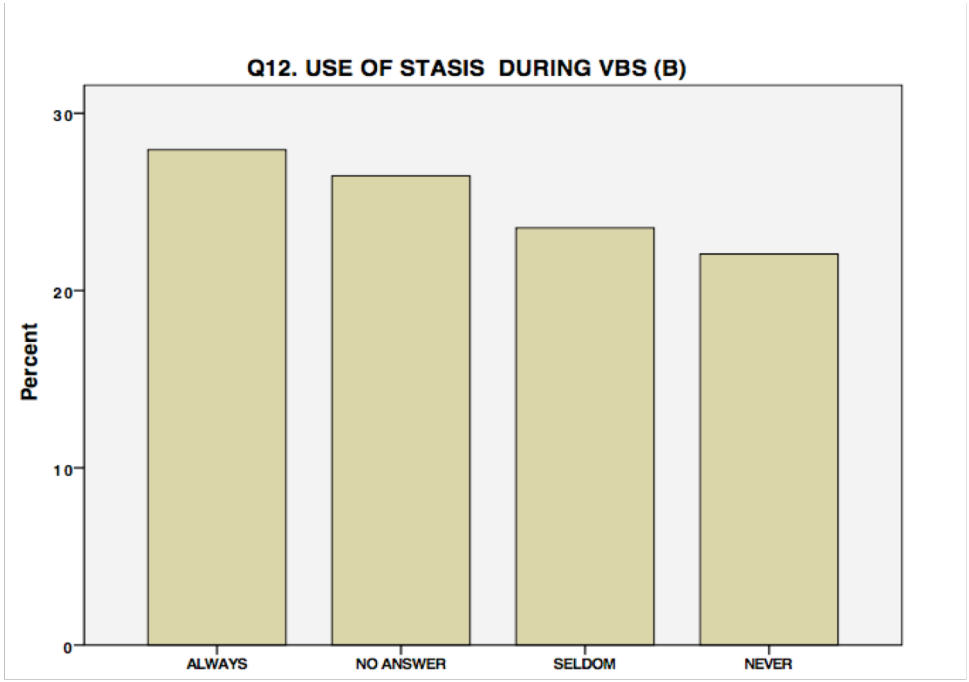
Q11. PATIENT POSTURE PROCEDURE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO TIME CHECK	37	54.4	54.4	54.4
	ZERO TO FIVE MINS	24	35.3	35.3	89.7
	NO ANSWER	4	5.9	5.9	95.6
	SIX TO TEN MINS	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



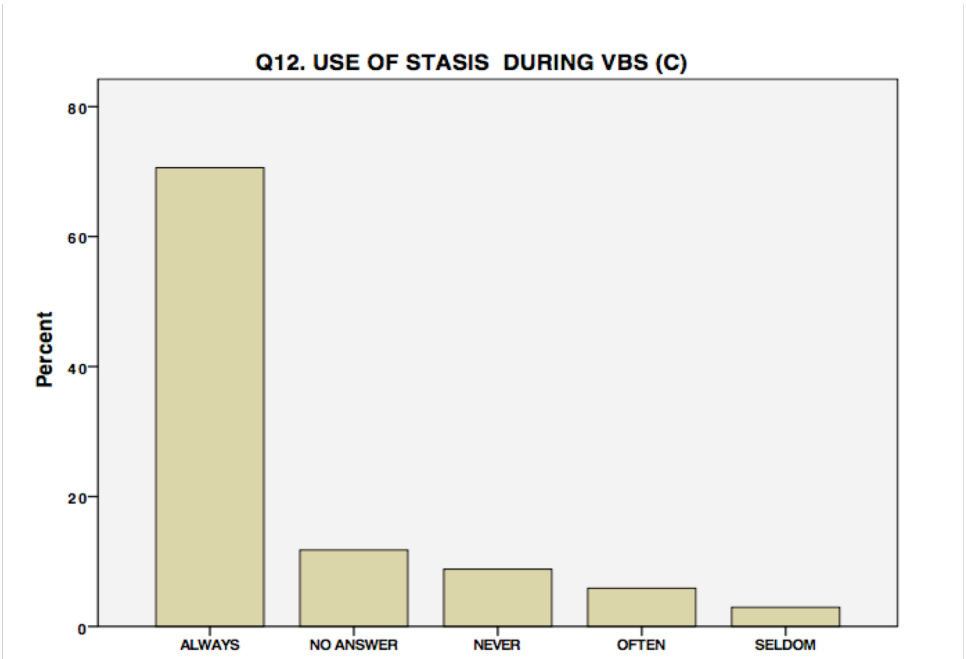
Q12. USE OF STASIS DURING VBS (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	36	52.9	52.9	52.9
	NO ANSWER	23	33.8	33.8	86.8
	SELDOM	7	10.3	10.3	97.1
	ALWAYS	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



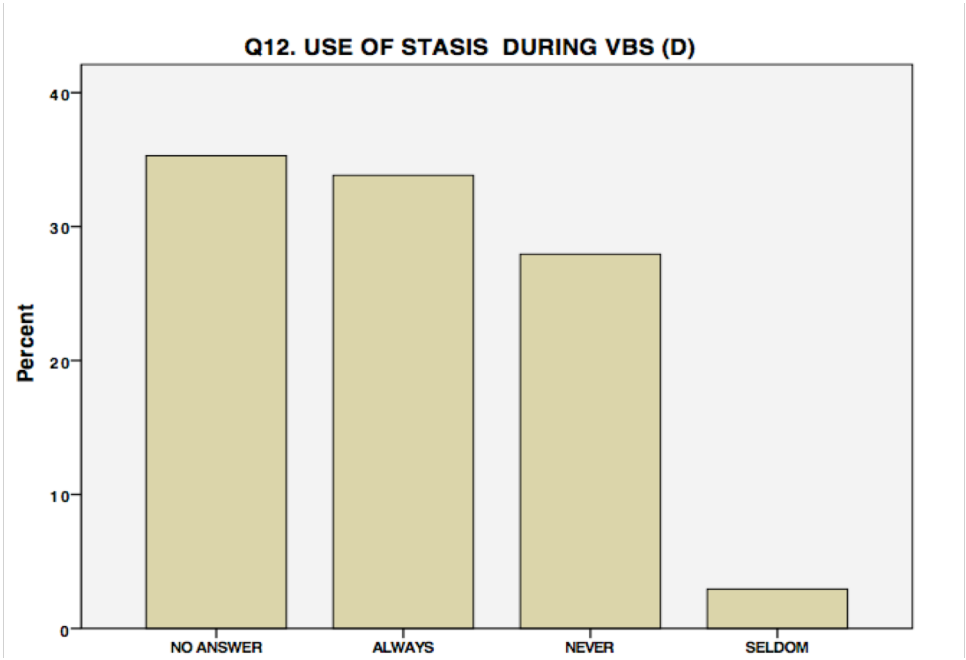
Q12. USE OF STASIS DURING VBS (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	19	27.9	27.9	27.9
	NO ANSWER	18	26.5	26.5	54.4
	SELDOM	16	23.5	23.5	77.9
	NEVER	15	22.1	22.1	100.0
	Total	68	100.0	100.0	



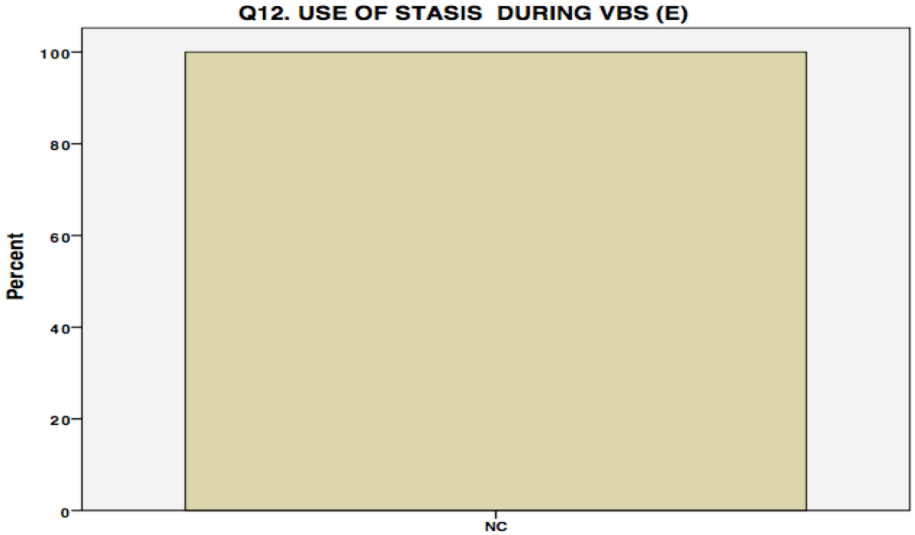
Q12. USE OF STASIS DURING VBS (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	48	70.6	70.6	70.6
	NO ANSWER	8	11.8	11.8	82.4
	NEVER	6	8.8	8.8	91.2
	OFTEN	4	5.9	5.9	97.1
	SELDOM	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



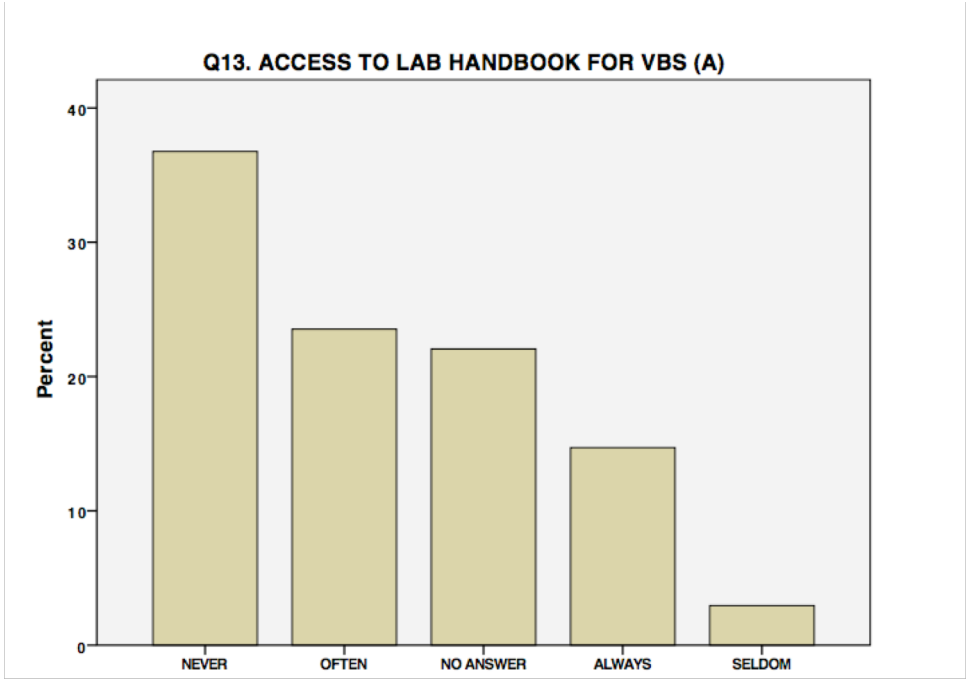
Q12. USE OF STASIS DURING VBS (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	24	35.3	35.3	35.3
	ALWAYS	23	33.8	33.8	69.1
	NEVER	19	27.9	27.9	97.1
	SELDOM	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



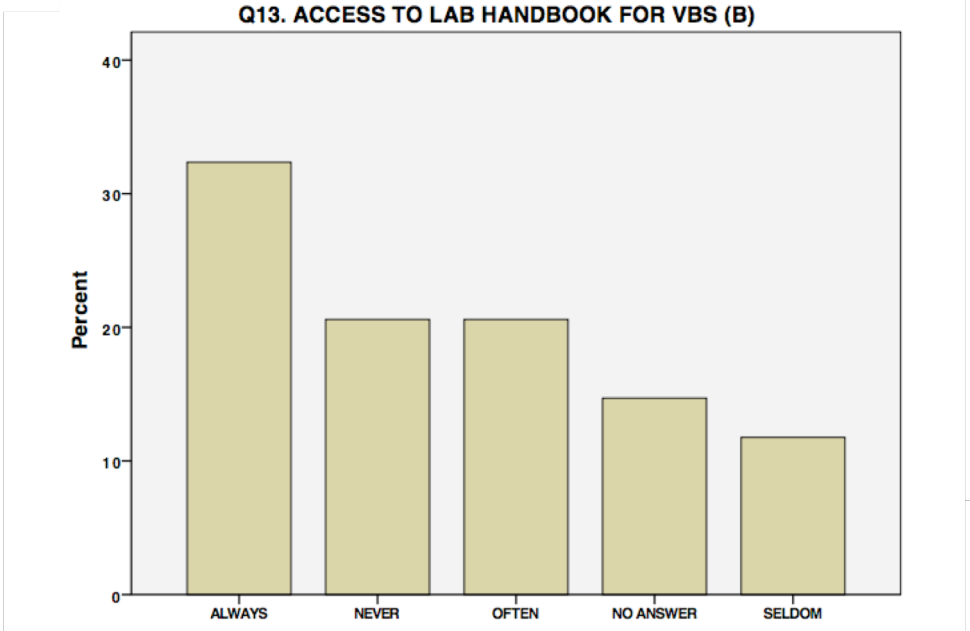
Q12. USE OF STASIS DURING VBS (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NC	68	100.0	100.0	100.0



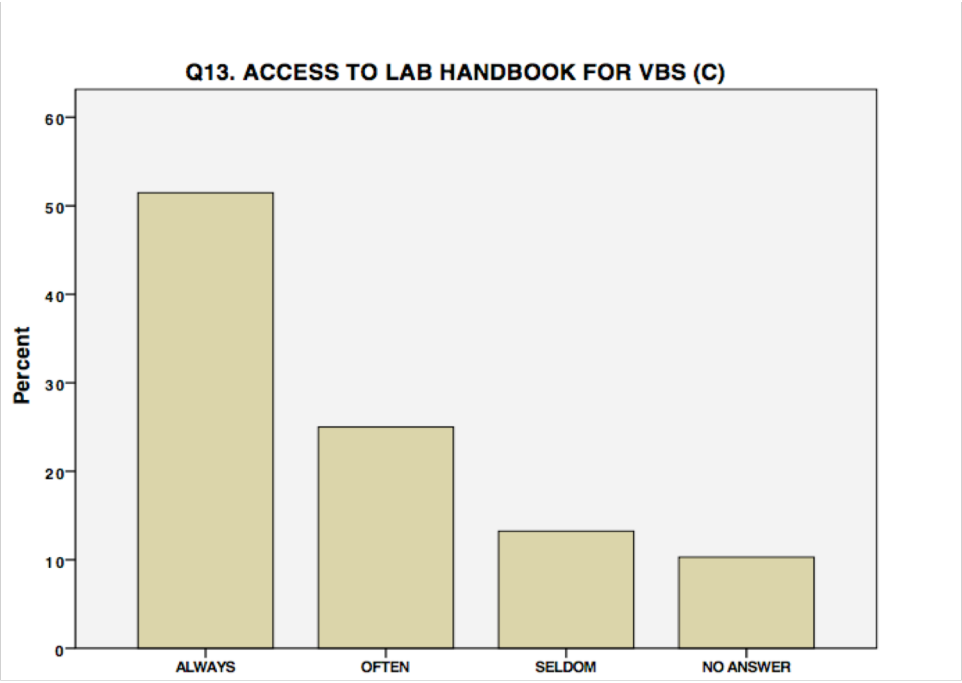
Q13. ACCESS TO LAB HANDBOOK FOR VBS (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	25	36.8	36.8	36.8
	OFTEN	16	23.5	23.5	60.3
	NO ANSWER	15	22.1	22.1	82.4
	ALWAYS	10	14.7	14.7	97.1
	SELDOM	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



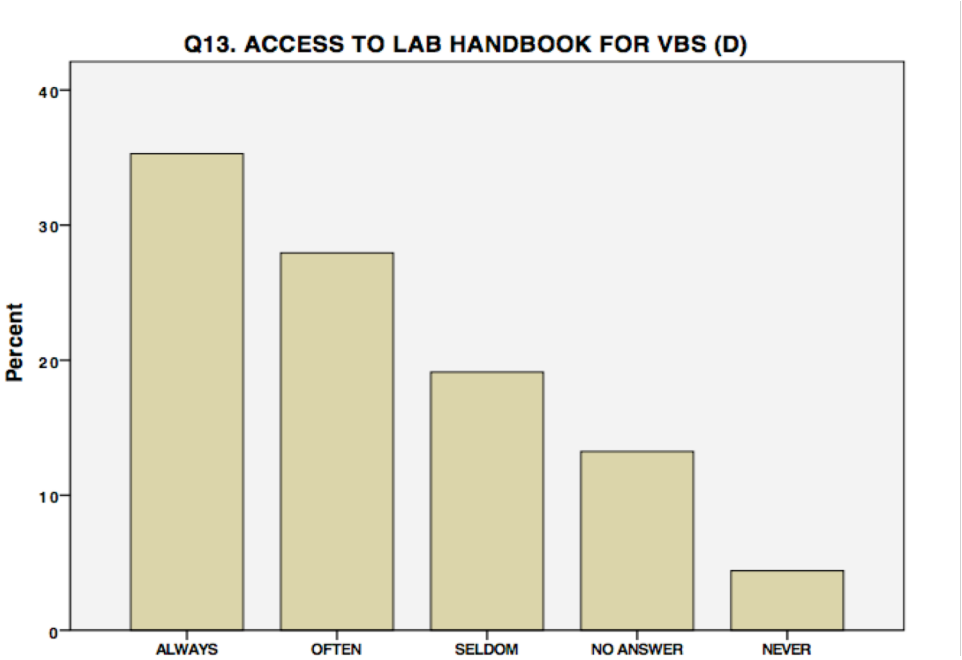
Q13. ACCESS TO LAB HANDBOOK FOR VBS (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	22	32.4	32.4	32.4
	NEVER	14	20.6	20.6	52.9
	OFTEN	14	20.6	20.6	73.5
	NO ANSWER	10	14.7	14.7	88.2
	SELDOM	8	11.8	11.8	100.0
	Total	68	100.0	100.0	



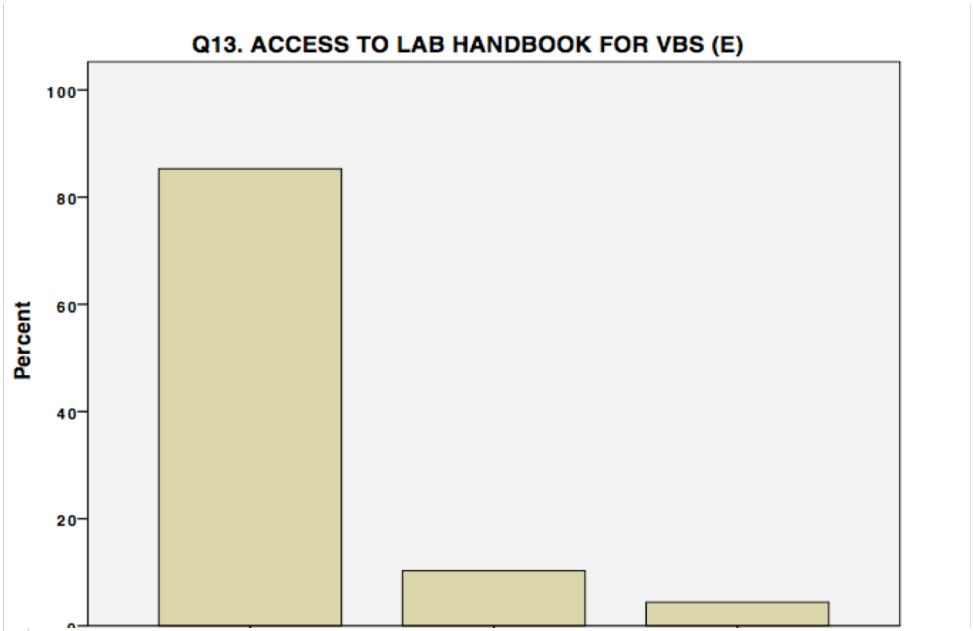
Q13. ACCESS TO LAB HANDBOOK FOR VBS (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	35	51.5	51.5	51.5
	OFTEN	17	25.0	25.0	76.5
	SELDOM	9	13.2	13.2	89.7
	NO ANSWER	7	10.3	10.3	100.0
	Total	68	100.0	100.0	



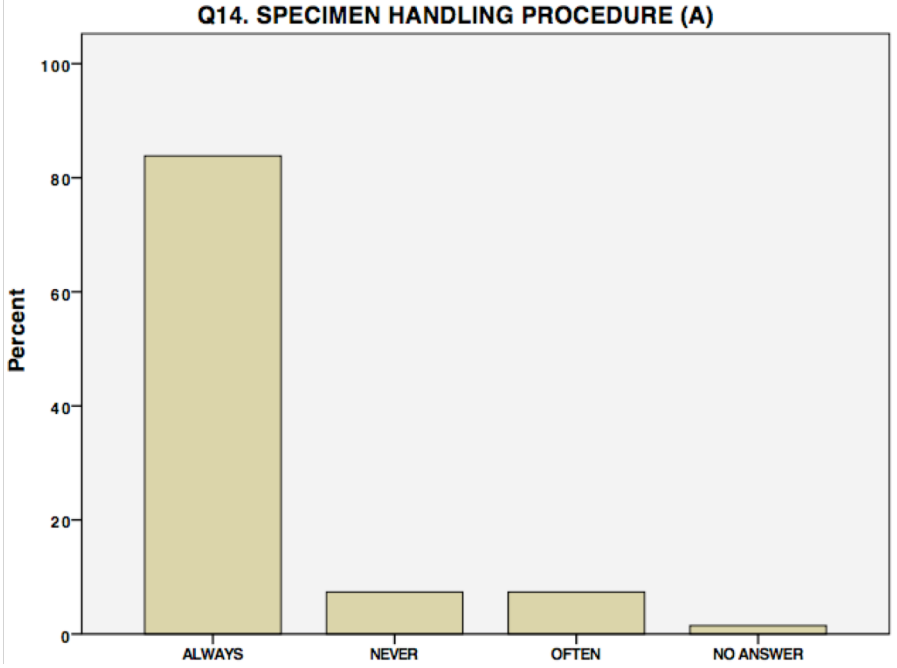
Q13. ACCESS TO LAB HANDBOOK FOR VBS (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	24	35.3	35.3	35.3
	OFTEN	19	27.9	27.9	63.2
	SELDOM	13	19.1	19.1	82.4
	NO ANSWER	9	13.2	13.2	95.6
	NEVER	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



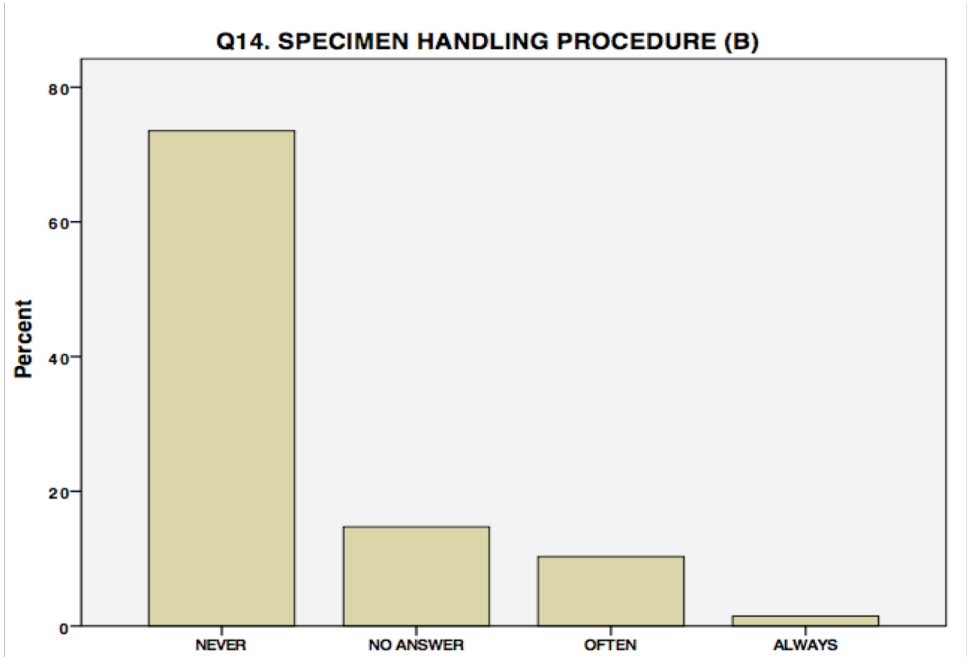
Q13. ACCESS TO LAB HANDBOOK FOR VBS (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	58	85.3	85.3	85.3
	Ask Medics/Phleb Hbook	7	10.3	10.3	95.6
	COMMENT	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



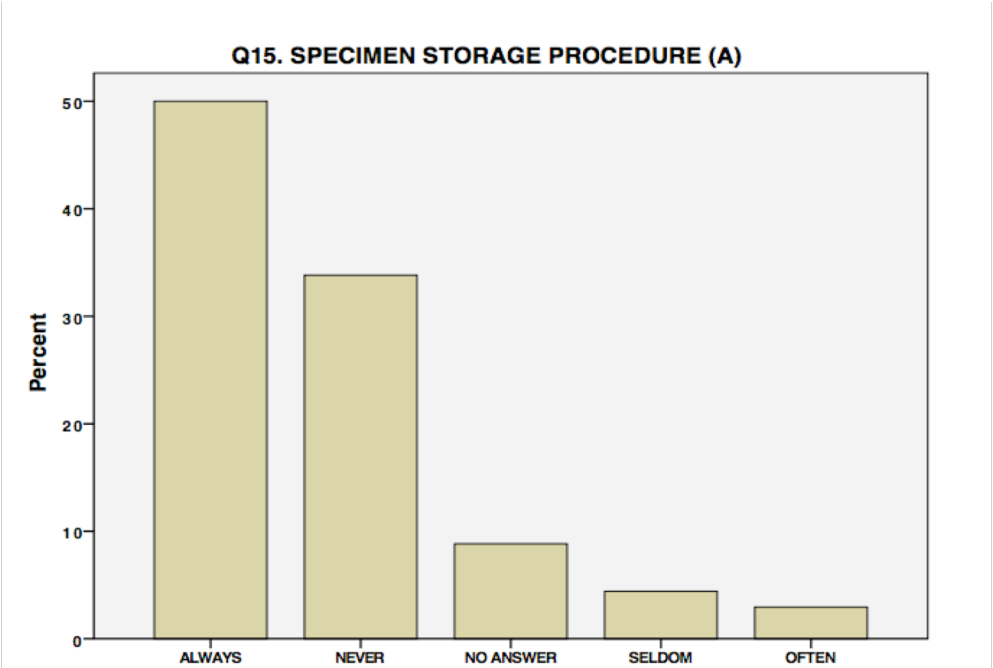
Q14. SPECIMEN HANDLING PROCEDURE (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	57	83.8	83.8	83.8
	NEVER	5	7.4	7.4	91.2
	OFTEN	5	7.4	7.4	98.5
	NO ANSWER	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



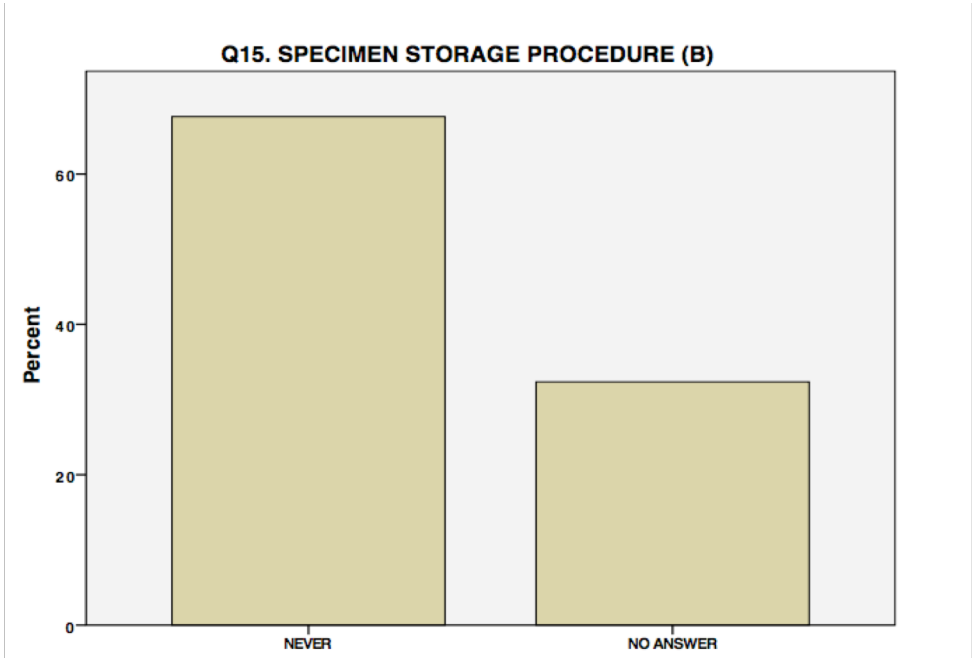
Q14. SPECIMEN HANDLING PROCEDURE (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	50	73.5	73.5	73.5
	NO ANSWER	10	14.7	14.7	88.2
	OFTEN	7	10.3	10.3	98.5
	ALWAYS	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



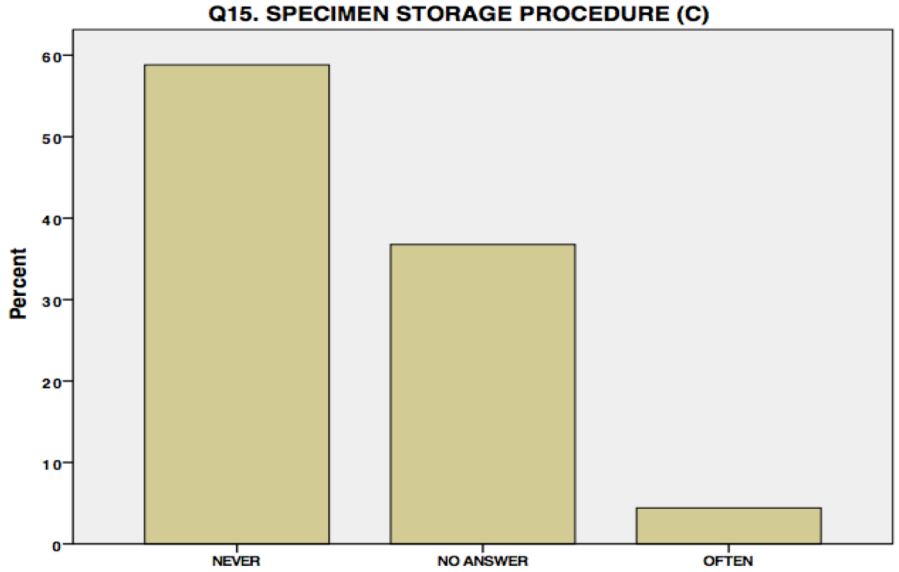
Q15. SPECIMEN STORAGE PROCEDURE (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALWAYS	34	50.0	50.0	50.0
	NEVER	23	33.8	33.8	83.8
	NO ANSWER	6	8.8	8.8	92.6
	SELDOM	3	4.4	4.4	97.1
	OFTEN	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



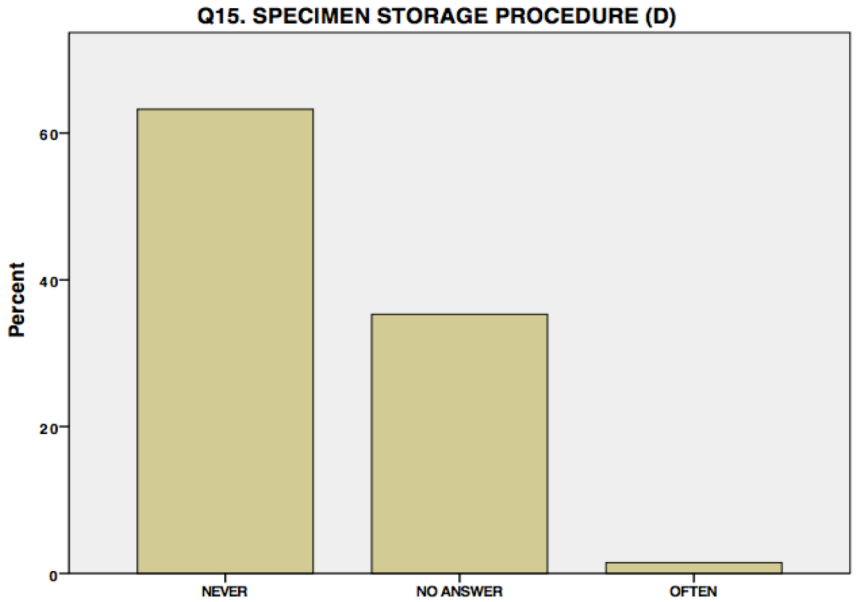
Q15. SPECIMEN STORAGE PROCEDURE (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	46	67.6	67.6	67.6
	NO ANSWER	22	32.4	32.4	100.0
	Total	68	100.0	100.0	



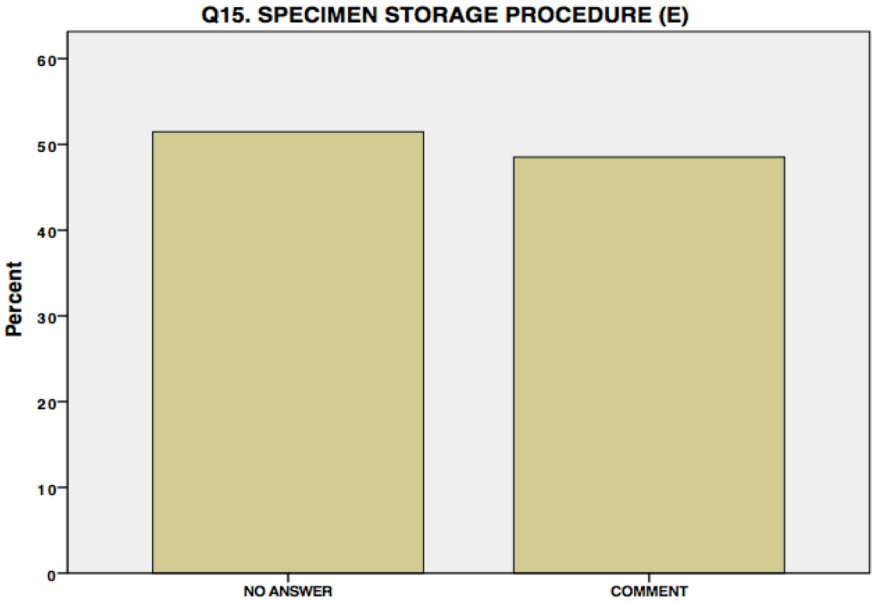
Q15. SPECIMEN STORAGE PROCEDURE (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	40	58.8	58.8	58.8
	NO ANSWER	25	36.8	36.8	95.6
	OFTEN	3	4.4	4.4	100.0
	Total	68	100.0	100.0	



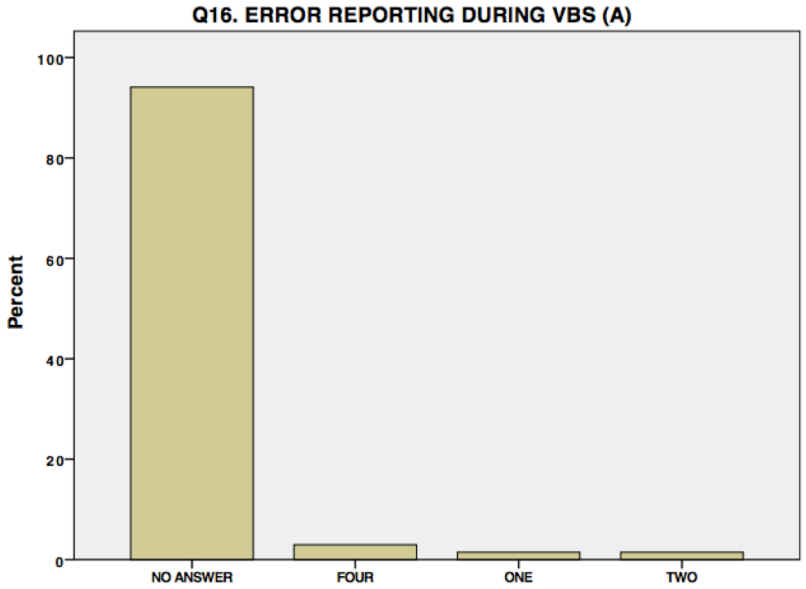
Q15. SPECIMEN STORAGE PROCEDURE (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER	43	63.2	63.2	63.2
	NO ANSWER	24	35.3	35.3	98.5
	OFTEN	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



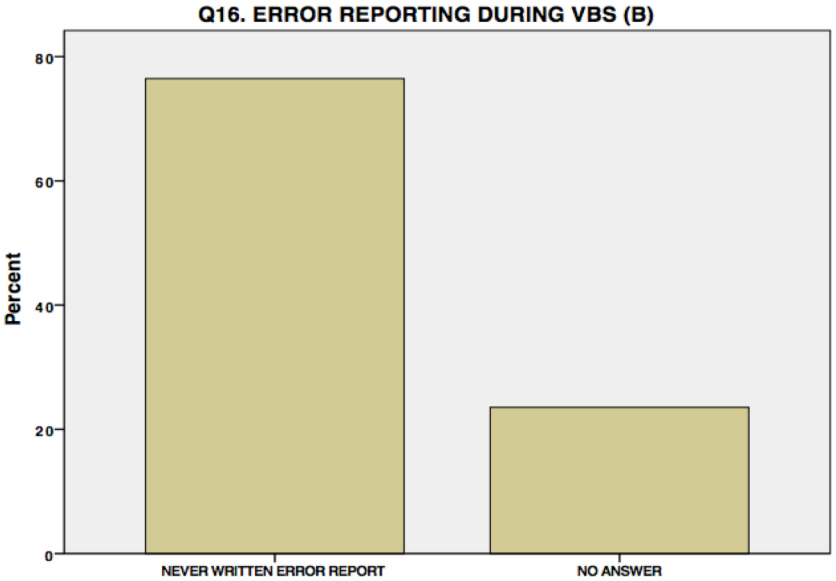
Q15. SPECIMEN STORAGE PROCEDURE (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	35	51.5	51.5	51.5
	COMMENT	33	48.5	48.5	100.0
	Total	68	100.0	100.0	



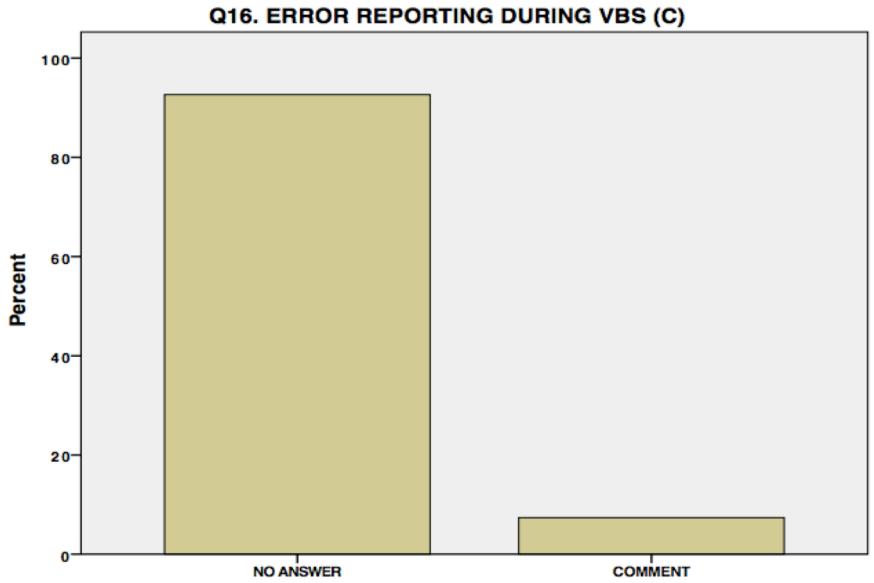
Q16. ERROR REPORTING DURING VBS (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	64	94.1	94.1	94.1
	FOUR	2	2.9	2.9	97.1
	ONE	1	1.5	1.5	98.5
	TWO	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



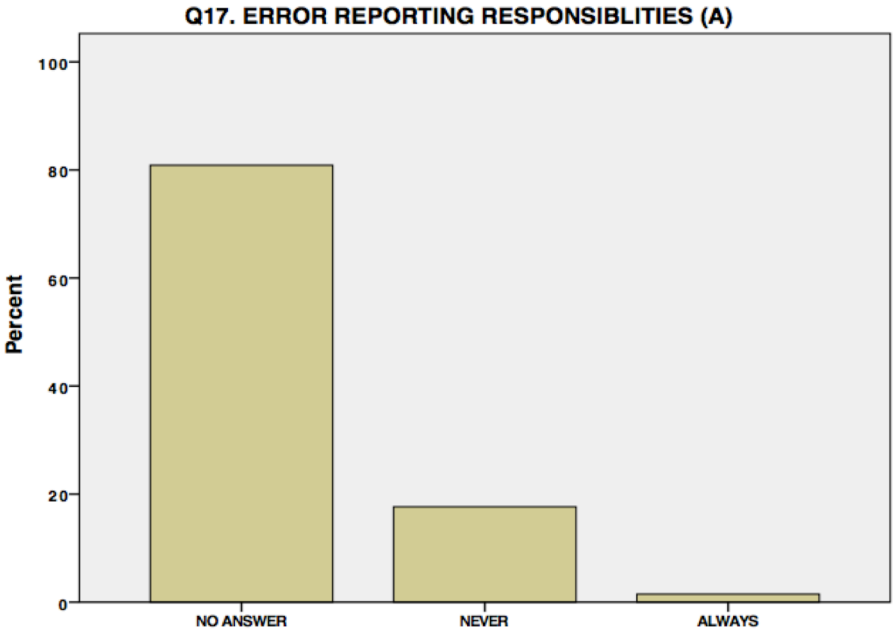
Q16. ERROR REPORTING DURING VBS (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEVER WRITTEN ERROR REPORT	52	76.5	76.5	76.5
	NO ANSWER	16	23.5	23.5	100.0
	Total	68	100.0	100.0	



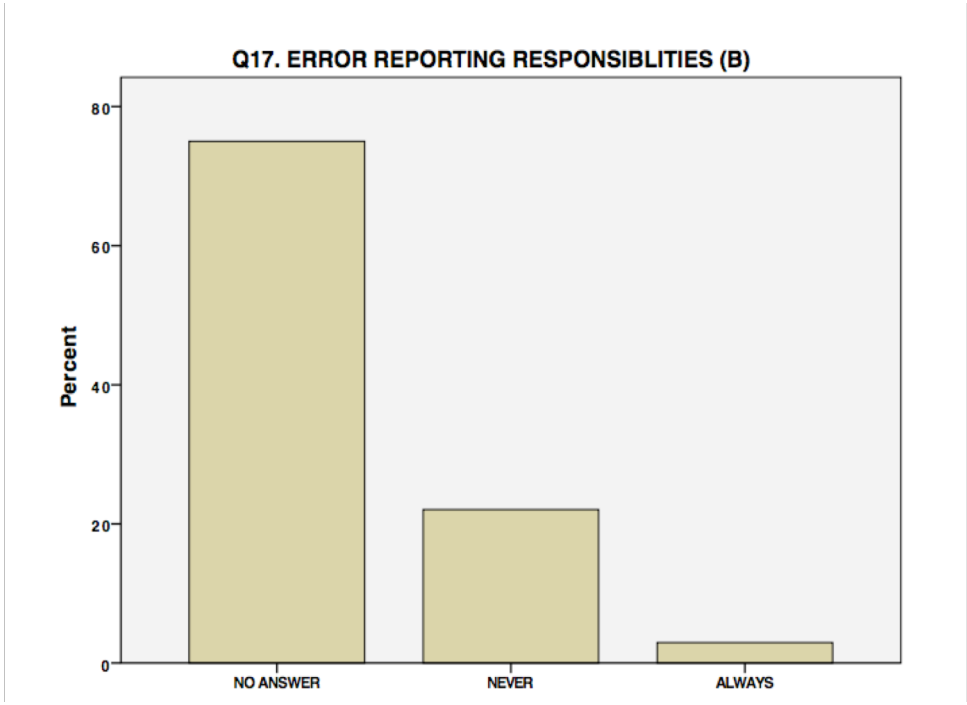
Q16. ERROR REPORTING DURING VBS (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	63	92.6	92.6	92.6
	COMMENT	5	7.4	7.4	100.0
	Total	68	100.0	100.0	



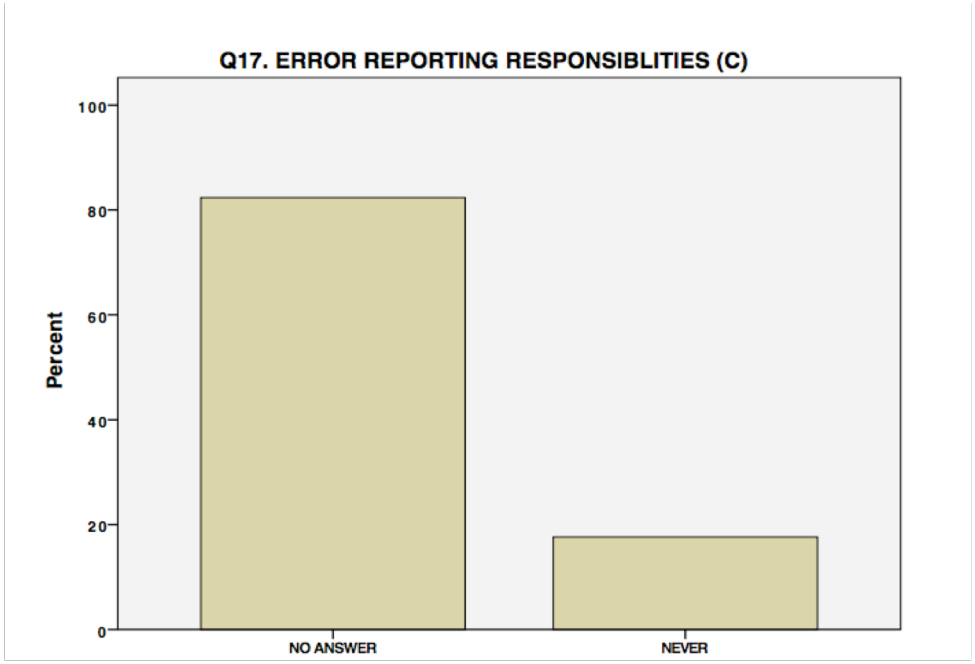
Q17. ERROR REPORTING RESPONSIBLITIES (A)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	55	80.9	80.9	80.9
	NEVER	12	17.6	17.6	98.5
	ALWAYS	1	1.5	1.5	100.0
	Total	68	100.0	100.0	



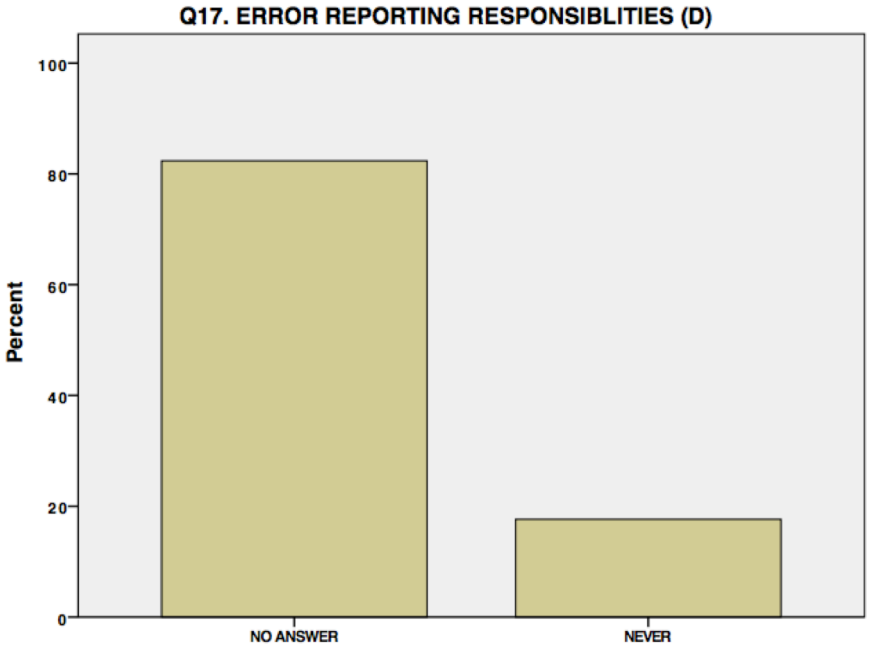
Q17. ERROR REPORTING RESPONSIBLITIES (B)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	51	75.0	75.0	75.0
	NEVER	15	22.1	22.1	97.1
	ALWAYS	2	2.9	2.9	100.0
	Total	68	100.0	100.0	



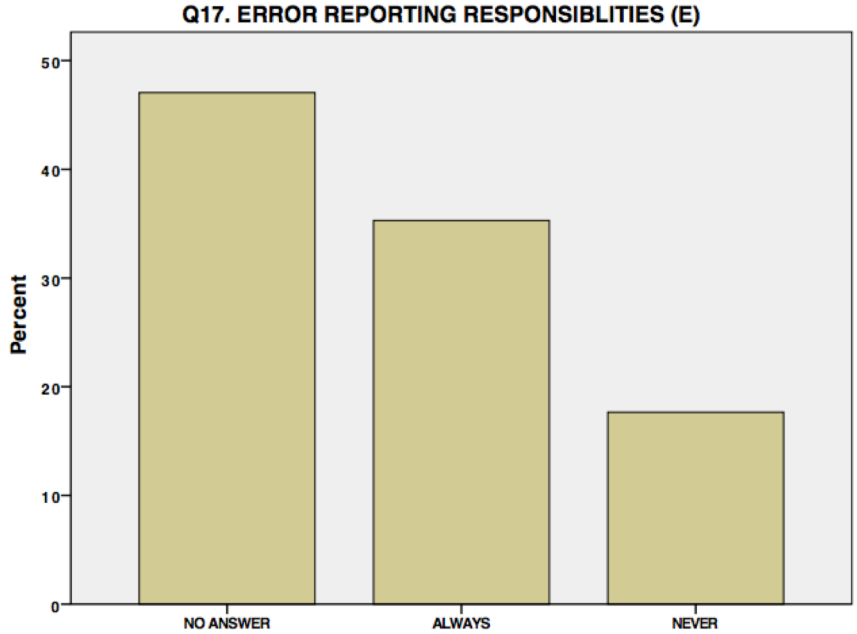
Q17. ERROR REPORTING RESPONSIBLITIES (C)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	56	82.4	82.4	82.4
	NEVER	12	17.6	17.6	100.0
	Total	68	100.0	100.0	



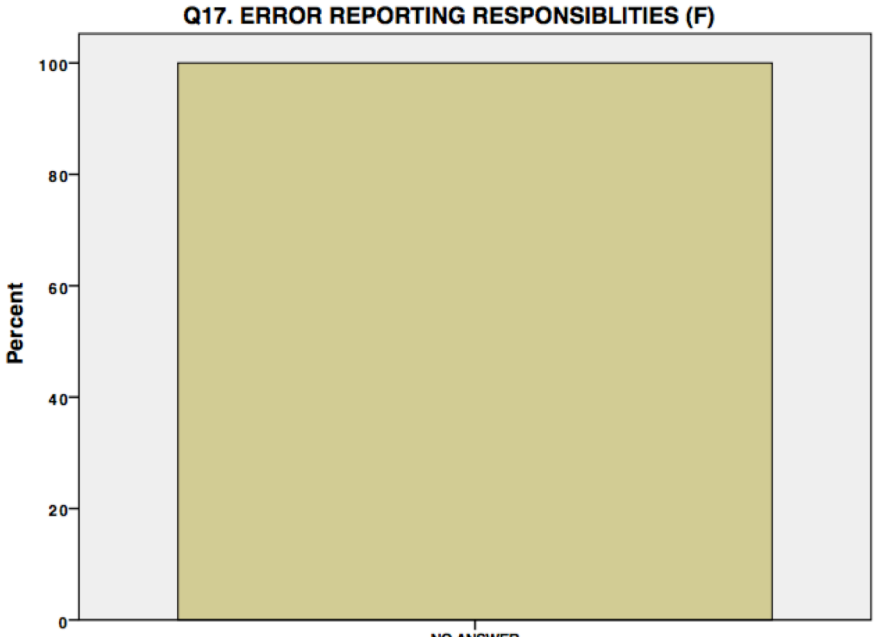
Q17. ERROR REPORTING RESPONSIBLITIES (D)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	56	82.4	82.4	82.4
	NEVER	12	17.6	17.6	100.0
	Total	68	100.0	100.0	



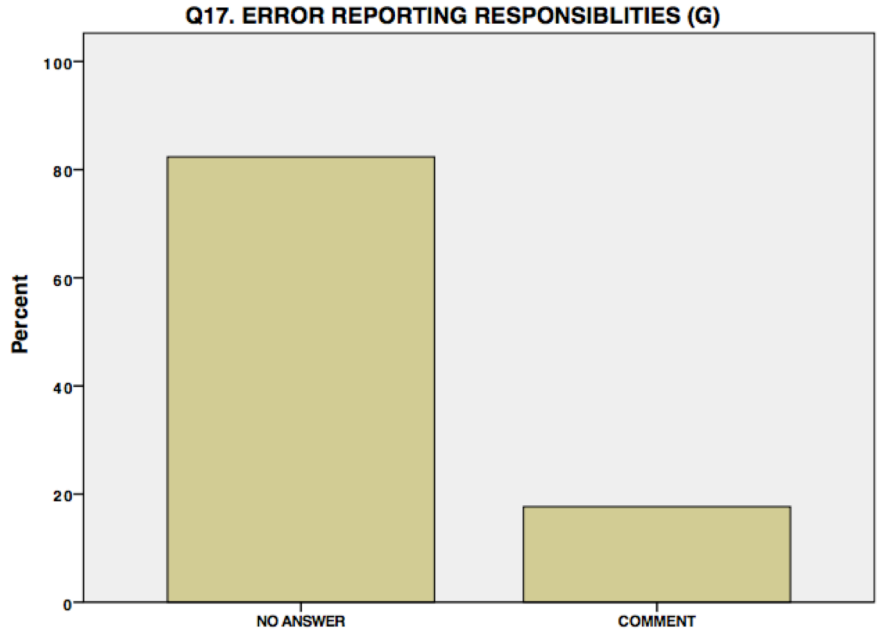
Q17. ERROR REPORTING RESPONSIBLITIES (E)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	32	47.1	47.1	47.1
	ALWAYS	24	35.3	35.3	82.4
	NEVER	12	17.6	17.6	100.0
	Total	68	100.0	100.0	



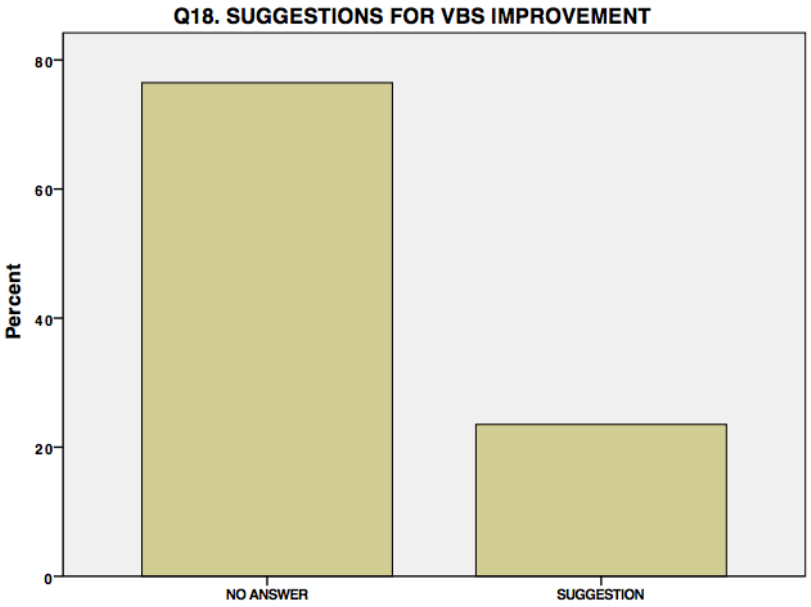
Q17. ERROR REPORTING RESPONSIBLITIES (F)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	68	100.0	100.0	100.0



Q17. ERROR REPORTING RESPONSIBLITIES (G)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	56	82.4	82.4	82.4
	COMMENT	12	17.6	17.6	100.0
	Total	68	100.0	100.0	



Q18. SUGGESTIONS FOR VBS IMPROVEMENT

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NO ANSWER	52	76.5	76.5	76.5
	SUGGESTION	16	23.5	23.5	100.0
	Total	68	100.0	100.0	

APPENDIX VII : CHI- SQUARED STATISTICAL ANALYSIS TO TEST SIGNIFICANCE LIMS STUDY

ERROR TYPE 1: BROKECENTI

TIME	ERROR TYPE BROKECENTI	BROKECENTI		Expected Values		
Post- ICE	1	1615	1616	2.2	1613.8	1616
Pre- ICE	4	2051	2055	2.8	2052.2	2055
TOTAL SAMP ERR	5	3666	3671	5	3666	3671

chi-squared statistic = 1.172327451
p-value = 0.278923528

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 = 0.062%
p3 = 0.195%
s.e.(p1 - p3) = 0.001152404

Confidence 95%
Lower limit -0.000931011
Upper limit 0.003586331

Difference 0.133%

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p = 0.001362027
s.e.(p1 - p3) = 0.001226203 (based on null hypothesis)

Z-statistic = 1.082740713
p-value = 0.139461764 (one-tailed)
0.278923528 (two-tailed)

ERROR TYPE 4: ICEERROR

Chi-squared test for 2x2 table

TIME	ERROR TYPE ICEERROR	ICEERROR		Expected Values		
Post- ICE	11	1605	1616	4.8	1611.2	1616
Pre- ICE	0	2055	2055	6.2	2048.8	2055
TOTAL SAMP ERR	11	3660	3671	11	3660	3671

chi-squared statistic = 14.03028374

p-value = 0.00017989

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.681%	s.e.(p1 - p3) =	0.00204537
p3 =	0.000%		
Confidence	95%	Lower limit	-0.010815782
		Upper limit	-0.00279808
Difference	-0.681%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.002996459		s.e.(p1 - p3) =	0.001817264 (based on null hypothesis)
Z-statistic =	-3.745702036			
p-value =	0.999910055	(one-tailed)		
	1.99982011	(two-tailed)		

ERROR 5: ILLEGIBL

Chi-squared test for 2x2 table

TIME	ERROR TYPE						
	ILLEGIBL	ILLEGIGBL			Expected Values		
Post- ICE	1	1615	1616		1.3	1614.7	1616
Pre- ICE	2	2053	2055		1.7	2053.3	2055
TOTAL SAMP ERR	3	3668	3671		3	3668	3671

chi-squared statistic = 0.139166129

p-value = 0.709111404

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.062%	s.e.(p1 - p3) =	0.000925108
p3 =	0.097%		
Confidence	95%	Lower limit	-0.001458754
		Upper limit	0.002167602
Difference	0.035%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.000817216	s.e.(p1 - p3) =	0.000950072	(based on null hypothesis)
Z-statistic =	0.373049767			
p-value =	0.354555702	(one-tailed)		
	0.709111404	(two-tailed)		

ERROR 6: INCOMPL

Chi-squared test for 2x2 table

TIME	ERROR TYPE				Expected Values		
	INCOMPL	INCOMPL					
Post- ICE	129	1487	1616		138.7	1477.3	1616
Pre- ICE	186	1869	2055		176.3	1878.7	2055
TOTAL SAMP ERR	315	3356	3671		315	3356	3671

chi-squared statistic = 1.316407655

p-value = 0.251237783

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	7.983%	s.e.(p1 - p3) =	0.009247283
p3 =	9.051%		
Confidence	95%	Lower limit	-0.007440125
		Upper limit	0.028808558
Difference	1.068%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.085807682	s.e.(p1 - p3) =	0.009312097	(based on null hypothesis)
Z-statistic =	1.147348097			
p-value =	0.125618892	(one-tailed)		
	0.251237783	(two-tailed)		

ERROR 7: INCORPAT

Chi-squared test for 2x2 table

PERIOD	ERROR TYPE				Expected Values		
	INCORPAT	INCORPAT					
Post- ICE	49	1567	1616		114.9	1501.1	1616
Pre- ICE	212	1843	2055		146.1	1908.9	2055
TOTAL SAMP ERR	261	3410	3671		261	3410	3671

chi-squared statistic = #NUM!

p-value = 1.527E-17

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	3.032%	s.e.(p1 - p3) =	0.007950889
p3 =	10.316%		
Confidence	95%	Lower limit	0.057257779
		Upper limit	0.088424691
Difference	7.284%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.071097794	s.e.(p1 - p3) =	0.008544343	(based on null hypothesis)
Z-statistic =	8.525083473			
p-value =	0	(one-tailed)		
	0	(two-tailed)		

ERROR 8: INCORSAM

Chi-squared test for 2x2 table

TIME	ERROR TYPE				Expected Values		
	INCORSAM	INCORSAM					
Post- ICE	167	1449	1616		148.8	1467.2	1616
Pre- ICE	171	1884	2055		189.2	1865.8	2055
TOTAL SAMP ERR	338	3333	3671		338	3333	3671

chi-squared statistic = 4.384994146

p-value = 0.036256617

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	10.334%	s.e.(p1 - p3) =	0.009719222
p3 =	8.321%		
Confidence	95%	Lower limit	-0.039179231
		Upper limit	-0.00108058
Difference	-2.013%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.092073005	s.e.(p1 - p3) =	0.009612962	(based on null hypothesis)
Z-statistic =	-2.094037761			
p-value =	0.981871692	(one-tailed)		
	1.963743383	(two-tailed)		

ERROR 9: INSUFF

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	INSUFF	INSUFF			Expected Values	
Post- ICE	97	1519	1616		86.3	1529.7	1616
Pre- ICE	99	1956	2055		109.7	1945.3	2055
TOTAL SAMP ERR	196	3475	3671		196	3475	3671

chi-squared statistic = 2.513227876

p-value = 0.11289448

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	6.002%	s.e.(p1 - p3) =	0.00756492
p3 =	4.818%		
Confidence	95%	Lower limit	-0.026676541
		Upper limit	0.002977401
Difference	-1.185%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.053391446	s.e.(p1 - p3) =	0.007474578	(based on null hypothesis)
Z-statistic =	-1.585316333			
p-value =	0.94355276	(one-tailed)		
	1.88710552	(two-tailed)		

ERROR 10: LABERRO

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	LABERRO	LABERROR		Expected Values		
Post- ICE	18	1598	1616	19.4	1596.6	1616
Pre- ICE	26	2029	2055	24.6	2030.4	2055
TOTAL SAMP ERR	44	3627	3671	44	3627	3671

chi-squared statistic = 0.174974974

p-value = 0.675727716

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	1.114%	s.e.(p1 - p3) =	0.003590927
p3 =	1.265%		
Confidence	95%	Lower limit	-0.005524634
		Upper limit	0.008551543
Difference	0.151%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.011985835	s.e.(p1 - p3) =	0.003618106	(based on null hypothesis)
Z-statistic =	0.418300101			
p-value =	0.337863858	(one-tailed)		
	0.675727716	(two-tailed)		

ERROR 11: LEAKTRANS

Chi-squared test for 2x2 table

TIME	ERROR TYPE LEAKTRANS	LEAKTRANS		Expected Values		
Post- ICE	7	1609	1616	18.5	1597.5	1616
Pre- ICE	35	2020	2055	23.5	2031.5	2055
TOTAL SAMP ERR	42	3629	3671	42	3629	3671

chi-squared statistic = 12.9004579

p-value = 0.000328502

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.433%	s.e.(p1 - p3) =	0.003288712
p3 =	1.703%		
Confidence	95%	Lower limit	0.00625419
		Upper limit	0.019145704
Difference	1.270%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.011441024	s.e.(p1 - p3) =	0.003535895	(based on null hypothesis)
Z-statistic =	3.591720744			
p-value =	0.000164251	(one-tailed)		
	0.000328502	(two-tailed)		

ERROR 12: LOST

Chi-squared test for 2x2 table

TIME	ERROR TYPE LOST	LOST		Expected Values		
Post- ICE	9	1607	1616	10.6	1605.4	1616
Pre- ICE	15	2040	2055	13.4	2041.6	2055
TOTAL SAMP ERR	24	3647	3671	24	3647	3671

chi-squared statistic = 0.416835082

p-value = 0.518520517

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.557%	s.e.(p1 - p3) =	0.00263689
p3 =	0.730%		
Confidence	95%	Lower limit	-0.003438246
		Upper limit	0.006898173
Difference	0.173%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.006537728	s.e.(p1 - p3) =	0.002679506	(based on null hypothesis)
Z-statistic =	0.645627665			
p-value =	0.259260258	(one-tailed)		
	0.518520517	(two-tailed)		

ERROR 13: NOEDTA

Chi-squared test for 2x2 table

TIME	ERROR TYPE NOEDTA	NOEDTA		Expected Values		
Post- ICE	159	1457	1616	143.9	1472.1	1616
Pre- ICE	168	1887	2055	183.1	1871.9	2055
TOTAL SAMP ERR	327	3344	3671	327	3344	3671

chi-squared statistic = 3.086681263

p-value = 0.078935649

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	9.839%	s.e.(p1 - p3) =	0.009561623
p3 =	8.175%		
Confidence	95%	Lower limit	-0.035379702
		Upper limit	0.002101173
Difference	-1.664%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.089076546	s.e.(p1 - p3) =	0.009470834	(based on null hypothesis)
Z-statistic =	-1.756895348			
p-value =	0.960532176	(one-tailed)		
	1.921064351	(two-tailed)		

ERROR 14: NOFLOX

Chi-squared test for 2x2 table

TIME	ERROR TYPE NOFLOX	NOFLOX		Expected Values		
Post- ICE	30	1586	1616	51.5	1564.5	1616
Pre- ICE	87	1968	2055	65.5	1989.5	2055
TOTAL SAMP ERR	117	3554	3671	117	3554	3671

chi-squared statistic = 16.56701124

p-value = 4.69608E-05

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	1.856%	s.e.(p1 - p3) =	0.005568101
p3 =	4.234%		
Confidence	95%	Lower limit	0.012858132
		Upper limit	0.034684688
Difference	2.377%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.031871425	s.e.(p1 - p3) =	0.005840269	(based on null hypothesis)
Z-statistic =	4.070259357			
p-value =	2.34804E-05	(one-tailed)		
	4.69608E-05	(two-tailed)		

ERROR 15: NOICE

Chi-squared test for 2x2 table

TIME	ERROR TYPE NOICE	NOICE	
Post- ICE	27	1589	1616
Pre- ICE	17	2038	2055
TOTAL SAMP ERR	44	3627	3671

Expected Values		
19.4	1596.6	1616
24.6	2030.4	2055
44	3627	3671

chi-squared statistic = 5.435634073

p-value = 0.019729926

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	1.671%	s.e.(p1 - p3) =	0.003762787
p3 =	0.827%		
Confidence	95%	Lower limit	-0.015810341
		Upper limit	-0.001060488
Difference	-0.844%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.011985835	s.e.(p1 - p3) =	0.003618106	(based on null hypothesis)
Z-statistic =	-2.331444632			
p-value =	0.990135037	(one-tailed)		
	1.980270074	(two-tailed)		

ERROR 16: NOSAMP

Chi-squared test for 2x2 table

TIME	ERROR TYPE NOSAMP	NOSAMP		Expected Values		
Post- ICE	233	1383	1616	228.9	1387.1	1616
Pre- ICE	287	1768	2055	291.1	1763.9	2055
TOTAL SAMP ERR	520	3151	3671	520	3151	3671

chi-squared statistic = 0.152262442

p-value = 0.696382596

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	14.418%	s.e.(p1 - p3) =	0.011611516
p3 =	13.966%		
Confidence	95%	Lower limit	-0.027281955
		Upper limit	0.018234353
Difference	-0.452%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.141650776	s.e.(p1 - p3) =	0.0115933	(based on null hypothesis)
Z-statistic =	-0.390208203			
p-value =	0.651808702	(one-tailed)		
	1.303617404	(two-tailed)		

ERROR 17: OLDSAMP

Chi-squared test for 2x2 table

TIME	ERROR TYPE						
	OLDSAMP	OLDSAMP			Expected Values		
Post- ICE	36	1580	1616		26.9	1589.1	1616
Pre- ICE	25	2030	2055		34.1	2020.9	2055
TOTAL SAMP ERR	61	3610	3671		61	3610	3671

chi-squared statistic = 5.660509825

p-value = 0.017351079

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	2.228%	s.e.(p1 - p3) =	0.00439616
p3 =	1.217%		
Confidence	95%	Lower limit	-0.018728092
		Upper limit	-0.001495463
Difference	-1.011%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.016616726	s.e.(p1 - p3) =	0.004250106	(based on null hypothesis)
Z-statistic =	-2.379182596			
p-value =	0.991324461	(one-tailed)		
	1.982648921	(two-tailed)		

ERROR 18: SAMCLOT

Chi-squared test for 2x2 table

TIME	ERROR TYPE				Expected Values		
	SAMCLOT	SAMCLOT					
Post- ICE	6	1610	1616		5.3	1610.7	1616
Pre- ICE	6	2049	2055		6.7	2048.3	2055
TOTAL SAMP ERR	12	3659	3671		12	3659	3671

chi-squared statistic = 0.174670309

p-value = 0.675994078

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.371%	s.e.(p1 - p3) =	0.001925012
p3 =	0.292%		
Confidence	95%	Lower limit	-0.004566118
		Upper limit	0.002979792
Difference	-0.079%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.003268864	s.e.(p1 - p3) =	0.001897811	(based on null hypothesis)
Z-statistic =	-0.417935771			
p-value =	0.662002961	(one-tailed)		
	1.324005922	(two-tailed)		

ERROR 19: SAMCONT

Chi-squared test for 2x2 table

TIME	ERROR TYPE SAMCONT	SAMCONT		Expected Values		
Post- ICE	28	1588	1616	22.9	1593.1	1616
Pre- ICE	24	2031	2055	29.1	2025.9	2055
TOTAL SAMP ERR	52	3619	3671	52	3619	3671

chi-squared statistic = 2.066425361

p-value = 0.150574085

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	1.733%	s.e.(p1 - p3) =	0.004019076
p3 =	1.168%		
Confidence	95%	Lower limit	-0.013525144
		Upper limit	0.002229343
Difference	-0.565%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.014165078	s.e.(p1 - p3) =	0.003928956	(based on null hypothesis)
Z-statistic =	-1.437506647			
p-value =	0.924712957	(one-tailed)		
	1.849425915	(two-tailed)		

ERROR 20: SINTEG

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	SINTEG	SINTEG		Expected Values		
Post- ICE	7	1609	1616	4.4	1611.6	1616
Pre- ICE	3	2052	2055	5.6	2049.4	2055
TOTAL SAMP ERR	10	3661	3671	10	3661	3671

chi-squared statistic = 2.746344653

p-value = 0.097477046

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.433%	s.e.(p1 - p3) =	0.001837999
p3 =	0.146%		
Confidence	95%	Lower limit	-0.006474241
		Upper limit	0.000730583
Difference	-0.287%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.002724053	s.e.(p1 - p3) =	0.00173293	(based on null hypothesis)
Z-statistic =	-1.6572099			
p-value =	0.951261477	(one-tailed)		
	1.902522954	(two-tailed)		

ERROR 21: SWAPDET

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	SWAPDET	SWAPDET		Expected Values		
Post- ICE	32	1584	1616	34.8	1581.2	1616
Pre- ICE	47	2008	2055	44.2	2010.8	2055
TOTAL SAMP ERR	79	3592	3671	79	3592	3671

chi-squared statistic = 0.404656585

p-value = 0.524694148

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	1.980%	s.e.(p1 - p3) =	0.004783929
p3 =	2.287%		
Confidence	95%	Lower limit	-0.006307262
		Upper limit	0.012445394
Difference	0.307%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.021520022	s.e.(p1 - p3) =	0.004824618	(based on null hypothesis)
Z-statistic =	0.636126234			
p-value =	0.262347074	(one-tailed)		
	0.524694148	(two-tailed)		

ERROR 22: TESTNAV

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	TESTNAV	TESTNAV		Expected Values		
Post- ICE	31	1585	1616	26.9	1589.1	1616
Pre- ICE	30	2025	2055	34.1	2020.9	2055
TOTAL SAMP ERR	61	3610	3671	61	3610	3671

chi-squared statistic = 1.163613544

p-value = 0.280717382

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	1.918%	s.e.(p1 - p3) =	0.004317784
p3 =	1.460%		
Confidence	95%	Lower limit	-0.013047329
		Upper limit	0.003878073
Difference	-0.458%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.016616726	s.e.(p1 - p3) =	0.004250106	(based on null hypothesis)
Z-statistic =	-1.078709203			
p-value =	0.859641309	(one-tailed)		
	1.719282618	(two-tailed)		

ERROR 23: TIMEDEL

Chi-squared test for 2x2 table

TIME	ERROR TYPE TIMEDEL	TIMEDEL		Expected Values		
Post- ICE	8	1608	1616	3.5	1612.5	1616
Pre- ICE	0	2055	2055	4.5	2050.5	2055
TOTAL SAMP ERR	8	3663	3671	8	3663	3671

chi-squared statistic = 10.19548576

p-value = 0.001407849

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.495%	s.e.(p1 - p3) =	0.001745927
p3 =	0.000%		
Confidence	95%	Lower limit	-0.008372448
		Upper limit	-0.001528542
Difference	-0.495%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.002179243	s.e.(p1 - p3) =	0.001550403	(based on null hypothesis)
Z-statistic =	-3.193037075			
p-value =	0.999296076	(one-tailed)		
	1.998592151	(two-tailed)		

ERROR 24: UNCODED

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	UNCODED	UNCODED		Expected Values		
Post- ICE	63	1553	1616	64.3	1551.7	1616
Pre- ICE	83	1972	2055	81.7	1973.3	2055
TOTAL SAMP ERR	146	3525	3671	146	3525	3671

chi-squared statistic = 0.046703567

p-value = 0.828901941

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	3.899%	s.e.(p1 - p3) =	0.006484159
p3 =	4.039%		
Confidence	95%	Lower limit	-0.011304572
		Upper limit	0.014112864
Difference	0.140%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.03977118	s.e.(p1 - p3) =	0.006497364	(based on null hypothesis)
Z-statistic =	0.216110082			
p-value =	0.414450971	(one-tailed)		
	0.828901941	(two-tailed)		

ERROR 25: UNLABL

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	UNLABL	UNLABL		Expected Values		
Post- ICE	300	1316	1616	320.0	1296.0	1616
Pre- ICE	427	1628	2055	407.0	1648.0	2055
TOTAL SAMP ERR	727	2944	3671	727	2944	3671

chi-squared statistic = 2.792619347

p-value = 0.094699319

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	18.564%	s.e.(p1 - p3) =	0.013177808
p3 =	20.779%		
Confidence	95%	Lower limit	-0.003685706
		Upper limit	0.047970354
Difference	2.214%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.198038682	s.e.(p1 - p3) =	0.013250044	(based on null hypothesis)
Z-statistic =	1.671113206			
p-value =	0.04734966	(one-tailed)		
	0.094699319	(two-tailed)		

ERROR 26: UNREQ

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	UNREQ	UNREQ		Expected Values		
Post- ICE	57	1559	1616	30.8	1585.2	1616
Pre- ICE	13	2042	2055	39.2	2015.8	2055
TOTAL SAMP ERR	70	3601	3671	70	3601	3671

chi-squared statistic = 40.52292805

p-value = 1.94322E-10

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	3.527%	s.e.(p1 - p3) =	0.004910795
p3 =	0.633%		
Confidence	95%	Lower limit	-0.038571225
		Upper limit	-0.019321262
Difference	-2.895%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.019068374	s.e.(p1 - p3) =	0.004547176	(based on null hypothesis)
Z-statistic =	-6.36576217			
p-value =	1	(one-tailed)		
	2	(two-tailed)		

ERROR 27: WRCONT

Chi-squared test for 2x2 table

TIME	ERROR TYPE WRCONT	WRCONT		Expected Values		
Post- ICE	35	1581	1616	19.8	1596.2	1616
Pre- ICE	10	2045	2055	25.2	2029.8	2055
TOTAL SAMP ERR	45	3626	3671	45	3626	3671

chi-squared statistic = 21.067563

p-value = 4.4337E-06

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	2.166%	s.e.(p1 - p3) =	0.003933021
p3 =	0.487%		
Confidence	95%	Lower limit	-0.024500816
		Upper limit	-0.009083656
Difference	-1.679%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.01225824	s.e.(p1 - p3) =	0.003658486	(based on null hypothesis)
Z-statistic =	-4.589941503			
p-value =	0.999997783	(one-tailed)		
	1.999995566	(two-tailed)		

ERROR 28: WRPRES

Chi-squared test for 2x2 table

TIME	ERROR TYPE					
	WRPRES	WRPRES		Expected Values		
Post- ICE	36	1580	1616	22.9	1593.1	1616
Pre- ICE	16	2039	2055	29.1	2025.9	2055
TOTAL SAMP ERR	52	3619	3671	52	3619	3671

chi-squared statistic = 13.60387746

p-value = 0.000225719

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	2.228%	s.e.(p1 - p3) =	0.004151815
p3 =	0.779%		
Confidence	95%	Lower limit	-0.022628747
		Upper limit	-0.006353932
Difference	-1.449%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.014165078	s.e.(p1 - p3) =	0.003928956	(based on null hypothesis)
Z-statistic =	-3.688343458			
p-value =	0.999887141	(one-tailed)		
	1.999774281	(two-tailed)		

ERROR 29: WRTEST

Chi-squared test for 2x2 table

TIME	ERROR TYPE WRTEST	WRTEST			Expected Values		
Post- ICE	0	1616	1616		1.3	1614.7	1616
Pre- ICE	3	2052	2055		1.7	2053.3	2055
TOTAL SAMP ERR	3	3668	3671		3	3668	3671

chi-squared statistic = 2.361053578

p-value = 0.124398148

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.000%	s.e.(p1 - p3) =	0.000842232
p3 =	0.146%		
Confidence	95%	Lower limit	-0.00019089
		Upper limit	0.003110598
Difference	0.146%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.000817216	s.e.(p1 - p3) =	0.000950072	(based on null hypothesis)
Z-statistic =	1.536572022			
p-value =	0.062199074	(one-tailed)		
	0.124398148	(two-tailed)		

ERROR 30: EXAIR

Chi-squared test for 2x2 table

TIME	ERROR TYPE EXAIR	EXAIR		Expected Values		
Post- ICE	0	1616	1616	0.9	1615.1	1616
Pre- ICE	2	2053	2055	1.1	2053.9	2055
TOTAL SAMP ERR	2	3669	3671	2	3669	3671

chi-squared statistic = 1.573606709

p-value = 0.209684004

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.000%	s.e.(p1 - p3) =	0.000687847
p3 =	0.097%		
Confidence	95%	Lower limit	-0.000374919
		Upper limit	0.002321391
Difference	0.097%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.000544811	s.e.(p1 - p3) =	0.000775836	(based on null hypothesis)
Z-statistic =	1.254434817			
p-value =	0.104842002	(one-tailed)		
	0.209684004	(two-tailed)		

ERROR 31: EXMATCH

Chi-squared test for 2x2 table

TIME	ERROR TYPE EXMATCH	EXMATCH		Expected Values		
Post- ICE	0	1616	1616	0.4	1615.6	1616
Pre- ICE	1	2054	2055	0.6	2054.4	2055
TOTAL SAMP ERR	1	3670	3671	1	3670	3671

chi-squared statistic = 0.786588967

p-value = 0.375133544

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.000%	s.e.(p1 - p3) =	0.0004865
p3 =	0.049%		
Confidence	95%	Lower limit	-0.000466904
		Upper limit	0.00144014
Difference	0.049%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.000272405	s.e.(p1 - p3) =	0.000548674	(based on null hypothesis)
Z-statistic =	0.88689851			
p-value =	0.187566772	(one-tailed)		
	0.375133544	(two-tailed)		

ERROR 32: EXTIME

Chi-squared test for 2x2 table

TIME	ERROR TYPE EXTIME	EXTIME		Expected Values		
Post- ICE	0	1616	1616	0.4	1615.6	1616
Pre- ICE	1	2054	2055	0.6	2054.4	2055
TOTAL SAMP ERR	1	3670	3671	1	3670	3671

chi-squared statistic = 0.786588967

p-value = 0.375133544

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.000%	s.e.(p1 - p3) =	0.0004865
p3 =	0.049%		
Confidence	95%	Lower limit	-0.000466904
		Upper limit	0.00144014
Difference	0.049%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.000272405	s.e.(p1 - p3) =	0.000548674	(based on null hypothesis)
Z-statistic =	0.88689851			
p-value =	0.187566772	(one-tailed)		
	0.375133544	(two-tailed)		

ERROR 33: NOPRESV

Chi-squared test for 2x2 table

TIME	ERROR TYPE NOPRESV	NOPRESV		Expected Values		
Post- ICE	0	1616	1616	3.5	1612.5	1616
Pre- ICE	8	2047	2055	4.5	2050.5	2055
TOTAL SAMP ERR	8	3663	3671	8	3663	3671

chi-squared statistic = 6.304737119

p-value = 0.012041577

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.000%	s.e.(p1 - p3) =	0.001373682
p3 =	0.389%		
Confidence	95%	Lower limit	0.001200577
		Upper limit	0.006585311
Difference	0.389%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p =	0.002179243	s.e.(p1 - p3) =	0.001550403	(based on null hypothesis)
Z-statistic =	2.510923559			
p-value =	0.006020788	(one-tailed)		
	0.012041577	(two-tailed)		

Chi-squared test for 2x2 table

TIME	ERROR TYPE UNLABL	UNLABL	
Post- ICE	300	903514	903814
Pre- ICE	427	416276	416703
TOTAL SAMP ERR	727	1319790	1320517

Expected Values		
497.6	903316.4	903814
229.4	416473.6	416703
727	1319790	1320517

chi-squared statistic = #NUM!

p-value = 4.80381E-56

Confidence Interval for Difference P3-P1, based on Normal approximation

p1 =	0.033%	s.e.(p1 - p3) =	5.31385E-05
p3 =	0.102%		
Confidence	95%	Lower limit	0.000588634
		Upper limit	0.000796933
Difference	0.069%		

Z-test for difference P3-P1 (two-sided), based on Normal approximation

p = 0.000550542 s.e.(p1 - p3) = 4.39233E-05 (based on null hypothesis)

APPENDIX VIII

Raw data from Laboratory Information Management System query

IK505555K 10/07/2007 SB	Regret blood sample for U/E and LFT broke in centrifuge
IK657940K 21/11/2007 SB	Regret sample broken in centrifuge. Please repeat for TSH analysis Many apologies
IK728053V 15/02/2008 SB	Regret sample was broken in centrifuge. Unable to analyse for U&E
IK439564S 03/05/2007 SB	regret sample for LFT broken in centrifuge - please repeat
IK067427F 09/04/2007 SB	Sample unsuitable for analysis of U&E and LFT as grossly haemolysed. Ward informed and repea
IK070109Q 21/04/2007 SB	SAMPLE GROSSLY HAEMOLYSED.UNSUITABLE FOR U&E
IK074271V 08/05/2007 SB	SAMPLE GROSSLY HAEMOLYSED- WARD CONTACTED FOR REPEAT SAMPLE AT 15:20
IK079514R 28/05/2007 SB	sample for U/E LFT CRP Calcium Glucose & Amylase grossly haemolysed - please repeat
IK080015M 31/05/2007 SB	sample for U/E & CRP grossly haemolysed - please repeat
IK083090A 14/06/2007 SB	repeat sample requested for U&E and full LFT at 13:55 due to gross haemolysis
IK084086F 19/06/2007 SB	regret sample haemolysed- sho contacted for repeat sample as previous sample had low potassiu
IK100063R 31/08/2007 SB	REGRET UNABLE TO ASSAY FOR HCG. SAMPLE DATED 2.5.07 AND VERY HAEMOLYSED.
IK330641L 21/08/2007 SB	Regret
IK340520R 12/02/2008 SB	Regret
IK340522L 12/02/2008 SB	Regret
IK427158D 03/04/2007 SB	regret as sample grossly haemolysed unsuitable for LFT analysis
IK455244H 23/05/2007 SB	SAMPLE FOR PHC STUDY GROSSLY HAEMOLYSED - PLEASE REPEAT
IK460345B 23/05/2007 SB	Sample grossly haemolysed
IK506859B 10/07/2007 SB	Regret sample very haemolysed. A repeat would be advisable. Oestradiol requested on this sampl
IK534067L 14/08/2007 SB	REGRET SAMPLE GROSSLY HAEMOLYSED- UNABLE TO ANALYSE SAMPLE FOR LFT'S NO
IK583757X 10/10/2007 SB	Sample analysed on 15/10/07 due to labelling error. Sample grossly haemolysed
IK607365M 20/11/2007 SB	Specimen unsuitable for analysis of U&Es
IK607367V 20/11/2007 SB	Specimen unsuitable for analysis of U&Es
IK609320G 24/11/2007 SB	CSF SAMPLE GROSSLY BLOOD STAINED UNSUITABLE FOR GLUCOSE ASSAY
IK619156M 13/01/2008 SB	Regret sample grossly haemolysed- repeat sample requested for UE
IK619598D 15/01/2008 SB	Sample grossly haemolysed unsuitable for analysis Repeat requested
IK621136Y 22/01/2008 SB	REGRET INSUFFICIENT SAMPLE FOR VIT D.PLEASE REPEAT. GROSSLY HAEMOLYSED SAI
IK637655P 27/03/2008 SB	Regret sample unsuitable for analysis as grossly haemolysed- WP contacted for a repeat sample
IK656806K 19/11/2007 SB	regret sample grossly haemolysed- Dr Newell-Price's secretary contacted for a repeat sample 19/
IK693438M 08/01/2008 SB	sample grossly haemolysed- unable to analyse UE and CRP- ward contacted for repeat sample

IK714484Q 30/01/2008 SB	Sample grossly haemolysed -repeat for UE
IK714904T 31/01/2008 SB	Regret sample grossly haemolysed- unable to analyse UE
IK752535L 12/03/2008 SB	Regret sample grossly haemolysed and unsuitable for analysis for LH
IK902072K 14/10/2007 SB	Specimen grossly haemolysed. Repeat sample requested.
IK902181E 14/10/2007 SB	regret sample grossly haemolysed- unable to analyse UE
IK102430Y 10/09/2007 SB	Sample received for Blood Gas analysis. Air had not been expelled from syringe - sample unsuitat
IK629396C 28/02/2008 SB	Air in blood gas sample unsuitable for analysis - Dr informed
IK081975A 07/06/2007 SB	regret samples received for vitamin E and thiamine analysis were not protected from light- please
IK315182A 13/04/2007 SB	Sample for Vitamin A
IK433691A 24/04/2007 SB	Porphyrin screen requested. EDTA blood received
IK436085K 30/04/2007 SB	Sample for Porphrin not kept in dark. Please note there is a protocol for collection of blood
IK466512V 25/05/2007 SB	REGRET SAMPLE FOR VITAMIN A REQUEST NOT PROTECTED FROM LIGHT- PLEASE ARR
IK467225Y 02/06/2007 SB	Urine sample for porphyrin studies not protected from light. Regret unable to analyse. Informed sta
IK658502P 20/11/2007 SB	REGRET SAMPLE RECEIVED FOR VITAMIN C INVESTIGATION WAS UNSUITABLE AS NOT F
IK668093Z 01/12/2007 SB	Regret sample for pyridoxine not protected from light- ward informed that purple top (potassium E
IK738131Z 27/02/2008 SB	Regret sample for Vitamin E analysis received unprotected from light- please send a repeat clotte
IK509646N 12/07/2007 SB	REGRET UNABLE TO ANALYSE FOR PORPHOBILINOGEN AS THE SAMPLE HAD NOT BEEN
IK529845A 08/08/2007 SB	regret sample received for vitamin E analysis was not protected from light- please send a repeat s
IK529928C 09/08/2007 SB	Unable to analyse for Vit A and E as sample was not protected from the light.
IK534783F 15/08/2007 SB	Regret sample received for vitamin E analysis was not protected from light- please send a repeat
IK544364Z 29/08/2007 SB	Vitamin E analysis not possible as the sample sent was not protected from the light
IK546986S 30/08/2007 SB	Thiamine analysis not possible as the sample was not sent protected from the light
IK556997F 12/09/2007 SB	Urine and faeces for porphyrin analysis unsuitable as samples were not protected from light.
IK612127P 08/12/2007 SB	Unable to carry out bloog gas analysis as the sample was left in the hatch in specimen reception v
IK884900N 19/11/2007 SB	Regret
IK885318P 27/11/2007 SB	Regret
IK071509W 27/04/2007 SB	Insufficient patient details on request form. Cannot analyse for U+Es
IK073488D 04/05/2007 SB	Regret
IK073512R 04/05/2007 SB	Regret
IK074505J 09/05/2007 SB	sample for TSH inadequately labelled - please repeat

IK075137X 12/05/2007 SB	Regret
IK079015T 26/05/2007 SB	Regret
IK080685W 03/06/2007 SB	Regret
IK080692N 03/06/2007 SB	Regret
IK082608R 12/06/2007 SB	Specimen and form received with patient name only. No other patient details given
IK086003N 29/06/2007 SB	regret unable to analyse sample left for blood gas analysis in clin. chem. tray as unaware to how l
IK090110J 15/07/2007 SB	Regret
IK090783T 19/07/2007 SB	REGRET INSUFFICIENT LABELLING ON SAMPLE- WARD CONTACTED AT 10:40 FOR REPEA
IK091712T 23/07/2007 SB	Regret
IK092966Y 29/07/2007 SB	Sample and form received without DOB - does not meet Directorate sample labelling acceptance
IK093408A 31/07/2007 SB	ONLY SURNAME WRITTEN ON SAMPLE BOTTLE. WARD INFORMED.
IK093624X 01/08/2007 SB	Regret
IK095126L 08/08/2007 SB	Insufficient patient details on sample. Unable to process for U+Es and LFTs. Please send repeat.
IK096411L 14/08/2007 SB	Insufficient patient details on sample. Unable to process for U+Es
IK099946G 29/08/2007 SB	UNABLE TO PROCESS SAMPLE FOR UE LFT CRP AND AMYLASE AS THERE WAS NO REGI
IK101638G 05/09/2007 SB	Regret
IK103510J 14/09/2007 SB	Insufficient patient details on both form and sample. Unable to process for CSF protein and glucos
IK106201A 25/09/2007 SB	Regret
IK106211W 25/09/2007 SB	Regret
IK106814E 28/09/2007 SB	No Hospital number on sample - fails sample acceptance criteria. Sample rejected
IK106978X 29/09/2007 SB	No DOB on sample - fails sample acceptance criteria. Sample rejected for U&E LFT and CK analy
IK316641M 16/04/2007 SB	Regret unable to analyse due to insufficient patient identifiers on sample (Name only).
IK320929W 20/04/2007 SB	Samples for U+E
IK372056S 08/07/2007 SB	Regret
IK373317T 26/07/2007 SB	SAMPLE FOR DRUGS OF ABUSE SCREENING NOT PROCESSED NO IDENTIFICATION OTHE
IK373635X 01/08/2007 SB	URINE SAMPLE for DRUGS of ABUSE SCREEN - Sample rejected - failed acceptance criteria.
IK373694Y 02/08/2007 SB	Regret
IK373695W 02/08/2007 SB	Regret
IK373768C 03/08/2007 SB	Regret
IK374047A 08/08/2007 SB	Unable to process drug screen. No patient details given apart from surname and forename.

IK375602Z 31/08/2007 SB	URINE SAMPLE for DRUGS of ABUSE SCREEN - Specimen rejected. Failed to meet minimum id
IK426833Z 02/04/2007 SB	Sample failed acceptance criteria
IK436363A 30/04/2007 SB	Regret unable to analyse this sample as it had insufficient patient identifiers (no DOB)
IK437045K 01/05/2007 SB	REGRET CANNOT ASSAY FOR LFTS AS SAMPLE RECEIVED WITH INSUFFICIENT IDENTIFI
IK438278Z 02/05/2007 SB	Insufficient patient details on form and sample. Cannot process for U+Es and LFTs. Please send
IK446127C 11/05/2007 SB	REGRET CANNOT ASSAY FOR U&E
IK446128T 11/05/2007 SB	SAMPLE LABELLED "HELEN" OLDFIELD.THEREFORE UNABLE TO ASSAY FOR FASTING LI
IK465990K 01/06/2007 SB	Specimen received with only two patient identifiers. At least THREE patient identifiers are requirec
IK466929Y 01/06/2007 SB	Specimen received with insufficient patient identifiers. Please note that we require at least THREE
IK467495H 04/06/2007 SB	samples for glucose U/E LFT TSH & Lipids insufficiently labelled - please repeat
IK474788P 15/06/2007 SB	Sample only labelled with pateint SURNAME - insufficeint patient details to process glucose samp
IK477664T 14/06/2007 SB	Regret stool sample for pancreatic elastase labelled with insufficient patient details. Please repeat
IK479233L 21/06/2007 SB	Regret sample for blood glucose incorrectly labelled- first name Suzanne on sample bottle.Please
IK492341S 22/06/2007 SB	Regret unable to analyse as incomplete demographics on sample
IK497467Q 28/06/2007 SB	REGRET UNABLE TO ANALYSE FOR FAECAL PANCREATIC ELASTASE AS THE SAMPLE WA
IK498147H 29/06/2007 SB	Regret
IK498153S 29/06/2007 SB	regret details on sample were not legible- please send a repeat random urine sample (in plain cor
IK502288Q 05/07/2007 SB	ANALYSIS REQUESTED: UE FIRST NAME MISSING FROM SAMPLE.
IK509352C 13/07/2007 SB	Regret unable to analyse this sample for U+E as it failed the Departments minimum acceptance c
IK515598D 20/07/2007 SB	Unable to analyse for U+E
IK515623Z 20/07/2007 SB	PROTEIN/CREATININE RATIO INSUFFICIENT DETAILS ON PATIENT SAMPLE PLEASE REPE/
IK529893D 08/08/2007 SB	Incomplete demographics on sample unable to analyse
IK530184H 09/08/2007 SB	UNABLE TO ANALYSE FOR UE
IK531916G 11/08/2007 SB	REGRET CANNOT ASSAY FOR U&E
IK570453Y 28/09/2007 SB	No surname on sample - fails sample acceptance criteria. Sample rejected.
IK594293K 23/10/2007 SB	regret unable to analyse for CRP as date of birth was omitted from blood sample- ward informed
IK601325C 21/10/2007 SB	WRONG FORENAME ON SAMPLE. UNABLE TO ANALYSE FOR ITU PROFILE. PLEASE REPE
IK604541E 06/11/2007 SB	unable to process sample as there was no first name on form and the wrong date of birth.
IK604715G 06/11/2007 SB	REGRET BLOOD SAMPLE FOR U/E
IK605232J 09/11/2007 SB	SAMPLE REJECTED BECAUSE THERE WAS NO REG NUMBER OR DOB ON SAMPLE. ALSC

APPENDIX IX

LABORATORY INCIDENT / ACCIDENT / UNTOWARD OCCURRENCE INVESTIGATION

Date of Incident		**NGH – RHH (Delete as required)**
Date of Investigation	**Time**	**Sample ID**
Patient / Employee/Other Details (Where relevant)		**Patient No.**
Name		**Inpatient / Out patient (Delete as required)**
Address		**DOB** **Job Title (Staff only)**
Nature of the incident / how was the incident discovered		
Clinical impact on patient yes / no **If yes specify**		
Procedural Change (Y/N)	**Actioned By**	**Date**
Outcome for patient /Comments/Preventative action		
Reported by		**Signed off by**

1 YEARS IN EMPLOYMENT rwn	2 YEARS IN TRAINNING	3 FREQ OF VENEPUCTURE	4A DOCUMENTED ROUTINES
1	1	EVERY WEEK	DON'T KNOW
1	1	EVERY WORKDAY	YES
1	1	EVERY WEEK	YES
1	1	EVERY WORKDAY	YES
1	1	EVERY WEEK	YES
1	1	EVERY WORKDAY	YES
3	1	EVERY MONTH	DON'T KNOW
3	3	EVERY WORKDAY	YES
3	2	EVERY WEEK	YES
3	1	EVERY WEEK	DON'T KNOW
4	3	EVERY WORKDAY	YES
4	1	EVERY WORKDAY	YES
4	1	EVERY WEEK	YES
4	3	EVERY WORKDAY	YES
4	2	EVERY WORKDAY	YES
4	1	EVERY WEEK	YES
5	1	EVERY WORKDAY	YES
5	5	EVERY MONTH	DON'T KNOW
5	3	EVERY WORKDAY	YES
5	1	EVERY WEEK	YES
5	3	EVERY WORKDAY	YES
5	4	EVERY WEEK	YES
5	4	EVERY MONTH	YES
5	1	EVERY WEEK	YES
5	1	EVERY WORKDAY	YES
6	1	EVERY WEEK	YES
6	3	EVERY WEEK	DON'T KNOW
6	1	EVERY WEEK	YES
7	NA	EVERY WORKDAY	YES

4B UNDOCUMENTED ROUTINES	5A FURTHER TRAINING	5B INFORM ON SAMP TECH	PATIENT ID 6A	PATIENT ID 6B	PATIENT ID 6C
YES	YES	YES	ALWAYS	OFTEN	NEVER
YES	YES	DON'T KNOW	ALWAYS	NEVER	ALWAYS
YES	YES	YES	ALWAYS	OFTEN	NEVER
YES	YES	YES	ALWAYS	NEVER	ALWAYS
YES	YES	YES	ALWAYS	NEVER	NEVER
NO	NO	YES	ALWAYS	NEVER	SELDOM
YES	DON’T KNOW	DON'T KNOW	ALWAYS	NEVER	NEVER
YES	DON’T KNOW	YES	ALWAYS	NEVER	SELDOM
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	YES	YES	ALWAYS	OFTEN	NEVER
DON'T KNOW	NO	DON'T KNOW	ALWAYS	NEVER	ALWAYS
NO	NO	YES	ALWAYS	NEVER	SELDOM
YES	YES	YES	ALWAYS	NEVER	ALWAYS
DON'T KNOW	NO	DON'T KNOW	ALWAYS	NEVER	ALWAYS
NO	NO	YES	ALWAYS	NEVER	SELDOM
YES	YES	YES	ALWAYS	NEVER	ALWAYS
YES	NO	YES	ALWAYS	NEVER	SELDOM
YES	DON’T KNOW	YES	ALWAYS	NEVER	NEVER
YES	DON’T KNOW	YES	ALWAYS	NEVER	SELDOM
YES	YES	YES	OFTEN	NEVER	NEVER
DON'T KNOW	NO	YES	ALWAYS	NEVER	ALWAYS
YES	YES	YES	OFTEN	NEVER	ALWAYS
YES	YES	NOT ANSWERED	ALWAYS	NEVER	NEVER
YES	YES	YES	OFTEN	NEVER	ALWAYS
YES	NO	YES	ALWAYS	NEVER	SELDOM
YES	YES	YES	OFTEN	NEVER	NEVER
YES	YES	YES	ALWAYS	NEVER	NEVER
YES	YES	YES	OFTEN	NEVER	NEVER
YES	NO	NO	ALWAYS	NEVER	NEVER

YES	NO	DON'T KNOW	ALWAYS	NEVER	NO ANSWER
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	D	DON'T KNOW	ALWAYS	NEVER	ALWAYS
YES	YES	YES	OFTEN	OFTEN	NEVER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	NO	DON'T KNOW	ALWAYS	NEVER	ALWAYS
YES	DON’T KNOW	YES	ALWAYS	NEVER	NEVER
YES	YES	YES	SELDOM	NEVER	NEVER
YES	DON’T KNOW	DON'T KNOW	ALWAYS	NEVER	ALWAYS
YES	YES	DON'T KNOW	ALWAYS	NEVER	ALWAYS
YES	NO	NO	ALWAYS	NO ANSWER	NO ANSWER
YES	DON’T KNOW	YES	ALWAYS	NEVER	NEVER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	NO	NO	ALWAYS	NO ANSWER	NO ANSWER
YES	NO	NO	ALWAYS	NO ANSWER	NO ANSWER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	YES	YES	OFTEN	OFTEN	NEVER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	NO	NO	ALWAYS	NO ANSWER	NO ANSWER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	YES	YES	ALWAYS	NO ANSWER	SELDOM
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	NO	NOT ANSWERED	ALWAYS	NEVER	NEVER
YES	YES	YES	ALWAYS	NEVER	ALWAYS
YES	YES	YES	ALWAYS	NEVER	ALWAYS
YES	YES	YES	ALWAYS	NEVER	SELDOM
YES	DON’T KNOW	YES	ALWAYS	NEVER	NEVER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER

YES	YES	YES	ALWAYS	NEVER	ALWAYS
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	YES	YES	ALWAYS	NEVER	ALWAYS
YES	NO	NO	ALWAYS	NEVER	NEVER
YES	YES	NO	ALWAYS	NEVER	NEVER
YES	YES	YES	ALWAYS	NEVER	NO ANSWER
YES	YES	NO	ALWAYS	NEVER	NEVER
YES	NO	NO	ALWAYS	NO ANSWER	NO ANSWER

PATIENT ID 6D	PATIENT ID 6E	PATIENT ID 6F	PATIENT ID 7A	PATIENT ID 7B	PATIENT ID 7C	PATIENT ID 7D	PATIENT ID 7E
NEVER	NEVER	NO COMMENT	OFTEN	OFTEN	OFTEN	SELDOM	ALWAYS
ALWAYS	NEVER	NO COMMENT	ALWAYS	NEVER	ALWAYS	ALWAYS	ALWAYS
NEVER	NEVER	NO COMMENT	OFTEN	OFTEN	OFTEN	SELDOM	ALWAYS
ALWAYS	NEVER	NO COMMENT	ALWAYS	NEVER	ALWAYS	ALWAYS	ALWAYS
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	NEVER	NEVER
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	SELDOM	ALWAYS
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	OFTEN	NEVER	ALWAYS
SELDOM	NEVER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	ALWAYS	ALWAYS
OFTEN	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	ALWAYS	ALWAYS
NEVER	NEVER	NO COMMENT	OFTEN	OFTEN	OFTEN	SELDOM	ALWAYS
NEVER	NEVER	NO COMMENT	ALWAYS	NEVER	NEVER	NEVER	NEVER
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	SELDOM	ALWAYS
NEVER	OFTEN	NO COMMENT	ALWAYS	NEVER	ALWAYS	NEVER	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	NEVER	NEVER	NEVER	NEVER
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	SELDOM	ALWAYS
NEVER	OFTEN	NO COMMENT	ALWAYS	NEVER	ALWAYS	NEVER	NEVER
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	SELDOM	ALWAYS
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	OFTEN	NEVER	ALWAYS
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	SELDOM	OFTEN
NEVER	OFTEN	NO COMMENT	ALWAYS	SELDOM	SELDOM	ALWAYS	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	NEVER	NEVER	NEVER	NEVER
NEVER	NEVER	SEE COMMENTS	ALWAYS	NEVER	NEVER	NEVER	NEVER
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NEVER	NEVER	SEE COMMENTS	ALWAYS	NEVER	NEVER	NEVER	NEVER
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NEVER	OFTEN	NO COMMENT	ALWAYS	SELDOM	SELDOM	ALWAYS	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	SELDOM	OFTEN	NEVER	ALWAYS
NEVER	OFTEN	NO COMMENT	ALWAYS	SELDOM	SELDOM	ALWAYS	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	NEVER	ALWAYS	ALWAYS	ALWAYS

NO ANSWER	NO ANSWER	NO COMMENT	ALWAYS	NO ANSWER	ALWAYS	ALWAYS	ALWAYS
NEVER	NO ANSWER	NO COMMENT	ALWAYS	NO ANSWER	ALWAYS	ALWAYS	ALWAYS
NEVER	SELDOM	NO COMMENT	ALWAYS	SELDOM	ALWAYS	SELDOM	SELDOM
NEVER	NEVER	NO COMMENT	ALWAYS	OFTEN	ALWAYS	OFTEN	NEVER
NO ANSWER	NO ANSWER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	NO ANSWER	SELDOM
SELDOM	ALWAYS	NO COMMENT	ALWAYS	NEVER	ALWAYS	ALWAYS	ALWAYS
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	OFTEN	NEVER	ALWAYS
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	NEVER	SELDOM
NEVER	SELDOM	NO COMMENT	ALWAYS	SELDOM	ALWAYS	SELDOM	SELDOM
ALWAYS	NEVER	NO COMMENT	ALWAYS	NEVER	ALWAYS	ALWAYS	ALWAYS
NO ANSWER	NO ANSWER	NO COMMENT	ALWAYS	NEVER	ALWAYS	OFTEN	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	OFTEN	NEVER	ALWAYS
SELDOM	NO ANSWER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	NO ANSWER	SELDOM
NO ANSWER	NO ANSWER	NO COMMENT	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO ANSWER
NO ANSWER	NO ANSWER	NO COMMENT	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO ANSWER
SELDOM	NO ANSWER	SEE COMMENTS	ALWAYS	ALWAYS	NO ANSWER	NO ANSWER	SELDOM
NEVER	NEVER	NO COMMENT	ALWAYS	OFTEN	ALWAYS	OFTEN	NEVER
SELDOM	NO ANSWER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	SEE COMMENT	SELDOM
OFTEN	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	ALWAYS	ALWAYS
D	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	ALWAYS	ALWAYS
NO ANSWER	NO ANSWER	NO COMMENT	ALWAYS	NEVER	ALWAYS	OFTEN	NO ANSWER
SELDOM	NO ANSWER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	SEE COMMENT	SELDOM
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	NEVER	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	NEVER	ALWAYS	ALWAYS	ALWAYS
SELDOM	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	ALWAYS	ALWAYS
SELDOM	NEVER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	NEVER	SELDOM
NEVER	OFTEN	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	NEVER	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	ALWAYS	NEVER	NEVER
NEVER	NEVER	NO COMMENT	ALWAYS	ALWAYS	OFTEN	NEVER	ALWAYS
SELDOM	NO ANSWER	SEE COMMENTS	ALWAYS	ALWAYS	ALWAYS	NO ANSWER	SELDOM

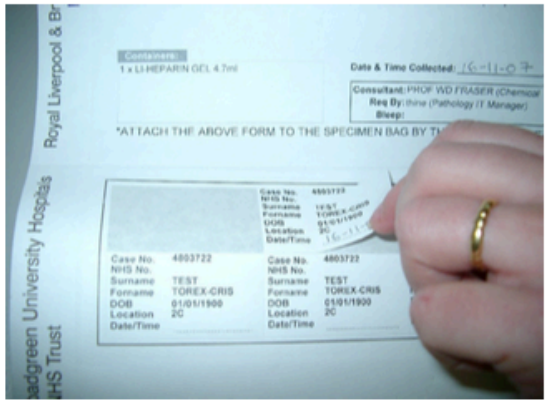
TEST LABEL 10B	TEST LABEL 10C	TEST LABEL 10D	TEST LABEL 10E	TEST LABEL 10F	PATIENT POSTURE 11	STASIS 12A	STASIS 12B	STASIS 12C	STASIS 12D	STASIS 12E	SAMP COLLECTION 13A	SAMP COLLECTION 13B	SAMP COLLECTION 13C
NO ANSWER	NO ANSWER	NO ANSWER	OFTEN	NO ANSWER	ZERO TO FIVE MINS	NEVER	SELDOM	A	A	NA	NA	NA	NA
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	B	A	C
NO ANSWER	NO ANSWER	NO ANSWER	SELDOM	OFTEN	ZERO TO FIVE MINS	NEVER	SELDOM	A	A	NA	NA	NA	NA
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	B	A	A
NO ANSWER	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	NA	NA	NA
ALWAYS	OFTEN	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	B	B	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	D	A	A
NEVER	NEVER	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	ALWAYS	D	A	MA	B	B	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NO ANSWER	ALWAYS	NA	NA	NA	NA	NA	A
NO ANSWER	NO ANSWER	NO ANSWER	OFTEN	NO ANSWER	ZERO TO FIVE MINS	NEVER	SELDOM	A	A	NA	NA	NA	NA
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	NEVER	A	D	NA	D	D	A
ALWAYS	OFTEN	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	B	B	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NO ANSWER	A	A	NA	B	B	A
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	NEVER	A	D	NA	D	D	A
ALWAYS	OFTEN	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	B	B	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NO ANSWER	A	A	NA	B	B	A
ALWAYS	OFTEN	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NO ANSWER	NO ANSWER	A	NA	NA	B	B	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	D	A	A
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO ANSWER	NEVER	ALWAYS	D	A	NA	B	B	B
ALWAYS	SELDOM	NEVER	NEVER	NEVER	SIX TO TEN MINS	SELDOM	ALWAYS	D	D	NA	D	B	C
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	NEVER	A	D	NA	D	D	A
NO ANSWER	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	ZERO TO FIVE MINS	NO ANSWER	ALWAYS	NA	NA	NA	NA	B	NA
ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	NA	NA	NA
NO ANSWER	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	ZERO TO FIVE MINS	NO ANSWER	ALWAYS	NA	NA	NA	NA	B	NA
ALWAYS	OFTEN	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NO ANSWER	NO ANSWER	A	NA	NA	B	B	B
ALWAYS	SELDOM	NEVER	NEVER	NEVER	SIX TO TEN MINS	SELDOM	ALWAYS	D	D	NA	D	C	C
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	D	A	A
ALWAYS	SELDOM	NEVER	NEVER	NEVER	SIX TO TEN MINS	SELDOM	ALWAYS	D	D	NA	D	C	C
NO ANSWER	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	A	A	A
ALWAYS	NEVER	NEVER	NEVER	NEVER	NO ANSWER	NEVER	ALWAYS	C	D	NA	B	B	B
NO ANSWER	SELDOM	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NEVER	NEVER	A	D	NA	A	A	A
NEVER	ALWAYS	SELDOM	NEVER	NEVER	NO ANSWER	SELDOM	ALWAYS	B	NA	NA	C	C	C
SELDOM	OFTEN	SELDOM	SELDOM	SELDOM	ZERO TO FIVE MINS	SELDOM	SELDOM	B	C	NA	A	C	B
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	SELDOM	A	A	NA	D	D see comm	A
ALWAYS	NEVER	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	ALWAYS	C	D	NA	A	A	A
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	D	A	A
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	SELDOM	A	A	NA	D	D	A
NEVER	ALWAYS	SELDOM	NEVER	NEVER	NO ANSWER	SELDOM	ALWAYS	B	NA	NA	C	C	C
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	B	A	C
NO ANSWER	OFTEN	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	A	A	A
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NEVER	NEVER	A	D	NA	D	A	A
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	SELDOM	A	A	NA	D	D see comm	A
NO ANSWER	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	NA	A	A
NO ANSWER	ALWAYS	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	NA	A	A
SELDOM	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	SELDOM	A	A	NA	D	D see comm	B
SELDOM	OFTEN	SELDOM	SELDOM	SELDOM	ZERO TO FIVE MINS	SELDOM	SELDOM	B	C	NA	A	C	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	SELDOM	A	A	NA	D	D	B
NEVER	ALWAYS	NEVER	NEVER	NEVER	ZERO TO FIVE MINS	NO ANSWER	ALWAYS	NA	NA	NA	NA	NA	A
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NO ANSWER	ALWAYS	NA	A	NA	A	A	A
NO ANSWER	OFTEN	NO ANSWER	NO ANSWER	NO ANSWER	NO TIME CHECK	NO ANSWER	NO ANSWER	A	NA	NA	A	A	A
NEVER	ALWAYS	NEVER	NEVER	NEVER	NO TIME CHECK	NEVER	SELDOM	A	A	NA	D	D	B

STORAGE 15C	STORAGE 15D	STORAGE 15E	ERROR REPORT 16A	ERROR REPORT 16B	ERROR REPORT 16C	ERROR 17A	ERROR 17B	ERROR 17C	ERROR 17D	ERROR 17E	ERROR 17F	ERROR 17 G	SUGGEST 18
NA	NA	NA	NA	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	see comment	0	B	NA	NA	A	NA	NA	NA	NA	NA	NA
NA	NA	NA	0	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	B	see comment	NA	B	NA	NA	A	NA	NA	NA	NA	NA	NA
NA	NA	see comment	NA	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	NA	NA	B	NA	D	D	D	D	D	NA	SC	NA
D	D	NA	NA	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
NA	NA	NA	NA	B	NA	NA	NA	NA	NA	NAN	AN	NA	NA
NA	NA	NA	NA	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	SC	NA	B	NA	NA	D	NA	NA	NA	NA	NA	NA
D	D	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
B	D	see comment	0	NA	NA	NA	NA	NA	NA	A	NA	see commen	see suggestions
D	D	SC	NA	B	NA	NA	D	NA	NA	NA	NA	NA	NA
D	D	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
B	D	see comment	0	NA	NA	NA	NA	NA	NA	A	NA	see commen	see suggestions
NA	NA	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	SC	NA	B	NA	D	D	D	D	D	NA	SC	NA
D	D	NA	NA	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	NA	2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NA	NA	see comment	NA	B	NA	A	D	NA	NA	NA	NA	NA	NA
NA	NA	see comment	NA	B	NA	NA	NA	NA	NA	D	NA	see commen	NA
NA	NA	see comment	0	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
NA	NA	see comment	NA	B	NA	NA	NA	NA	NA	D	NA	see commen	NA
NA	NA	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	NA	4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	SCAS	0	B	NA	D	D	D	D	D	NA	NA	see suggestions
D	D	NA	4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NA	NA	NA	NA	NA	C	NA	NA	NA	NA	A	NA	NA	NA
D	D	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	NA	NA	NA	C	NA	NA	NA	NA	A	NA	NA	NA
D	D	see comment	0	B	NA	D	D	D	D	D	NA	NA	NA
D	D	NA	0	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	see comment	NA	NA	NA	D	D	D	D	D	NA	NAP	see suggestions
D	D	NA	NA	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	SNC	NA	B	NA	D	D	D	DD	NA	NA	SNC	NA
D	D	see comment	0	B	NA	NA	NA	NA	NA	NA	NA	NA	NA
D	D	see comment	0	B	NA	D	D	D	D	D	NA	NA	NA
D	D	see comment	0	B	NA	NA	A	NA	NA	NA	NA	NA	NA
NA	NA	NA	0	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	SNC	NA	B	NA	D	D	D	DD	NA	NA	SNC	NA
D	D	see comment	NA	NA	NA	D	D	D	D	D	NA	NAP	see suggestions
NA	NA	NA	0	B	NA	NA	NA	NA	NA	A	NA	NA	NA
NA	NA	NA	0	B	NA	NA	NA	NA	NA	A	NA	NA	NA
D	D	see comment	0	NA	NA	NA	NA	NA	NA	NA	NA	NAP	see suggestions
D	D	NA	NA	B	NA	NA	NA	NA	NA	NA	NA	NA	see suggestions
NA	NA	see comment	NA	B	NA	NA	NA	NA	NA	NA	NA	NAP	see suggestions

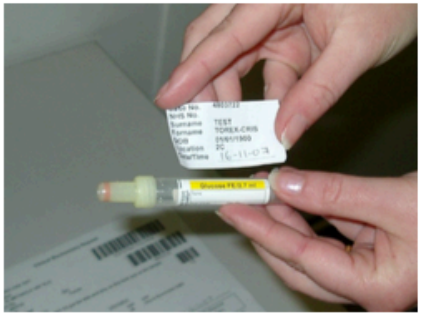
APPENDIX XI Using ICE Request Forms and Specimen Bags

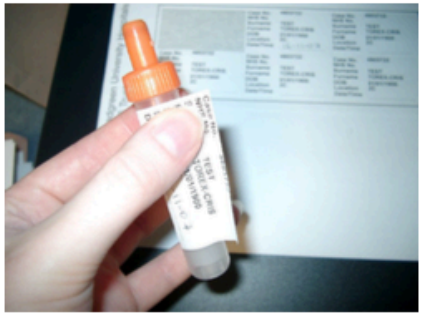
1. Produce request form using ICE Requesting system

2. Write the date on the form and also remember to write the date on the labels at the bottom of the form.



3. Detach labels from bottom half of form





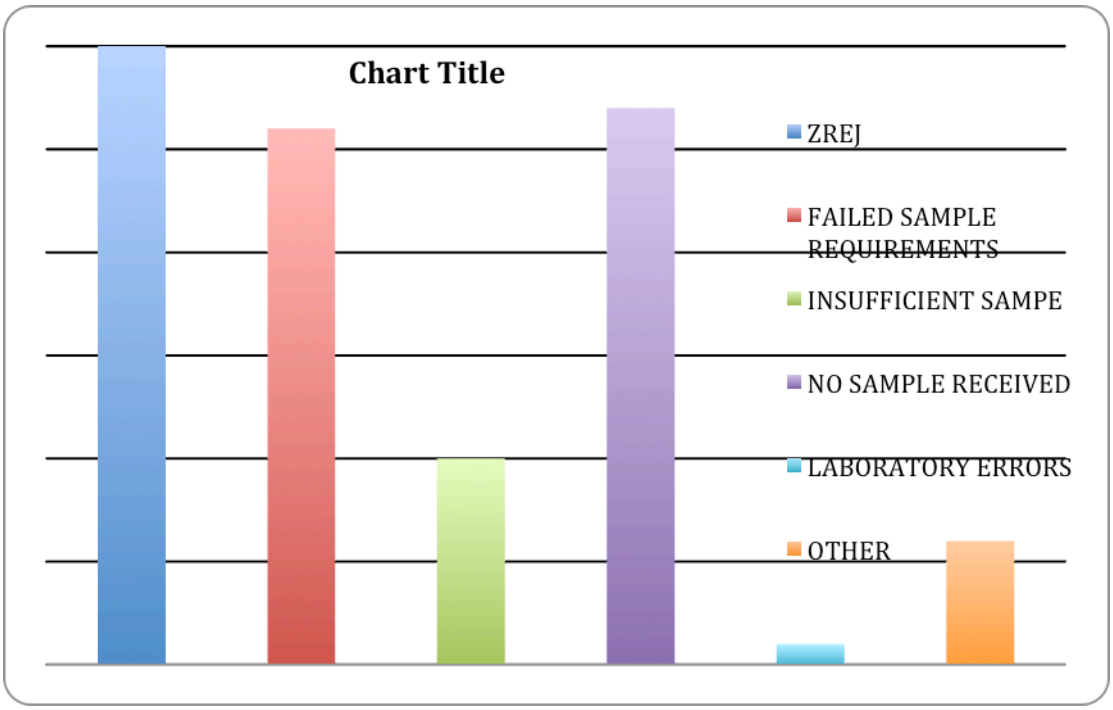
4. Stick labels onto all sample tubes.

APPENDIX XII
Pilot Study (Dprof Research)

Project planning 2 – Epistemology, Methodology and Method

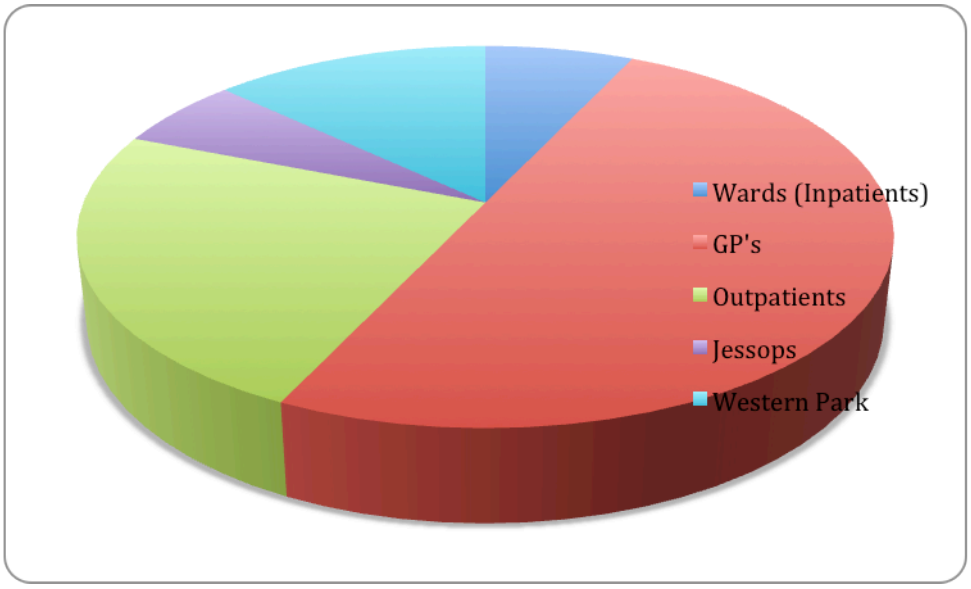
A list of all samples errors (i.e requests booked in as set code "error" in Clinical Chemistry between February-March in 2013 were pulled in from APEX. The total number of errors booked into APEX within this time was 333. The table below shows the different errors that were booked in and how often they occurred.
Table 1

ERROR	Total	% Occurred
Sample failed acceptance criteria (ZREJ)	99	30
Sample requirements (incorrect bottle, preservative, unsuitable for analysis-contamination, viscosity)	85	26
Insufficient sample for tests	33	10
No sample received	90	27
Laboratory error (mechanical, tests missed off when booked into APEX)	4	1
Other (test requested multiple times, test not required, additional tests required, tests not available, sample lost in transit	22	6



The graph on the previous page above shows approximately 30% of these samples had to be booked in as an "error" with the ZREJ study code because the sample failed the acceptance criteria- (samples/requests that are unlabelled, insufficiently labelled or incorrectly labelled as set out in SOP LMCP026). 27% of errors were booked in because no sample was received in the laboratory for the specified request.

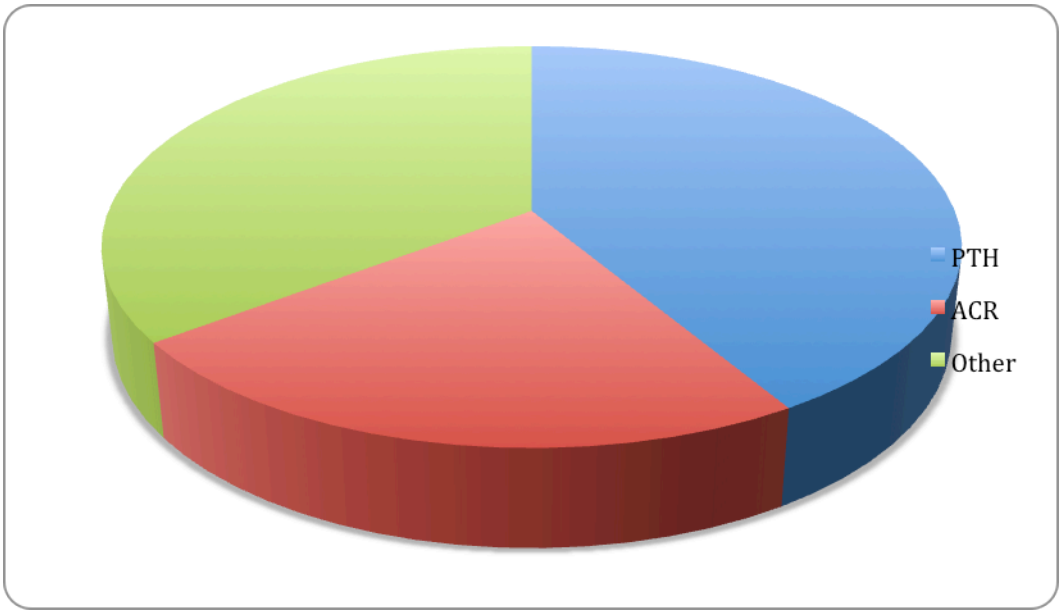
Location	% of Samples
Wards (Inpatients)	7
GP's	50
Outpatients	24
Jessops	6
Western Park	13



The chart above shows the majority of samples that failed the acceptance criteria came from GP surgeries. From the outpatient samples 58% of samples that failed the acceptance criteria came from the locations PHC/AMBRIS studies.

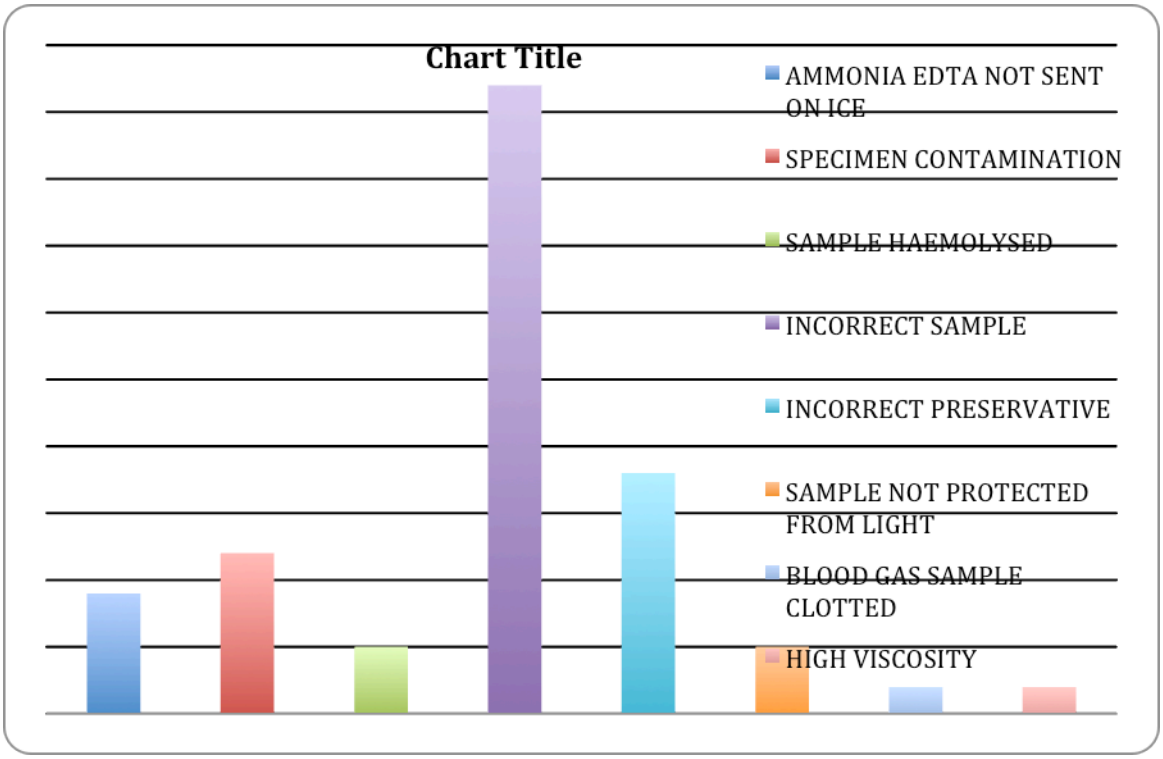
As table 1 show's 27% of errors were booked in because no sample was received in the laboratory for the specified request. Approximately 41% of these requests were for the PTH test and the majority of these requests came from GP surgeries. 23% of requests were for urine albumin: creatinine ratio test and again majority of these requests were from GP surgeries.

Error	% Occurred
PTH	41
ACR	23
Other	35

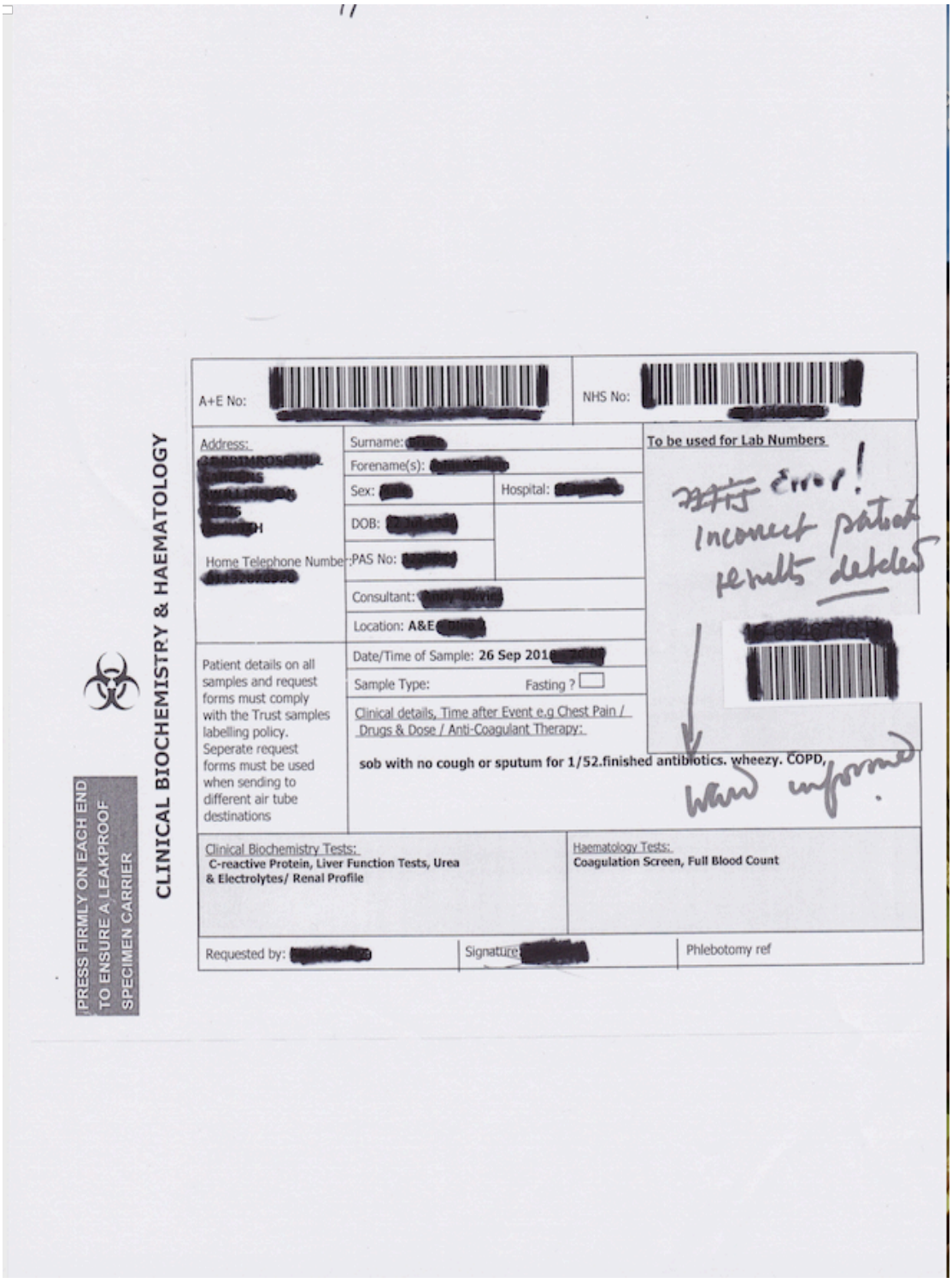


26% of errors were booked in because of sample requirements failure. The chart below shows the various errors that were booked in. 47% of the errors was due to incorrect sample being sent for the specified test. 12% of errors was due to specimen contamination such as sample taken from drip arm, EDTA contamination. 18% of the errors was because of the incorrect perservative being used for the required test with the most common one being sending a 24 urine sample for Catecholmaines and Metanepharines in a plain bottle rather than in an acidifed container.

Error	% Error Occurred
Ammonia EDTA not sent on ICE	9
Specimen contamination	12
Sample haemolysed	5
Incorrect sample	47
Incorrect preservative	18
Sample not protected from light	5
Blood gas sample clotted	2
High viscosity	2



Appendix XIII – **ICE** test request form



CLINICAL BIOCHEMISTRY & HAEMATOLOGY

PRESS FIRMLY ON EACH END TO ENSURE A LEAKPROOF SPECIMEN CARRIER

A+E No: [redacted]

NHS No: [redacted]

Address: [redacted]

Surname: [redacted]

Forename(s): [redacted]

Sex: [redacted] Hospital: [redacted]

DOB: [redacted]

Home Telephone Number: [redacted] PAS No: [redacted]

Consultant: [redacted]

Location: A&E [redacted]

To be used for Lab Numbers

~~HHS~~ Error! Incorrect patient results deleted

[redacted]

Patient details on all samples and request forms must comply with the Trust samples labelling policy. Seperate request forms must be used when sending to different air tube destinations

Date/Time of Sample: 26 Sep 201[redacted]

Sample Type: Fasting ? ☐

Clinical details, Time after Event e.g Chest Pain / Drugs & Dose / Anti-Coagulant Therapy:

sob with no cough or sputum for 1/52.finished antibiotics. wheezy. COPD,

ward informed

Clinical Biochemistry Tests:
C-reactive Protein, Liver Function Tests, Urea & Electrolytes/ Renal Profile

Haematology Tests:
Coagulation Screen, Full Blood Count

Requested by: [redacted] Signature: [redacted] Phlebotomy ref

Appendix XIV – Manual test request form

Appendix XV

Standard Operating Procedure for the Phlebotomy Unit on C-Floor (Outpatients Block, Royal Hallamshire Hospital)

Contents

Introduction Page 1
Equipment Page 1
Venepuncture Procedure Page 2
Protocol for needle-stick injuries Page 4

(i) Introduction

The operating procedures for venepuncture are outlined below. Safety is paramount in the practice of phlebotomy, and the STHFT Phlebotomy Training Manual describes measures aimed at minimising the risk of injury or harm to staff or patient. The last section (copy of controlled Document from Laboratory Medicine Risk Management section) include the protocol for dealing with a needle-stick injury

- Please refer to the Department of STHFT Phlebotomy Training Manual for requirements regarding professional attributes, health and safety, and pre-analytical variables. There is a departmental Quality Assurance programme in which phlebotomists are assessed according to the standards in the Training Manual by means of both observation of practice and assessment of theoretical knowledge.
- Professionalism includes respecting patient confidentiality, and the need to obtain informed consent for venepuncture is emphasised.

(ii) Equipment:

The workstation / trolley must be **clean**, **tidy**, and well stocked at all times; and contain the following items.

- Medi swab isopropyl alcohol cleaning pad.
- Cotton wool balls and dental rolls
- Hand cleansing gel
- Sharps bin.
- Assorted plasters and micropore tape
- Latex free gloves
- Vacutainer barrels
- 21G (green) and 22G (black) Vacutainer 'safer' needles *
- Assorted Vacutainer bottles.
- Assorted luer slip syringes
- Disposable needles for use with luer slip syringes
- Butterfly 'safer' needles 21G and 22G *
- Vacutainer adapters for luer fittings.
- Tourniquet
- Spillage kit

* Needles must be of a type that have integrated features to protect staff and patients from needle-stick injury by shielding the needle tip after venepuncture.

(iii) Venepuncture Procedure:

- Call a patient into phlebotomy area by pressing 'NEXT' on the QMS keypad. Maintain a professional attitude and courtesy towards all patients at all times. Remember to prioritise ambulance patients.
- Direct your patient to the appropriate cubicle
- Approach the patient in a confident manner, explain the procedure and obtain consent.
- Check patient details against the request form by asking them for their full name and date of birth.
- Allow the patient time to discuss any previous problems with venepuncture.
- Ask patient if they have a 'preferred' arm.
- Check the request forms and assemble the correct bottles. Take note of any variables which need recording: e.g. fasting, time of day.
- Wash hands, or use hand sanitizer, between each patient.
- Support the chosen arm
- Apply tourniquet to the upper arm on the chosen site approximately 4 to 5 cms above the elbow. The tourniquet must be applied with just enough tension to distend the vein.
- Select a vein by feeling ('palpating') with a finger (never a thumb). The vein should give under pressure from your finger, it should not pulsate. Check also the direction of the vein.
- If a prominent vein does not appear, ask to look at the patient's other arm. Veins can be encouraged to 'show ' by moving the tourniquet slightly, or by warming the arm. Release tourniquet if necessary.
- Select device required to obtain the correct amount of blood for the size and site of the vein, etc.
- Gloves must be worn unless the phlebotomist has difficulty locating a vein, (and always with Category 3 patients).
- Reapply tourniquet if necessary.
- Clean skin over vein with alcohol swab leave to air dry
- Unwrap and visually inspect all needles carefully to detect any barbed or faulty equipment.
- Assemble the vacutainer system or syringe and needle maintaining asepsis. Do not touch the steel part of the needle or let it touch anything else.
- Hold the barrel with two fingers underneath the barrel and your thumb on the top, This will leave the lower end of the barrel free for careful insertion of vacutainer blood tubes.
- Anchor the vein by applying traction with the thumb on the skin a few centimetres below the proposed insertion site. The skin must be pulled in alignment with the course of the vein.
- Insert the needle smoothly with the 'eye' uppermost in a single 'gliding' motion aiming for the centre of the vein. To ensure correct angle, your fingers should gently brush the patient's arm as you approach with the needle. A 'flashback' of blood should be seen in the hub of a needle and syringe, but is not seen with a vacutainer.

- From now on, hold the device so that the tip of the needle remains perfectly still. Rest your fingers on the patient's arm to achieve this.
- If you are collecting blood into sample tubes containing anticoagulants or other additives, consider the order of draw carefully.
- If using the vacutainer system, slide the appropriate empty vacutainer tubes into the holder (taking care not to move the tip of the needle) and withdraw the required amount of blood. This can be achieved by applying counter-pressure via the flange on the holder.
- If using needle and syringe, pull back the plunger gently but steadily (taking care not to move the tip of the needle) to collect the correct amount of blood.
- Release the tourniquet.
- Remove the last sample tube or stop pulling back the syringe plunger.
- Place a clean dental roll or cotton wool ball over the puncture site, remove the needle and apply digital pressure directly over puncture site. Do not press until needle is removed. Whilst keeping fingers away from the needle tip, flip the needle-guard over the needle.
- Apply pressure until bleeding ceases. Patients can apply pressure themselves, but you must ensure they understand the need to press for 2 – 3 minutes. (Especially those on anticoagulants.)
- Dispose of vacutainer guarded-needle and holder immediately into sharps bin. Never re-sheath needles. Refer to lab guidelines regarding waste disposal. Should needlestick occur refer to lab guidelines. Procedures available above both hand wash basins in phlebotomy.
- Mix contents of all tubes by gently inverting 5 or 6 times. If using a syringe, use vacuette adaptor to transfer blood into vaccutainer bottles. Allow the correct quantity to be drawn into each vacutainer in the correct order. Invert to mix as above.
- Dispose of syringe and guarded-needle into sharps bin.
- Label all sample tubes with patient's details ie:, Surname, Fore name, Registration Number (or NHS number for GP patients), and D.O.B. Sign, date and time the sample. Refer to Laboratory Medicine Safer Labelling Policy.
- Check bleeding has ceased by gently stroking in the direction of the vein. Do not wipe over the puncture site, as this will initiate further bleeding.
- Ask the patient if they are allergic to elastoplast and if not, cover the puncture site with an elastoplast. Fasten a clean piece of cotton wool or dental roll in place with micropore if the patient is allergic to elastoplast or prefers this option
- Ensure the patient is comfortable and fit to leave the department. Ambulance patients may require assistance of porters to return to waiting area.
- Clear workstation or trolley of any soiled cotton wool/dental rolls, or any paper debris to ensure area is clean and tidy for next patient. No specimens or forms from the previous patient should be in the cubicle when a new patient is called.

(iv) Needlestick and contamination incidents

Any injury or splash incident which causes exposure to blood or high-risk body fluids

More detailed information for staff and managers is available in the 'Blood and Body Fluid Exposure Incident Management Pack'. These packs **must** be used when dealing with any contamination incident. **All** supervisory staff should be aware of the procedure; this guideline must be used in conjunction with the Incident Management Pack.

HOW CAN THIS OCCUR?

- Puncture of the skin with a dirty needle or sharp.
- Exposure through cuts or breaks in the skin, e.g. cuts or skin conditions
- Splashes of blood or body fluids in the eye or mouth.

WHICH BODY FLUIDS ARE INFECTIOUS?

- **High risk :-** Blood, visibly blood stained body fluids and those derived from blood, e.g. amniotic fluid, vaginal secretions, semen, breast milk, cerebrospinal fluid, peritoneal fluid, saliva in association with dentistry, unfixed tissues and organs, and synovial fluid.
- **Low risk** :- Urine, vomit, saliva, faeces with no visible blood staining.

IF I HAVE A CONTAMINATION INJURY WHAT SHOULD I DO?

FIRST AID. **SPEED IS ESSENTIAL !**

For a wound
Encourage bleeding by gently squeezing the site - do not suck! Wash in warm running water with soap or handwash liquid, dry. Apply a waterproof dressing.

For a splash in the eye
Irrigate thoroughly for at least five minutes with eyewash solution or sterile water (or tap water if others not available). Remove contact lenses.

For a splash in the mouth
Irrigate thoroughly for at least five minutes with drinking water. Do not swallow this water.

CONTACT THE OCCUPATIONAL HEALTH SERVICE AS FOLLOWS:

Monday - Friday 8.30 - 4.30
Northern General Department ext 4737 or Direct Line (0114) 271 4737
Royal Hallamshire Department ext 3360 or Direct Line (0114) 271 3360

Out-of hours
If the source patient is HIV or Hepatitis B positive contact the on-call occupational physician through the NGH switchboard.

Inform your supervisor or manager -
As soon as possible after the incident so that they can ensure that correct action is taken and complete both the blood exposure incident form an accident report form.

All contamination incidents must be reported on Datix as soon as possible.

Appendix XVI

Service Evaluation Report

Please note: If the project is performance managed this report will be submitted to the Clinical Effectiveness Committee

Abstract: *This section must be completed and written as a short paragraph only.*

Efficient laboratory service is the cornerstone of modern health care systems. The RHH clinical chemistry laboratory services play a major role in modern healthcare. Attending patients are entitled to health care with a high degree of quality and safety. Diagnostics in Clinical Chemistry laboratory is a pivotal part of clinical decision-making but not exempt from 'human errors'. Scientific innovations have contributed to substantial improvements in the field of laboratory science, but errors still occur. One major example of such failing is connected to the prevalence of errors occurring in the Total Testing Process (TTP).

The results of the first part of the study indicate that of the 416,703 specimens collected pre-Anglia ICE, 2,055 (0.49%) were recorded as errors compared with 1,616 errors (0.11%) of 903,814 specimens collected post-Anglia ICE implementation, which represents a 0.31% ($p<0.05$) absolute error reduction rate, although more samples were received post-Anglia-ICE.

The results of the second part (questionnaire survey) indicate that recommended procedure for phlebotomy practice was not strictly followed by a large percentage of the staffs. The results suggests low compliance by staffs with recommended practice, which may be responsible for the prevalence of certain categories of pre-analytical errors in the TTP and may also be associated with increased risks to attending patients. It is suggested that the development of a local guideline for VBS and compliance to this guideline will improve phlebotomy practice, improve the quality of sample testing in clinical chemistry laboratory, reduce pre-analytical errors in TTP and consequently improve the safety of patients.

Project Title: Identification and Reduction of Pre-analytical Errors in Clinical Chemistry		
Site: RHH/NGH	**Project Registration Number: 5683**	**Project Priority:**

1. Project Team

Name	Job Title	Role
Ben Sholademi	Biomedical Scientist	Specialist BMS

2. Background

Diagnostics in Clinical Chemistry laboratory is a pivotal part of clinical decision-making but is not exempt from 'human errors'. Scientific innovations such as automation and electronic order test requesting have contributed to substantial improvements in the field of laboratory science, but errors still occur. One major example of such failing is connected to the prevalence of errors occurring in pre-analytical phase of the Total Testing Process (TTP). Pre-analytical errors can occur at the time of patient assessment, test order entry, patient identification, sample collection, sample transport, or sample receipt in the laboratory. Such errors are frequently the results of human mistakes during phlebotomy practice. Previous work and clinical insights suggest that most errors in the TTP are extra-laboratory (i.e. they occur before the sample reaches the laboratory for analysis). Therefore to reduce these errors the pre-analytical phase of the TTP must be prioritized.

3. Aim and Objectives

The first part of this study involved an interrogation of the laboratory information management system to compare two separate periods before and after the implementation of Anglia-ICE (electronic test ordering) to find out whether the introduction of Anglia-ICE played a key role in reducing the occurrences of these pre-analytical errors. This study also included a survey of pre-analytical procedures in the phlebotomy units of Sheffield Teaching Hospitals NHS Foundation Trust (STH NHS FT), in order to identify the potential sources of these errors and whether these practices play a role in reducing the pre-analytical errors encountered in clinical chemistry laboratory.

Specific aims are:

- To investigate, categorise and determine the frequencies of pre-analytical errors in the TTP.
- To conduct a survey of pre-analytical procedures by phlebotomy staff to identify key error prone steps in the TTP.
- To draw any conclusions from phlebotomy staff practice and specific errors identified in the TTP.
- To engage with experts and seek advice to improve phlebotomy practice in STH NHS FT and to communicate the outcomes from the study to service users with the aim of improving the service and promote patient safety.

4. Methodology

1. Interrogating the Laboratory Information Management System (LIMS)
The first part of this project is a restrospective interrogation of LIMS to retrieve data of pre-analytical errors. This included all test requests booked in as a set code "ERROR" in the clinical chemistry laboratory of RHH (STH FT) to cover 2 periods:

a) Pre-introduction of electronic test requesting (2007 - 2008)
b) Post implementation of electronic test requesting (2012 - 2013)

Statistical Analysis – LISM study
Pre-analytical raw data extracted from LIMS were entered into Excel 2010 spread sheet (Microsoft Corp., Redmond, WA) for pre-processing and coding. Differences in error frequencies between Pre-ICE procedure requesting and Post-ICE requesting procedure were compared using Chi-squared test. A p-value less than 0.05 was considered statistically significant.

2. Questionnaire Study
The second part of the project was a questionnaire survey of pre-analytical practice in the phlebotomy unit in STH NHS FT. This also involved a pilot study (that included a small group of the target population) to test the validity of the study design.

Statistical analysis of questionnaire data
Completed questionnaire data and background characteristics of the respondents were typed in to an Excel 2010 for Macintosh data sheet (Microsoft Corp., Redmond, WA) and then transferred to Statistical

package for Macintosh, Version 23 (SPSS Inc., Chicago, IL), and basic descriptive statistics were used. Further analyses of data were performed with Prism 7 statistical software (GraphPad Software, Inc. 7825 Fay Avenue, La Jolla, CA 92037, USA) and Stats Direct statistical package (Stats Direct Ltd, 9 Bonville Chase, Altrincham, Cheshire WA14 4QA, UK).

Participants: study population and sampling

The population was drawn from a group of staff working in the phlebotomy units and wards at STH NHS FT. 80 copies of anonymous questionnaires were sent out to respondents. The questionnaire contained 18 questions, including open-ended questions and sections for comments/suggestion. A copy of the study questionnaire is included in the appendices section.

Ethical considerations

This study did not involve patients attending STH. This study was a survey of volunteer phlebotomy unit staffs across both campuses of STH only. Respondents were asked to state how they performed phlebotomy/error-reporting practices (Soderberg, 2009). The survey was to identify error prone steps in the TTP in order to be able to appropriately target interventions to improve practice. The questionnaire was strictly anonymous and informed consent was made available to the respondents, explaining fully the procedures involved in the research; the return of the completed questionnaires was translated as acceptance of consent to participate in the study, which was stated on the questionnaire.

5. Results and Discussion

Results show a definitive decrease in the occurrence of some pre-analytical errors following the implementation of the Anglia-ICE system in 2012. The introduction and implementation of electronic requisitioning of laboratory samples has almost certainly drastically reduced the rate of one error-prone manual test requesting procedure that is related to patient identification (incorrect patient details). Overall an absolute error reduction rate of 0.31% was attained and the result agrees with previous findings of Hill *et al.*, (2010) who similarly achieved a 0.31% reduction in institutional sample labelling error rate. Although it has been argued that introduction of new and advanced technology such electronic ordering combined with sample bar-coding systems (Valenstein *et al.*, 2006) can go far in reducing patient identification errors, it is certainly also the case that electronic systems will increase other types of ordering errors (Hill *et al.*, 2010) not detected or reported to the laboratory such as electronic order generated errors, no-test request errors and unspecified pre-analytical error types. For illustration, it is fairly easy to select the wrong patient's details from two different patient's with very similar surnames and their names appear closely together on computer screen of an electronic order system. There is therefore a need for continuous evaluation of practice and monitoring (Sölderberg, 2009) by experts in clinical chemistry laboratory practice.

A number of patient identification and test ordering errors were still recorded in the LISM post Anglia-ICE implementation (e.g. patient's details illegible, incomplete patient's details, swapped patient demographics, test not routinely available in laboratory, unspecified pre-analytical error type, unlabelled sample received, unrequested test received, wrong test request received - indicating that the electronic test ordering alone is not sufficient for a reliable error-free pre-analytical procedure. Nonetheless the implementation of Anglia-ICE technology is still the way forward to reduce errors associated with manual paper-based test requests.

Evidence of possible linkage between the pre-analytical error frequency statistics from LIMS and the questionnaire survey exists. High frequencies of unlabelled tubes, mislabelled tubes, incorrect sample tubes and incomplete patient demographics on sample tubes have been identified through the LISM database, which directly supports the results in the questionnaire survey relating to patient identification procedures and vacutainer tube labelling. A high percentage of the respondents were not following the

recommended standard procedure for identification of patients. In this study, nearly half of the respondents never to checked wristbands for the purpose of patient identification; this is undesirable practice and may lead to improper identification of the patient. Correct patient identification and correct tube labelling are undoubtedly the most crucial procedures in laboratory medicine. Hence, there is need to prioritize efforts to ensure compliance by staff with standardized patient identification practices.

The demonstration that occurrence of vacutainer tube labelling errors have increased post Anglia-ICE, raises some concerns. Results from the questionnaire survey show low compliance with recommended practice. According to recommended guidelines, vacutainer tubes should always be labelled immediately alongside the patient (CLSI, 2010; WHO, 2014) after VBS to avoid labelling errors (Wallin *et al.*, 2009; Kiechle, 2013; WHO, 2014). Regrettably a significant number of the respondents reported to always label the vacutainer tubes alongside the patient, before VBS procedure. This is not in line with recommended practices (CLSI, 2007, 2008, 2010; WHO, 2014; IBMS, 2016). About a third of the total numbers of respondents were unsure about which standard procedure was available for vacutainer tube labelling in VBS. This indicates unacceptable practice and associated with increased risks of the wrong patient's blood in the labelled vacutainer tube (CLSI, 2007; Soderberg *et al.*, 2009, IBMS, 2016).

The survey also revealed that close to 30% of the phlebotomy staff will ask another colleague to label a vacutainer tube, either before or after sampling, a practice which increases the risk of unlabelled, mislabelling or sample mismatches and are important sources of pre-analytical errors in the clinical chemistry laboratory (Plebani and Carraro, 2007; Plebani, 2007; Sciacovelli and Plebani, 2009). These findings appear to be a combination of factors relating to staff shortages and time pressures on the service. Therefore there is a need for adequate staffing to maintain VBS standards (Lippi *et. al.,* 2006), which provides an additional edge of expertise (Ashikiran et. al., 2011). Mislabelled tubes or tubes with incomplete patient demographics may result in adverse events (Kalra, 2004; Valenstein *et al*, 2006) and in some cases, fatalities. Drawing blood from the wrong patient, or labelling the correct patient's sample with a different patient's label can undoubtedly contribute to pre-analytical errors in the laboratory (CLSI, 2008; IBMS, 2016).

The vacutainer tube labelling procedures adopted by staff as reported in the questionnaire survey clearly demonstrates an association with a significant risk (CSLI, 2010; ISO 15189; 2012; IBMS; 2015), resulting from mislabelling / inadequate labelling of vacutainer tubes, and represents a significant area for patient safety improvement (Kalra, 2004; Plebani, 2009) that needs to be addressed. Results also show that the occurrences of other common errors such as sample received contaminated, sample received in wrong container, and sample received in wrong preservative have increased in frequency. These pre-analytical errors can be avoided by implementing good practices, such as strictly adhering to the correct order of draw, not drawing the blood sample immediately after catheter insertion, and never collecting from an infusion line. Common errors can be also made in the transportation of phlebotomy samples, thus it is important that laboratory staff are made aware of the optimum time and transport conditions.

Lastly there appears to be considerable underreporting of pre-analytical errors in the phlebotomy units of STH NHS, where this study was carried out. Underreporting of filing of pre-analytical incidents can lead to clinically important errors (Kolovos *et al.*, 2008). Results show that more than 95% of phlebotomy staff had never filed an error incident regarding VBS procedure. These findings supported by results from a previous study by Söderberg (2009), where 69% of respondents in the investigated primary health care setting, stated to have never filed an incident report regarding VBS practice. Shortage of time and the complicated process of error reporting currently in place have been voiced as possible reasons for the majority of the VBS staff refraining from filing an error report. Other reasons for a lack of compliance are fear of punishment, and a lack of perceived benefits (Kalra *et al.*, 2013). This is in contrast to practice that exists in the clinical chemistry laboratory, where error reporting by staff is greatly encouraged.

Therefore, it is crucial to douse the blame and shame culture that surrounds staffs, causing them to keep vital evidence or information about errors away from other colleagues or senior members of staff (Darosa and Pugh, 2012). Increased reporting of pre-analytical incidents regarding phlebotomy practices in STH NHS should be intensified through continuous education and training, specifically defining whose responsibility it is to report or file errors. Education about errors and their preventability may result in approaches to decrease errors and improve quality, and prevention can better happen through learning about mistakes and near misses (Kalra *et al.*, 2013).

The finding of undesirable practices within the questionnaire survey largely reflect the lack of compliance with standardised procedures in place for VBS, including sample handling, storage and transport. Staff relied mainly on uncontrolled documents (such as leaflets kept in the unit), asking other colleagues or calling the laboratory for information when they are confronted with any challenging aspect of their practice. There was no correlation between the length of employment of staff and their period of recent training when a statistical test was applied.

6. Limitations

One of the limitations of this present study was the relatively small sample size of 68 respondents involved in the questionnaire survey. A larger sample size would perhaps be more representative of the findings. This study was conducted in the phlebotomy units of the inpatient and outpatient wards of STH NHS only and excludes A&E department and GP surgeries.

Another restrain to this study is that the research methodology was restricted to questionnaire study only. Although the anonymity offered by the questionnaire approach may well have yielded more open responses from respondents, a mixed methodology to include direct observational studies combined with structured interviews could have offered more participant involvement.

This study is the first inquiry to linking VBS practices in phlebotomy to retrospective LISM pre-analytical data by comparing two separate periods pre- and post electronic order requesting in an NHS Hospital, which meant that there were very few published work available for reference purposes or to compare results of findings, although there were a number published articles on electronic order requesting, which relates to this present study and have already been cited in this thesis. It is important to emphasize that the data presented in this study represent only those pre-analytical errors that were identified by laboratory personnel and recorded in LIMS. Nonetheless, an electronic test requisition system can introduce new source(s) of error not readily detectable by laboratory staff. There is no knowledge of how many pre-analytical sample errors went undetected or unreported. No harm or injury were linked to any patient as a direct result of a pre-analytical event during the period of this study.

Lastly, there were some difficulties encountered with the returns of completed questionnaire. A number of participants took over two months to return their completed questionnaires.

7. Recommendations and Action Plan

Recommendation	Action	Deadline (Date)	Person Responsible
The development of a vigorous incident reporting and error filing system. Error reporting can be a valuable data collection tool for			

designing approaches for future VBS training.			
A thorough review of all pre-analytical procedures in the TTP, with specific focus on manual tasks involving patient identification and vacutainer test tube labelling.			
Focus on frequent training and competency assessment to involve all phlebotomy staff performing VBS procedures.			
Development of a standardized coding system for entry of all categories pre-analytical errors			

8. Conclusion

In general improvements to clinical chemistry laboratory services requires periodic objective evaluation of practices (Shaw, 2003), procedures, staffs and organizations against valid and unambiguous standards in order to identify and implement appropriate changes. The majority of pre-analytical errors detected in the clinical chemistry laboratory are avoidable. By strengthening the education of healthcare professionals (doctors, nurses, phlebotomists and clinical support staffs) about pre-analytical quality, and establishing a comprehensive system of quality in the pre-analytical phase that entails systematic monitoring of non-conformance, desired outcomes of reduction in errors can be achieved. Continual local observational studies with error frequency assessment and risk analysis (The Pathologist, 2015) of pre-analytical practice errors, combined with direct feedback, discussions and reflection amongst involved personnel, seems to be the most efficient strategy for sustained good pre-analytical practices.

Overall the key steps to improve the pre-analytical phase are standardization of VBS procedures, education, re-training, clear definition of responsibilities and fluid communication with phlebotomy staff, development of new technologies and automation, all of which require continuous funding and monitoring (The Pathologist, 2015). The loop will not be complete without continuous feedback from the users of the laboratory service –as we can only improve the phases of laboratory services that we can measure.

9. Dates for future re-evaluation

10. Approval Process

Meeting	**Approved (√)**			**Date**
	Yes	No	On hold	
Comments:				

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12. Please attach any appendices and or supporting documentation.

Appendix I (LISM Study)
Please see the attached file on categorisation of error and their frequencies in the pre-analytical phase of TTP

Appendix II (Questionnaire survey for second part of study)

Please see the attached Questionnaire file

Appendix III (SPSS and Prism 7 Analysis of Questionnaire Study)

Please see the attached SPSS Analysis file